Renewal Assessment Report
18 December 2013
Revised
29 January 2015
31 March 2015
Volume 3
Annex B.6.1
RMS: Germany Co-RMS: Slovakia
Version history (Volume 3, chapter B.6)

Date	Reason for revision
19 December 2013	Initial Renewal Assessment Report
29 January 2015	Updated following RAR peer review, taking into account the reporting table, the evaluation table and additional data
31 March 2015	Updated following Pestidices Peer Review 125 expert meeting (25-27 February 2015)

Contents

B.6 Toxicology and metabolism
General introduction and explanation of the approach taken by RMS
This health evaluation of glyphosate is based on the following sources:
• Toxicological and ADME studies that were submitted by the GTF for this re- evaluation.
• Toxicological studies and ADME studies that had been reported in the previous DAR (1998, ASB2010-10302) already and, thus, were part of previous EU evaluation. However, they were subject to re-assessment by the RMS according to current quality standards and were used only when regarded as acceptable or at least supplementary. In very few cases, NOAELs/LOAELs were revised. Unacceptable (old or new) studies were usually deleted with justifications given in the respective sections of Volume 3. In exceptional cases, such studies are still mentioned, i.e., if they were formerly taken into consideration for, e.g., ADI setting.
• Scientific publications and other relevant information that were submitted either by the GTF or by third parties or of which the RMS was aware before. It must be emphasised that a large part of the publications was on formulations different from the representative one and, thus, is of limited value for the toxicological evaluation of the active ingredient. With rather few exceptions in the areas of genotoxicity and human data, mainly scientific literature published since 2000 was assessed.
Due to the large numer of submitted toxicological studies, the RMS was not able to report the original studies in detail and an alternative approach was taken instead. The study descriptions and assessments as provided by GTF were amended by deletion of redundant parts (such as the so-called ”executive summaries”) and new enumeration of tables. Obvious errors were corrected. Each new study was commented by the RMS. These remarks are clearly distinguished from the original submission by a caption, are always written in italics and may be found on the bottom of the individual study summaries.
Furthermore, in Volume 3, assessment was performed on the individual study level. Overall evaluation of the diverse toxicological endpoints was transferred into Volume 1 (section 2.6).
The technical databases that have been used for the literature search include: Web of ScienceSM, BIOSIS Previews®, CAB Abstracts® (CABI), MEDLINE®, and CA Plus (Chemical Abstracts Plus). The searches were made on glyphosate acid, glyphosate salts (including isopropyl amine, potassium, ammonium, and methylamine), and AMPA, and their related chemical names and CAS numbers. Searches based on these search terms were also found suitable to identify publications that consider glyphosate and surfactants (such as polyoxyethylenealkylamines, or POEA) in the context of glyphosate formulations.
Additional publications cited in a recent document prepared by the NGO ”Earth Open Source” (Antoniou M, et al., 2011, ASB2011-7202) have also been included in the literature review.
The peer-reviewed publications identified for inclusion during the literature search were reviewed and classified into one of the categories listed below.
• Category 0 publications: These are publications in which glyphosate is only mentioned as an

example substance or is discussed/studied in a context that is not
relevant or related to any of the regulatory sections or the exposure/hazard assessments within this submission; the publication is therefore outside of the scope of this submission.

• Category 1 publications: These are publications which discuss glyphosate in a context relevant or related to the regulatory dossier sections and the conclusions fall within the conclusions of the exposure/hazard assessment. The publication is submitted with minimal or no comment or discussion.

• Category 2 publications: These are publications which discuss glyphosate in a context relevant or related to the regulatory dossier sections and have conclusions that call into question the endpoints/conclusions in the exposure/hazard assessment. Additionally, Category 2 also includes publications with conclusions that support the risk/hazard assessment, and may be included in discussion of other relevant publications. For selected Category 2 publications, an OECD Tier-II type summary is provided in addition to a reliability assessment (Klimisch rating, see Klimisch et al. 1997, ASB2010-14388); limited comments and critical remarks are provided, as appropriate.

• Category 3 publications: These are publications that discuss glyphosate in a context relevant or related to (1) non-regulatory endpoints that need to be addressed as per new Regulation (EC) 1107/2009; or (2) in a context relevant to sensitive allegations that have emerged or could emerge in the media; or (3) in a context relevant to the regulatory dossier sections and have conclusions that are in disagreement with endpoints/conclusions in the exposure/hazard assessment (although the experimental design seems relevant at first glance). An OECD Tier-II type summary is provided and a Klimisch rating assigned, and supplemented with critical review and discussion.

• Category 'E' publications: These are peer-reviewed publications that were cited in the Earth Open Source document. This category includes publications that were already captured by the literature search and are addressed within the appropriate discipline, as well as publications that were out of scope of the search (primarily as a result of being published prior to 2001). Publications already captured in the literature search were assigned a Category 1, 2 or 3 rating (as appropriate) in addition to a Category 'E' rating. An OECD Tier-II type summary has been prepared and a Klimisch rating assigned for each of the Category E publications. All Category 'E' publications are reviewed within the appropriate discipline, with most of the reviews provided within the toxicology dossier under Section IIA 5.10.

A full description of the literature search methodology was provided by the GTF in a separate document (Carr and Bleeke, 2012, ASB2012-11583).

Five separate publication subject areas are addressed in the literature review.

1. Developmental and Reproductive Toxicity (DART) and Endocrine Disruption (ED)
2. Neurotoxicity
3. Carcinogenicity
4. Genotoxicity
5. Category E and other publications

The publications on subject areas 1-4 are presented in the chapters on Genotoxicity, Long term toxicicity and carcinogenicity, Reproductive Toxicity and Neurotoxicity of the report.

Furthermore, publications are presented in the chapters "Further toxicological studies" and "Medical data".

Important publications are presented in summaries as quoted from the articles followed by Klimisch ratings and by RMS comments on the paper.

In the process of public consultation after the submission of the first draft of this RAR PAN- Europe, PAN-Germany and PAN-UK conducted a PubMed literature search on the keywords 'glyphosate' and

‘toxicity’ and stated they got significant differences in comparison conducted by the notifier. The GTF repeated the PubMed search on June 11, 2014, using the same keywords (Glyphosate Task Force 2014, ASB2014-9624).
Thus, of the 349 articles identified in the search, only 4 were determined to be relevant and were not already identified in the GTF literature search process.

B.6.1 Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA 5.1)

Introduction into this chapter by the RMS

In this section, only studies on toxicokinetics and metabolism of glyphosate are reported in detail and commented by the RMS that were not available when the previous evaluation by the EU in the 1990ies was performed. In addition, re-evaluation of those studies which were mentioned in the original monograph (DAR, 1998, ASB2010-10302) has been performed by RMS, mainly with regard to their quality and reliability. For more detailed description of the individual studies from this group, we refer to the old DAR. The outcome of this re-evaluation is briefly given at the end of this section, as well as a short summary of published information. Overall evaluation is presented in Volume 1, including two tables in which the (new and previously known) critical studies and the distribution of glyphosate in excreta and tissues are summarised.

B.6.2 Acute toxicity including irritancy and skin sensitisation (Annex IIA 5.2)

Introduction to this chapter by RMS:

The acute studies already evaluated in 2001 are only summarised in the tables below. These studies were not re-evaluated for the present renewal procedure. Even if some of these old studies would be considered now as not acceptable according to current standards, the assessment of the acute toxicity potential (incl. irritancy & skin sensitisation) of glyphosate will remain unchanged due to the huge amount of valid (new) studies. For details regarding studies reviewed during the 2001 EU evaluation please refer to the DAR.
The new submitted studies are summarized as well, additionally described in detail and commented by the RMS.
For higher efficiency of the review and for the sake of transparency, the descriptions of methods and study results in the GTF dossier were virtually not amended and even the conclusions were kept as provided. However, each study that is described in detail was commented by RMS. These remarks on bottom of each study description are clearly distinguished from the original submission by a caption and are always written in italics. In addition, the so-called ”executive summaries” have been deleted to clearly represented the new studies.

B.6.3 Short-term toxicity (Annex IIA 5.3)

Introduction into this chapter by the RMS

Those short-term studies are reported in detail in this section that were not mentioned in the original DAR (1998, ASB2010-10302) because they either had not been submitted for previous EU evaluation or were conducted more recently. Using the GTF dossier as basis, study decriptons were amended where necessary and each of these “new” studies was commented by RMS. Redundant parts were deleted. The structure of the document was changed. Some summary tables have been included and, where available, studies with formulations are also mentioned now in separate sub-sections.
Most of the previously known studies from the 1998 DAR may be still used for risk assessment purposes. They were all subject to re-evaluation with regard to quality and reliability. For the study design and their results, however, we refer to the old DAR.
Overall evaluation is presented in Volume 1, including tables in which the (new and previously known) valid oral subchronic studies in rats and dogs are summarised.

B.6.4 Genotoxicity (Annex IIA 5.4)

Introduction into this chapter by the RMS

In this section, only genotoxicity studies are reported in detail that were not contained in the original DAR (1998, ASB2010-10302) because they either had not been submitted for previous EU evaluation or were conducted more recently. The study decriptions, evaluations and tables as submitted for the new studies were amended where necessary and each of these studies was commented by the RMS. Redundant parts were deleted. The previously known studies from the 1998 DAR were re-evaluated and used only if considered still acceptable or at least supplementary. A detailed descripton of these studies and their results may be found in the old DAR. If studies were regarded now as "not acceptable", they were only briefly mentioned and deleted from the summary tables.

A sub-section on mutagenicity of formulations was included that is mainly based on an Addendum to the original DAR that was prepared in 2000 (ASB2013-2748). In the last sub- section of this chapter, more recent publications dealing with mutagenicity of glyphosate or its formulations are discussed

Overall evaluation of genotoxicity is presented in Volume 1.

B.6.5 Long-term toxicity and carcinogenicity (Annex IIA 5.5)

Introduction into this chapter by the RMS

The chronic toxicity/carcinogenicity part is mainly based on the extensive descriptions of the available valid studies which were provided by the GTF in its dossier. It was noted that a different approach was taken in the dossier with regard to the studies in rats and those in mice. In the section compiling the rat studies, all of them were reported in detail, including the four long-term studies that had been reviewed during previous EU evaluation. In the section on studies on the mouse, only the new studies are described whereas for those already known reference to the old DAR (DAR, 1998, ASB2010-10302) was made.

For higher efficiency of the review and for the sake of transparency, the descriptions of methods and study results in the GTF dossier were virtually not amended and even the conclusions were kept as provided. However, each study that is described in detail was commented by RMS. These remarks on bottom of each study description are clearly distinguished from the original submission by a caption and are always written in italics. In addition, redundant parts (in particular the so-called "executive summaries") have been deleted and the structure of the original submission was significantly changed to make it more transparent and comprehensible.

With regard to the "old" studies in mice that were not reported in the GTF dossier once more, at least re-evaluation for quality and reliability was performed by the RMS and the NOAELs/LOAELs were checked.

A paragraph on testing of formulations for long-term effects in rats has been included.

The overall assessment of chronic toxicity/carcinogenicity of glyphosate by the RMS is provided in Vol. 1 (2.6.5).

In chapter B.6.5.3 publications on glyphosate and carcinogenicity are presented. These publications include a number of epidemiology studies which are focused on pesticide exposure and associated health outcomes.

B.6.6 Reproductive toxicity (Annex IIA 5.6)

Introduction into this chapter by the RMS

For higher efficiency of the review and for the sake of transparency, the descriptions of methods and study results in the GTF dossier were virtually not amended and even the conclusions were kept as provided. However, each study that is described in detail was commented by RMS. These remarks on bottom of each study description are clearly distinguished from the original submission by a caption

and are always written in italics. In addition, redundant parts (in particular the so-called ”executive summaries”) have been deleted and the structure of the original submission was significantly changed to make it more transparent and comprehensible.
The overall assessment of reproductive toxicity of glyphosate by the RMS is provided in Volume 1 (2.6.6) of the present RAR.
Comments by the GTF on the first draft of the RAR (July 1013) have been partly included in the present report. Responses by RMS to GTF are written in italcs and given below. This approach was taken to avoid doubling of comments/responses at a later timepoint.

B.6.6.2 Separate male and female studies
Not required according to Regulation 1107/2009/EEC and Directive 91/414/EEC.
B.6.6.3 Three segment designs
Not required according to Regulation 1107/2009/EEC and Directive 91/414/EEC.
B.6.6.4 Dominant lethal assay for male fertility
Studies considered not necessary. Information provided in chapter IIA 5.4.6.
B.6.6.5 Cross-matings of treated males with untreated females and vice versa
Not required according to Regulation 1107/2009/EEC and Directive 91/414/EEC.
B.6.6.6 Effects on spermatogenesis
Studies considered not necessary. Effects on spermatogenesis are assessed in the two- generation reproductive toxicity studies (see IIA 5.6.1).
B.6.6.7 Effects on oogenesis
Studies considered not necessary. Effects on oogenesis are assessed in the two-generation reproductive toxicity studies (see IIA 5.6.1).
B.6.6.8 Sperm motility and morphology
Studies considered not necessary. Parameters are assessed in the two-generation reproductive toxicity studies (see IIA 5.6.1).
B.6.6.9 Investigation of hormonal activity
Separate studies considered not necessary. The potential hormonal activity is assessed in two-generation and developmental toxicity studies (see IIA 5.6.1, IIA 5.6.10 and IIA 5.6.11).

B.6.7 Delayed neurotoxicity (Annex IIA 5.7.2)
Introduction into this chapter by the RMS
Two neurotoxicity studies in rats have been provided by the GTF for this re-evaluation of glyphosate. These studies are summarised in the table below and, subsequently, are described in detail. Some editiorial changes to the descriptions in the GTF dossier have been made and redundant parts were deleted. Comments by the RMS may be found below the conclusions.
The delayed neurotoxicity studies in chicken that were reported in the original DAR (1998, ASB2010-10302) were re-evaluated by the RMS and found not acceptable from a today’s point of view. Thus, these studies using either the active ingredient (1987, TOX9551839) or the formulation Glycel 41 SL (1988, TOX9551963) should not be used any longer for risk assessment. However, it was noted that a more recent delayed neurotoxicity study of superior quality had been performed by (1996 ASB2013-9828). Unfortunately, this study was not part of the GTF dossier and was not submitted on request so far but was available to the RMS and could be evaluated for comprehensiveness of the database. Description of this study and its results has been amended. This study had been also reviewed by WHO/FAO in 2004 (JMPR, ASB2008-6266).
Since 2000, a number of publications have adressed glyphosate with respect to neurotoxicity endpoints. Three papers report two human cases of Parkinson`s desease. In further studies, effects

on cells and animals (worms) are investigated and discussed in relation to Parkinson`s desease. These publications are presented below.
An overall evaluation of neurotoxicity of glyphosate is presented in Volume 1 (2.6.7).

B.6.8 Further toxicological studies
Introduction into this chapter by the RMS
The metabolite aminomethyl phosphonic acid (AMPA) was extensively investigated for acute and subchronic effects, mutagenicity and developmental toxicity. Most of these studies had been submitted for the previous EU evaluations of either glyphosate or glyphosate-trimesium yet and were re-evaluated now by the RMS for reliability and acceptability. Previously known toxicity and genotoxicity studies of insufficient quality (from a today's perspective) have been deleted (1973, TOX9552394; 1978, TOX9552399; 1991, TOX9552415; 1980, TOX9552408; 1991, TOX9552404). The same holds
true for a brief information concerning kinetics and (absent) metabolism of AMPA (
, 1973, TOX9552354). Main exclusion criteria were lacking information on purity of AMPA, severe reporting deficiencies, a too low number of animals employed or the absence of relevant examinations such as histopathology that are usually required. Range- findings studies have not been considered so far a subsequent definitive main study is available.
Meanwhile, a few more studies on acute toxicity in rats and mice, on skin sensitisation and genotoxicity have been submitted that were not subject to former EU evaluation and, therefore, are reported in detail below.
All valid studies with AMPA are compiled and summarised in Table B.6.8-1.
Other metabolites of glyphosate have not been adressed in the GTF dossier from a toxicological point of view and, indeed, may be not relevant when only the intended applications and the representative formulation are taken into consideration.
However, the metabolite N-acetyl glyphosate is newly proposed to be part of the residue definition that will occur in some genetically modified plants after application of glyphosate (see also EFSA, 2009; ASB2012-3480). Toxicological studies with this metabolite have not been submitted as part of the GTF dossier to support new approval of glyphosate in the EU but were subject to a previous (2008) evaluation by the RMS that was performed in order to set import tolerances for gyphosate in soy beans and maize from genetically modified plants. This evaluation may be included in this re-evaluation of glyphosate on request by EFSA or other MS.
Sometimes, the minor metabolite N-methyl-N-(phosphonomethyl)glycine was detected. An acute oral toxicity in rats with that metabolite was described in the 1998 DAR (
1991, TOX9552398). In this (acceptable upon re-evaluation) study, no deaths occurred at the limit dose of 5000 mg/kg bw but some clinical signs were observed.
The second sub-section deals with possible effects on farm animals. In contrast to most other active substances, experimental toxicological studies in goats and cows are available with glyphosate and were described in detail by GTF on request of the RMS. Below each study description, the RMS conclusions and an assessment of validity/acceptability of this study may be found.
Recent findings of glyphosate in the urine of cows are reported and have been put into perspective by comparing the estimated systemic dose with proposed ADI and with the NOAELs/LOAELs in the abovementioned studies in cattle. Furthermore, a number of recent publications is discussed in which a possible impact of glyphosate on gut microflora of farm animals has been investigated.
A large number of studies on toxicity of glyphosate was published since 2000. Most of these studies are presented in the chapters on genotoxicity, carcinogenicity, reproductive toxicity and

neurotoxicity of this report because they are discussed there in context with these endpoints. However, some additional studies that could not be allocated to a certain endpoint are presented at the end of this chapter.

B.6.8.1.1 Further studies
Introduction by RMS:
In this section, different studies are compiled that cover various aspects of toxicology of glyphosate. Two studies were submitted as part of the GTF dossier, are summarised in Table B.6.8-15 and described in detail and commented by the RMS below. Amendments or corrections have been made where necessary.
In the 1998 DAR, some information on mechanisms of toxicity (, 1992, TOX9552421; 1987; TOX9552430) and a possible additive toxic effect of glyphosate with either dalapon or 2,4-D (1987, TOX9551964) is given. The brief descriptions of these studies with conclusions obtained during previous evaluation are copied from the old DAR, subsequent to the new studies.

B.6.8.4 Further published data (released since 2000)
Introduction by RMS:
A large number of studies on toxicity of glyphosate and its formulations was published since 2000. Most of these studies are presented in the chapters on genotoxicity, carcinogenicity, reproductive toxicity and neurotoxicity of this report because they are discussed there in context with these endpoints. However, some additional studies are presented below that could not be allocated to these endpoints.

B.6.13 Toxicological data on non active substances (Annex IIIA 7.9 and point 4 of the introduction)
B.6.13.1 Material safety data sheet for each formulant
Copies of the safety data sheets of the formulants are provided in Document J of this dossier.

B.6.15 References relied on
Studies marked in yellow are not part of the dossier for renewal.
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5
KIIIA1 7 (OECD)
EFSA
2009
Reasoned opinion: Modification of the residue definition of Glyphosate in genetically modi- fied maize grain and soybeans, and in products of animal origin
EFSA Journal 2009; 7(9):1310 ! EFSA-Q-
2009-00372

ASB2012-3480
N

KIIA 5
KIIIA1 7 (OECD)
EFSA
2012
Final review of the Séralini et al. (2012a) pub- lication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology
EFSA Journal 2012;10(11):2986
ASB2012-15513
N

KIIA 5
KIIIA1 7 (OECD)
European Commission
2002
Review report for the active substance glypho- sate. Finalised in the Standing Committee on Plant Health at its meeting on 29 June 2001in view of the inclusion of glyphosate in Annex I of Directive 91/414/EEC.
Glyphosat 6511/VI/99-final
ASB2009-4191
N

KIIA 5
KIIIA1 7 (OECD)
Germany
1998
Glyphosate (Monograph) ASB2010-10302
N

KIIA 5
KIIIA1 7 (OECD)
Germany
1998
Glyphosate-trimesium (Monograph), ASB2010-10493
N

KIIA 5
KIIIA1 7 (OECD)
Germany
2000
Glyphosate (Monograph): Addendum B.6, ASB2013-2748
N

KIIA 5
KIIIA1 7 (OECD)
OECD
2002
OECD;
Guidance Notes for Analysis and Evaluation of Chronic Toxicity and Carcinogenicity Studies
ENV/JM/MONO(2002)19
ASB2013-3754
N
---
5 Only notifier listed
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5
KIIIA1 7 (OECD)
Anonymous
2006
Backgrounder Response to “Glyphosate Toxic & Roundup Worse”. Monsanto statement.
http://www.monsanto.com/products/Document s/glyphosate-background-
materials/Response_ISIS_apr_06.pdf
ASB2013-5455
N

KIIA 5.1
K IIA 5.6 (OECD
Antoniou M, Habib MEEM, Howard CV, Jennings RC, Leifert C, No- dari RO, C Robinson, Fa-
gan J.
2011
Roundup and birth defects: Is the public being kept in the dark?
Earth Open Source report. Available from: http://www.earthopensource.org/files/pdfs/Rou ndup-
and-birth- defects/RoundupandBirthDefectsv5.pdf ASB2011-7202
N

KIIA 5.1
KIIA 5.10 (OECD)
Carr, K.H., Bleeke, M.S.
2012
Process Description for Identification, Review, and Categorization of Scientific Literature Concerning

Glyphosate and AMPA Side- Effects on Health, the Environment, and Non-
Target Species k.A.
GLP: N, published: Y
2309656 / ASB2012-11583
N
LIT
KIIA 5.1
KIIA 5.10 (OECD)
Klimisch, H.J., Andreae, M., Tillmann, U.
1997
A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data
Regulatory Toxicology and Pharmacology 25, 1-5
GLP: N, published: Y
2309856 / ASB2010-14388
N
LIT
KIIA 5.1.1
KIIA 5.5.3
KIIA 5.9
KIIA 5.10
KIIIA1 7.6.4 (OECD)
Acquavella, J.F., Alexander, B.H., Mandel, J.S., Gustin, C., Baker, B., Chapman, P.,
Bleeke, M.
2004
Glyphosate biomonitoring for farmers and their families: Results from the farm family exposure study
Environmental Health Perspectives 112, 321-
326
GLP: N, published: Y 2309536 / ASB2012-11528
N
LIT
KIIA 5.1.1
KIIA 5.4.4
KIIA 5.7.4
KIIA 5.10 (OECD)
Anadon, A., Martinez- Larranaga, M.R., Martinez, M.A.,
Castellano, V.J., Martinez, M., Martin, M.T.,
Nozal, M.J.,
Bernal, J.L.
2009
Toxicokinetics of glyphosate and its metabolite aminomethyl phosphonic acid in rats
Toxicol Lett 190, 91-95 GLP: N, published: Y 2309568 / ASB2012-11542
N
LIT
Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.1.1 (OECD)
1995
Glyphosate: ADME-study in rats - Final report A&M 038/94,
TOX9552251
N

KIIA 5.1.1
KIIA 5.4.4 (OECD)
1991
Metabolism of glyphosate in Sprague-Dawley rats: Tissue distribution, identification, and quantitation of glyphosate-derived materials following a single oral dose, Fundamental and Applied Toxicology 17(1991): 43-51
TOX9551791
N

KIIA 5.1.1
KIIA 5.3.2
KIIA 5.4
KIIA 5.5
KIIA 5.10 (OECD)
1992
NTP technical report on toxicity studies of Glyphosate administered in dosed feed to F344/N rats and B6C3F1 mice,
National Institutes of Health 16(1992) 1-57 TOX9551954
N

KIIA 5.1.1 (OECD)
1973
Final report on CP 67573 residue and metabo- lism. Part 9: The gross distribution of n-phosphonomethylglycine-14C in the rabbit
TOX9552353
N

KIIA 5.1.1 (OECD)
1973
CP 67573 residue and metabolism. Part 13: The dynamics of accumulation and depletion of orally ingested N-phosphonomethylglycine-
14C

TOX9552355
N

KIIA 5.1.1 (OECD)
1996
Glyphosate acid: Excretion and tissue retention of a single oral dose (10 mg/kg) in the rat CTL/4940 SYN
GLP: Y, published: N
2309074 / TOX2000-1977
N
SYN
KIIA 5.1.1 (OECD)
1996
Glyphosate acid: Excretion and tissue retention of a single oral dose (1000 mg/kg) in the rat CTL/4942 SYN
GLP: Y, published: N
2309076 / TOX2000-1978
N
SYN
KIIA 5.1.1
KIIA 5.1.3 (OECD)
1996
Glyphosate acid: Excretion and Tissue Retention of a Single Oral Dose (10 mg/kg) in the Rat Following Repeat Dosing CTL/P/4944 SYN
GLP: Y, published: N
2309078 / TOX2000-1979
N
SYN
KIIA 5.1.1
KIIA 5.1.3 (OECD)
1996
Glyphosate acid: Whole body autoradiography in the rat (10 mg/kg)
CTL/P/4943 SYN
GLP: Y, published: N 2309080 / TOX2000-1980
N
SYN
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5

KIIA 5.1.1
KIIA 5.9
KIIA 5.10 (OECD)
Hoppe, H.-W.
2013
Glyphosate and AMPA: Determination of glyphosate residues in human urine samples from 18 European countries
Medical Laboratory Bremen, MLHB-2013-06- 06
ASB2013-8037
N

KIIA 5.1.1 (OECD)
1988
The metabolism of glyphosate in Spra- gue/Dawley rats. Part II. Identification, charac- terization, and quantitation of glyphosate and its metabolites after intravenous and oral ad- ministration,
MSL-7206 ! 206300, TOX9552357
N

KIIA 5.1.1 (OECD)
1996
[14C]-glyphosate: Absorption, distribution, metabolism and excretion following oral ad- ministration to the rat
1413/2-1011 NUF
GLP: Y, published: N 2309072 / ASB2012-11380
Y
NUF
KIIA 5.1.1 (OECD)
1995
Metabolism study of 14C-labelled glyphosate after single oral and intravenous administration to Sprague-Dawley rats, 9202/95
TOX9650071
N

KIIA 5.1.1
KIIA 5.1.3 (OECD)
1996
Glyphosate acid: Biotransformation in the rat CTL/P/5058 SYN
GLP: Y, published: N
2309082 / TOX2000-1981
N
SYN
KIIA 5.1.1
KIIA 5.10 (OECD)
Mage, D.T.
2006
Suggested corrections to the Farm Family Exposure Study

Environmental Health Perspectives 114, A633-A634
GLP: N, published: Y
2309900 / ASB2012-11888
N
LIT
KIIA 5.1.1 (OECD)
1995
HR-001: Metabolism in the rat SNY 332/951256 HLS
GLP: Y, published: N
2309070 / ASB2012-11379
N
ALS
KIIA 5.1.1 (OECD)
1992
(14C)-glyphosate: Absorption and distribution in the rat - preliminary study
TOX9552358
N

KIIA 5.1.1 (OECD)
1992
(14C)-glyphosate: Absorption, distribution, metabolism and excretion in the rat, TOX9300343
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.1.1 (OECD)
1988
The metabolism of glyphosate in Spra- gue/Dawley rats. I. Excretion and tissue distri- bution of Glyphosate and its metabolites fol- lowing intravenous and oral administration MSL-7215 ! EHL 86139 ! ML-86-438
TOX9552356
N

KIIA 5.2.1 (OECD)
2007
Glyphosate technical material: Acute oral toxicity study in rats (Up and Down procedure) B02755; T007035-05 SYN
GLP: Y, published: N

2309111 / ASB2012-11391
Y
SYN
KIIA 5.2.1 (OECD)
1981
Acute oral toxicity of MON 0139 to rats 800257 ! ML-80-261
TOX9552321
N

KIIA 5.2.1 (OECD)
1990
Acute oral toxicity in the rat: Glyphosate tech- nical
R231 ! AGC-900823B ! AGC-101
TOX9500261
N

KIIA 5.2.1 (OECD)
1995
Glyphosate technical 95 %: Acute oral toxicity (LD50) test in rat
10670 ! IRI 556073
TOX9500377
N

KIIA 5.2.1 (OECD)
1989
Glyphosate technical: Acute oral toxicity (lim- it) test in rats
5883 ! IRI 243268
TOX9552319
N

KIIA 5.2.1 (OECD)
1991
Assessment of acute oral toxicity of "Glypho- sate technical" to mice - incl. Addendum 12321
TOX9552320
N

KIIA 5.2.1 (OECD)
2008
Acute Oral Toxicity Study in Wistar Hannover Rats for Glyphosate Technical
RF -3996.305.475.07 HAG
GLP: Y, published: N 2309100 / ASB2012-11389
Y
HAG
KIIA 5.2.1 (OECD)
1996
Glyphosate Acid: Acute Oral Toxicity Study in Rats

CTL/P/4660 SYN
GLP: Y, published: N 2309109 / TOX2000-1982
N
SYN
KIIA 5.2.1 (OECD)
1994
Glyphosate premix: Acute oral toxicity (limit test) in the rat
545/37
TOX9552322
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.1
1995
Acute Toxicity Study of MON 0139 By Oral
Y
MON
(OECD)
.
Administration in Mice
XX-95-205 MON
GLP: Y, published: N
2309115 / ASB2012-11393
KIIA 5.2.1
2009
Acute Oral Toxicity Study of Glyphosate TC
Y
HAG
(OECD)
in Rats
23910 HAG
GLP: Y, published: N
2309092 / ASB2012-11385
KIIA 5.2.1
2010
Acute Oral Toxicity Study of Glyphosate TC
Y

HAG
(OECD)
in Rats
24874 HAG
GLP: Y, published: N
2309094 / ASB2012-11386
KIIA 5.2.1
2010
Acute Oral Toxicity Study of Glyphosate TC
Y
HAG
(OECD)
in Rats
24602 HAG
GLP: Y, published: N
2309096 / ASB2012-11387
KIIA 5.2.1
1979
Acute Oral Toxicity Study in Rats.
N
MON
(OECD)
BD-77-428 MON
GLP: N, published: N
2309107 / Z35541
KIIA 5.2.1
1995
HR-001: Acute Oral Toxicity Study In Rats
Y
ALS
(OECD)
IET 94-0134 ALS
GLP: Y, published: N
2309086 / ASB2012-11382
KIIA 5.2.1
1995
HR-001: Acute Oral Toxicity Study In Mice
Y
ALS
(OECD)
IET 94-0133 ALS
GLP: Y, published: N
2309088 / ASB2012-11383
KIIA 5.2.1
2005
Glyphosate Acid Technical - Acute Oral

Y
HAG
(OECD)
Toxicity Up and Down Procedure in Rats
PSL 15274 HAG
GLP: Y, published: N
2309098 / ASB2012-11388
KIIA 5.2.1
1999
NUP5a99 62 % glyphosate MUP: Acute oral
Y
NUF
(OECD)
toxicity study in rats - Limit test
7907 NUF
GLP: Y, published: N
2309117 / ASB2012-11394
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.1 (OECD)
2014
Glyphosate: Acute oral toxicity in the rat - fixed dose method
Report No.: 41401853, Harlan Laboratories Ltd., Derbyshire, DE72 2GD, UK
Date: 2014-00-01, not published
ASB2014-9147
Y
KIIA 5.2.1 (OECD)
1987
Acute oral LD50 study of MON-8750 in Spra- gue-Dawley rats
FDRL 9308A
TOX9552323
N

KIIA 5.2.1 (OECD)
1987
Acute oral toxicity of MON 8750 in Sprague- Dawley rats
FD-86-431/9308A
Z85869

N

KIIA 5.2.1 (OECD)
1988
Acute Oral Toxicity Study of Glyphosate Batch/lot/nbr no. XLI-55 in Sprague/Dawley rats
FD-88-29 (FDRL 88.20 MON 88.2053.007)
GLP: Y, published: N 2309105 / Z35389
N
MON
KIIA 5.2.1 (OECD)
1995
Final report for oral and dermal LD50 tests with Sanachem glyphosate acid technical in rats, limit test
00917
TOX9650909
N

KIIA 5.2.1
KIIA 5.2.2 (OECD)
1995
Final report for oral and dermal LD50 tests with Sanachem glyphosate 62 % IPA in rats, limit test
00926
TOX9650910
N

KIIA 5.2.1 (OECD)
2009
Glyphosate Technical: Acute oral Toxicity Study in Rat, C22864,
C22864 EXC
GLP: Y, published: N 2309090 / ASB2012-11384
Y
EXC
KIIA 5.2.1 (OECD)
1994
Glyphosate: Acute oral toxicity (limit test) in the rat
710/14
TOX9500245
N

KIIA 5.2.1 (OECD)
1991
Acute oral toxicity study with glyphosate tech- nical (FSG 03090 H/05 march 90) in Wistar rats
ES.874.AOR ! ES-GPT-AOR ! TOXI- 874/1990
TOX9551088
N

Annex point/ reference number

Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.1
1991
Acute oral toxicity study with glyphosate tech-
N

(OECD)
nical (FSG 03090 H/05 march 90) in swiss
albino mice
ES.875.AOM ! ES-GPT-AOM ! TOXI-
875/1990
TOX9551089
KIIA 5.2.1
2007
GLYPHOSATE TECHNICAL (NUP05068) :
Y
NUF
(OECD)
Acute oral toxicity study in rats
BO2272 NUF
GLP: Y, published: N
2309103 / ASB2012-11390
KIIA 5.2.1
2011
Glyphosate technical - Acute Oral Toxicity
Y
SYN
(OECD)
Study in the Rat (Up and Down Procedure)
10/218-001P SYN
GLP: Y, published: N
2309113 / ASB2012-11392
KIIA 5.2.1
1994
Glyphosate (Alkaloida, Tiszavasvari): Acute
N

(OECD)

oral toxicity in rats
GHA-94-401/R
TOX9650142
KIIA 5.2.1
1994
Glyphosate technical: Acute oral toxicity study
N

(OECD)
in mice
940020 ! PRO629
TOX9551624
KIIA 5.2.1
1989
Acute oral toxicity study with glyphosate tech-
N

(OECD)
nical (isopropylamine salt 62 % in water
equivalent to 46 % of N-
phosphonomethylglycine acid) in rats
238050 ! PRO439
TOX9551623
KIIA 5.2.1
1992
Glyphosate technical: Acute oral toxicity (limit
N

(OECD)
test) in the rat
134/37
TOX9551810
KIIA 5.2.1
1987
Acute oral toxicity of 41 % SN750721 solution
N

(OECD)
in mice - Test report entrusted by Shinung
Corporation
TX58AO2
TOX9500376
KIIA 5.2.1
1987
Acute oral toxicity of 64 % SN750721 tech-
N

(OECD)
nical liquid in mice Test report entrusted by
Shinung Corporation
TX58AO1
TOX9500375
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.1 (OECD)
2009
Glyphosate: Acute Oral Toxicity Study (UDP) In Rats
12170-08 HEL
GLP: Y, published: N 2309084 / ASB2012-11381
Y
HAG
KIIA 5.2.2 (OECD)
2007
Glyphosate technical material: Acute dermal toxicity study in rats
B02766 (T007036-05) SYN
GLP: Y, published: N 2309141 / ASB2012-11404
Y
SYN
KIIA 5.2.2 (OECD)
1981
Acute dermal toxicity of MON 0139 to rabbits 800258 ! ML-80-261
TOX9552326
N

KIIA 5.2.2 (OECD)
1990
Acute dermal toxicity study in the rat: Glypho- sate technical
AGC-900823A ! AGC-301 ! R232
TOX9551793
N

KIIA 5.2.2 (OECD)
1987
Acute dermal toxicity study of Mon 8750 in New Zealand white rabbits

FDRL 9308A ! FD-86-431
TOX9552327
N

KIIA 5.2.2 (OECD)
1987
Acute dermal toxicity study of Mon 8722 in New Zealand white rabbits
FDRL 9307A ! FD-86-430
TOX9552328
N

KIIA 5.2.2 (OECD)
1989
Glyphosate Technical Acute Dermal Toxicity (Limit) Test in Rats
5884 CHE
GLP: Y, published: N 2309119 / TOX9300328
N
CHE
KIIA 5.2.2 (OECD)
2008
Acute Dermal Toxicity in Wistar Hannover Rats for Glyphosate Technical
RF-3996.310.456.07 HAG
GLP: Y, published: N 2309135 / ASB2012-11402
Y
HAG
KIIA 5.2.2 (OECD)
1996
Glyphosate Acid: Acute Dermal Toxicity in the Rat
CTL/P/4664 SYN
GLP: Y, published: N 2309139 / TOX2000-1983
Y
SYN
KIIA 5.2.2 (OECD)
2009
Acute Dermal Toxicity Study of Glyphosate TC in CD Rats
LPT 23912 HAG
GLP: Y, published: N 2309127 / ASB2012-11398
Y
HAG
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number

Data protection claimed
Y/N
Owner5
KIIA 5.2.2
2010
Acute Dermal Toxicity Study of Glyphosate
Y
HAG
(OECD)
TC in CD Rats
LPT 24876 HAG
GLP: Y, published: N
2309129 / ASB2012-11399
KIIA 5.2.2
2010
Acute Dermal Toxicity Study of Glyphosate
Y
HAG
(OECD)
TC in CD Rats
LPT 24604 HAG
GLP: Y, published: N
2309131 / ASB2012-11400
KIIA 5.2.2
1995
HR-001: Acute dermal toxicity study in rats
N
ALS
(OECD)
IET 94-0154 ALS
GLP: Y, published: N
2309123 / ASB2012-11396
KIIA 5.2.2
2005
Glyphosate Acid Technical: Acute Dermal
Y
HAG
(OECD)
Toxicity Study in Rats - Limit Test
PSL 15275 HAG
GLP: Y, published: N
2309133 / ASB2012-11401
KIIA 5.2.2
1994
Acute dermal toxicity of glyphosate technical
N

(OECD)
in the rat
T1586.3.A
TOX9500378
KIIA 5.2.2
1988
Acute dermal toxicity of glyphosate
N

(OECD)
Batch/lot/nbr no. XLI-55 in new zealand white
rabbits
88.2053.008 ! FD-88-29
TOX9552325
KIIA 5.2.2
2009
Glyphosate Technical: Acute Dermal Toxicity
Y
EXC
(OECD)
Study in Rat
C22875 EXC
GLP: Y, published: N
2309125 / ASB2012-11397
KIIA 5.2.2
1994
Glyphosate: Acute dermal toxicity (limit test)
N

(OECD)
in the rat
710/15
TOX9500246
KIIA 5.2.2
1991
Acute dermal toxicity study with glyphosate
N

(OECD)
technical (FSG 03090 H/05 march 90) in
Wistar rats
ES.876.ADR ! ES-GPT-ARD ! TOXI-
876/1990
TOX9551090
Annex point/ reference number

Author(s) Year Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.2 (OECD)
KIIA 5.2.2 (OECD)
2007 GLYPHOSATE TECHNICAL (NUP05068):
Acute dermal toxicity study in rats B02283 NUF
GLP: Y, published: N 2309137 / ASB2012-11403
1994 Glyphosate (Alkaloida, Tiszavasvari): Acute dermal toxicity in rats
GHA-94-402/R TOX9650143
Y NUF
N ---
KIIA 5.2.2 (OECD)
.
KIIA 5.2.2 (OECD)
KIIA 5.2.2 (OECD)
KIIA 5.2.2 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
1989 Acute dermal toxicity study with glyphosate technical (isopropylamine salt 62 % in water equivalent to 46 % of N- phosphonomethylglycine acid) in rats 238061 ! PRO425
TOX9551625
1992 Glyphosate technical: Acute dermal toxicity (limit test) in the rat
134/38
TOX9551813
2009 Glyphosate - Acute Dermal Toxicity Study in Rats
12171-08 HAG
GLP: Y, published: N 2309121 / ASB2012-11395
2011 Glyphosate Technical - Acute Dermal Toxicity Study in Rats - Final Report Amendmend 1
10/218-002P SYN
GLP: Y, published: N 2309143 / ASB2012-11405
1988 Acute inhalation study of MON 8750 technical EHL 87147 ! ML-87-228
TOX9552332
1994 Glyphosate premix: Acute inhalation toxicity study four-hour exposure (nose only) in the rat
523-001 ! 545/39
TOX9552331
1995 Glyphosate: Acute inhalation toxicity study four-hour exposure (nose only) in the rat 710/16
TOX9500247
2004 An acute nose-only inhalation toxicity study in rats with MON 78623
SB-2003-116 MON

GLP: Y, published: N 2309169 / ASB2012-11417
N ---
N ---
Y HAG
Y SYN
N ---
N ---
N ---
Y MON
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.3
2009
Glyphosate - Acute Inhalation Toxicity Study
Y
HAG
(OECD)
in Rats
12107-08 HAG
GLP: Y, published: N
2309155 / ASB2012-11411
KIIA 5.2.3
2007
Glyphosate technical (NUP05068) : 4-Hour
Y
NUF
(OECD)
acute inhalation toxicity study in rats
B02327 NUF
GLP: Y, published: N
2309161 / ASB2012-11414
KIIA 5.2.3
1987
Acute toxicity of Rodeo herbicide adminis-
N

(OECD)
tered by inhalation to male and female Spra-

gue-Dawley rats
EHL 86105 ! ML-86-281 ! MSL 6582
TOX9552330
KIIA 5.2.3
2009
Glyphosate Tech: Acute Inhalation Toxicity
Y
EXC
(OECD)
(Nose only) Study in the Rat
2743/0001 EXC
GLP: Y, published: N
2309149 / ASB2012-11408
KIIA 5.2.3
2009
Acute Inhalation Toxicity Study of Glyphosate
Y
HAG
(OECD)
TC in Rats
LPT 23911 HAG
GLP: Y, published: N
2309151 / ASB2012-11409
KIIA 5.2.3
2010
Acute Inhalation Toxicity Study of Glyphosate
Y
HAG
(OECD)
TC In Rats
24603 HEL
GLP: Y, published: N
2309145 / ASB2012-11406
KIIA 5.2.3
2010
Acute Inhalation Toxicity Study of Glyphosate
Y
HAG
(OECD)
TC in Rats
LPT 24875 HAG
GLP: Y, published: N
2309153 / ASB2012-11410
KIIA 5.2.3
1995
HR-001: Acute inhalation toxicity study in rats

Y
ALS
(OECD)
IET 94-0155 ALS
GLP: Y, published: N
2309147 / ASB2012-11407
KIIA 5.2.3
1989
Glyphosate technical: Acute inhalation toxicity
N

(OECD)
study in rats (limit test)
5993 ! IRI 642062
TOX9552329
Annex point/ reference number
Author(s) Year Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
KIIA 5.2.3 (OECD)
2005 Glyphosate Acid Technical: Acute Inhalation Toxicity Study in Rats - Limit Test
PSL 15276 HAG
GLP: Y, published: N 2309157 / ASB2012-11412
2011 Glyphosate Technical - Acute inhalation Toxicity Study (Nose-only) in the Rat 11/054-004P SYN
GLP: Y, published: N 2309165 / ASB2012-11415
1996 Glyphosate Acid: 4-Hour Acute Inhalation Toxicity Study in the Rat
CTL/P/4882 SYN
GLP: Y, published: N 2309163 / TOX2000-1984
1989 4-hour, acute inhalation toxicity study with glyphosate technical in rats
238105 ! PRO426 TOX9551626
1994 Glyphosate (Alkaloida, Tiszavasvari): Acute inhalation toxicity in rats
GHA-94-403/R TOX9650144

Y HAG
Y SYN
Y SYN
N ---
N ---

KIIA 5.2.3 (OECD)
KIIA 5.2.4 (OECD)
KIIA 5.2.4 (OECD)
KIIA 5.2.4 (OECD)
1999 NUP5a99 62 % glyphosate MUP: Acute inhalation toxicity study in rats - Limit test 7909 NUF
GLP: Y, published: N 2309167 / ASB2012-11416
2007 Glyphosate technical material: Primary skin irritation study in rabbits (4-hour semi- occlusive application)
B02777 (T007037-05) SYN
GLP: Y, published: N 2309193 / ASB2012-11426
1990 Acute dermal irritation/corrosion of glyphosate technical in the rabbit (intact and abraded skin)
AGC-900822A ! AGC-001 ! R233 TOX9551794
1987 Primary dermal irritation study of Mon-8750 in New Zealand white rabbits
FDRL 9308A ! FD-86-431 TOX9552336
Y NUF
Y SYN
N ---
N ---
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.4
2008
Acute Dermal Irritation/Corrosion Study in
Y
HAG
(OECD)
Rabbits with Glyphosate Technical
RF-3996.311.476.07 HAG
GLP: Y, published: N
2309185 / ASB2012-11425
KIIA 5.2.4
1989
Glyphosate technical: Primary skin irritation
N

(OECD)
test in rabbits
5885 ! IRI 243268

TOX9552333
KIIA 5.2.4
1996
Glyphosate Acid: Skin Irritation To The Rabbit
Y
SYN
(OECD)
CTL/P/4695 SYN
GLP: Y, published: N
2309191 / TOX2000-1985
KIIA 5.2.4
1994
Glyphosate premix: Acute dermal irritation test
N

(OECD)
in the rabbit
565-003 ! 545/40
TOX9552335
KIIA 5.2.4
1995
HR-001: Primary Dermal irritation study in
Y
ALS
(OECD)
rabbits
IET 95-0035 ALS
GLP: Y, published: N
2309175 / ASB2012-11420
KIIA 5.2.4
2009
Acute Dermal Irritation/Corrosion Test (Patch
Y
HAG
(OECD)
Test) of Glyphosate TC In Rabbits
24877 HEL
GLP: Y, published: N
2309173 / ASB2012-11419
KIIA 5.2.4
2009
Acute Dermal Irritation/Corrosion Test (Patch
Y
HAG
(OECD)
Test) of Glyphosate TC in Rabbits

LPT 23913 HAG
GLP: Y, published: N
2309177 / ASB2012-11421
KIIA 5.2.4
2010
Acute Dermal Irritation/Corrosion Test (Patch
Y
HAG
(OECD)
Test) of Glyphosate TC in Rabbits
LPT 24605 HAG
GLP: Y, published: N
2309179 / ASB2012-11422
KIIA 5.2.4
2005
Glyphosate Acid Technical - Primary Skin
Y
HAG
(OECD)
Irritation Study in Rabbits
PSL 15278 HAG
GLP: Y, published: N
2309183 / ASB2012-11424
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.4
1988
Primary Dermal Irritation Study of Glyphosate
N
MON
(OECD)
Batch/lot/nbr no. XLI-55 in New Zealand
White Rabbits
FD-88-29 (FDRL 88.20 MON
GLP: Y, published: N
2309187 / Z35394
KIIA 5.2.4
1994

Glyphosate 360g/L: Acute dermal irritation
N

(OECD)
test in the rabbit
710/29
TOX9500248
KIIA 5.2.4
1991
Primary skin irritation study with glyphosate
N

(OECD)
technical (FSG 03090 H/05 march 90) in New Zealand white rabbits
ES.878.SKIN ! TOXI-878/1990 ! ES-GPT-SKIN
TOX9551092
KIIA 5.2.4
2007
Glyphosate Technical (NUP 05068): Primary
Y
NUF
(OECD)
Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application)
B02294 NUF
GLP: Y, published: N
2309171 / ASB2012-11418
KIIA 5.2.4
1994
Glyphosate (Alkaloida, Tiszavasvari): Primary
N

(OECD)
dermal irritation study in rabbits
GHA-93-404/N
TOX9650145
KIIA 5.2.4
1991
Acute dermal irritation study in New Zealand
N

(OECD)
White rabbits treated with the test article glyphosate tecnico 98 %

910259 ! PRO495
TOX9551627
KIIA 5.2.4
1989
Primary skin irritation study with glyphosate
N

(OECD)
technical (isopropylamine salt 62 % in water
equivalent to 46 % of N-
phosphonomethylglycine acid) in rabbits (4-
hour semi-occlusive application on intact and
abraded skin)
238072 ! PRO438
TOX9551628
KIIA 5.2.4
2009
Glyphosate - Acute Dermal Irritation Study in
Y
HAG
(OECD)
Rabbits
12173-08 HAG
GLP: Y, published: N
2309181 / ASB2012-11423
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.4
2011
Glyphosate technical - Primary skin irritation
Y
SYN
(OECD)
study in rabbits - Final report Amendment 1
10/218-006N SYN
GLP: Y, published: N
2309195 / ASB2012-11427
KIIA 5.2.5

2007
Glyphosate technical material: Primary eye
Y
SYN
(OECD)
irritation study in rabbits
B02788 (T007038-05) SYN
GLP: Y, published: N
2309219 / ASB2012-11437
KIIA 5.2.5
1990
Acute eye irritation/corrosion of glyphosate
N

(OECD)
technical in the rabbit
AGC-900822 ! AGC-002 ! R234
TOX9500264
KIIA 5.2.5
1987
Primary eye irritation of Mon 8722 in New
N

(OECD)
Zealand white rabbits
FDRL 9307A ! FD-86-430
TOX9552342
KIIA 5.2.5
2008
Acute Eye Irritation/Corrosion Study in
Y
HAG
(OECD)
Rabbits with Glyphosate Technical
RF-3996.312.599.07 HAG
GLP: Y, published: N
2309213 / ASB2012-11436
KIIA 5.2.5
1989
Glyphosate technical: Primary eye irritation
N

(OECD)
test in rabbits
5886 ! IRI 243268
TOX9552338

KIIA 5.2.5
1994
Glyphosate premix: Acute eye irritation test in
N

(OECD)
the rabbit
566-003 ! 545/41
TOX9552340
KIIA 5.2.5
1995
HR-001: Primary Eye Irritation study in rabbits
Y
ALS
(OECD)
IET 95-0034 ALS
GLP: Y, published: N
2309201 / ASB2012-11430
KIIA 5.2.5
1997
Glyphosate Acid: Eye Irritation to the Rabbit
Y
SYN
(OECD)
CTL/P/5138 SYN
GLP: Y, published: N
2309217 / TOX2000-1986
KIIA 5.2.5
1996
CHA 440: Primary eye irritation study in rab-
N

(OECD)
bits
2981-96 ! S9-FF81-4.C41
TOX1999-881
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5

KIIA 5.2.5
2009
Acute Eye Irritation/Corrosion Test Of
Y
HAG
(OECD)
Glyphosate TC In Rabbits
24878 HEL
GLP: Y, published: N
2309199 / ASB2012-11429
KIIA 5.2.5
2009
Acute Eye Irritation/Corrosion Test of
Y
HAG
(OECD)
Glyphosate TC in Rabbits
LPT 23914 HAG
GLP: Y, published: N
2309205 / ASB2012-11432
KIIA 5.2.5
2010
Acute Eye Irritation/Corrosion Test of
Y
HAG
(OECD)
Glyphosate TC in Rabbits
LPT 24606 HAG
GLP: Y, published: N
2309207 / ASB2012-11433
KIIA 5.2.5
2005
Eye Irritation/Corrosion Effects in Rabbits
Y
HAG
(OECD)
(Oryctolagus cuniculus) of Glyphosate 95 TC
PSL 15277 HAG
GLP: Y, published: N
2309211 / ASB2012-11435
KIIA 5.2.5
1988
Primary Eye Irritation Study of Glyphosate
N
MON
(OECD)

FD-88-29 MON
GLP: N, published: N
2309215 / Z35395
KIIA 5.2.5
2009
Expert Statement Expert Statement Expert
Y
EXC
(OECD)
Statement Glyphosate technical: Primary eye
irritation study in rat
C22897 EXC
GLP: Y, published: N
2309203 / ASB2012-11431
KIIA 5.2.5
1994
Glyphosate: Acute eye irritation test in the
N

(OECD)
rabbit
710/18
TOX9500249
KIIA 5.2.5
1991
Primary eye irritation study with glyphosate
N

(OECD)
technical (FSG 03090 H/05 march 90) in New
Zealand white rabbits
ES.879.EYE ! TOXI-879/1990 ! ES-GPT-EYE
TOX9551093
KIIA 5.2.5
2007
Glyphosate Technical (NUP 05068): Primary
Y
NUF
(OECD)
Eye Irritation Study In Rabbits
B02305 NUF
GLP: Y, published: N
2309197 / ASB2012-11428
Annex point/ reference number
Author(s)
Year

Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.5 (OECD)
2011
Glyphosate Technical - Acute Eye Irritation Study in Rabbits
10/218-005N NUF
GLP: Y, published: N 2309221 / ASB2012-11438
Y
SYN
KIIA 5.2.5
1994
Glyphosate (Alkaloida, Tiszavasvari): Primary
N

(OECD)
eye irritation study in rabbits
GHA-93-405/N
TOX9650146
KIIA 5.2.5
1991
Acute eye irritation study in New Zealand
N

(OECD)
White rabbits treated with the test article
glyphosate tecnico 98 %
910260 ! PRO496
Z101610
KIIA 5.2.5
1989
Primary eye irritation with glyphosate tech-
N

(OECD)
nical (isopropylamine salt 62 % in water
equivalent to 46 % of N-
phosphonomethylglycine acid) in the rabbit
(rinsed / unrinsed eyes) 238083 ! PRO423
TOX9551629
KIIA 5.2.5 (OECD)
2009

Glyphosate - Acute Eye Irritation Study in Rabbits
12172-08 HAG
GLP: Y, published: N 2309209 / ASB2012-11434
Y
HAG
KIIA 5.2.6 (OECD)
1983
A dermal sensitization study in guinea pigs with Glyphosate
BD-83-008 ! B/d 4235-82
Z35238
N

KIIA 5.2.6 (OECD)
2007
Glyphosate Technical Material - Skin Sensitisation (Local Lymph Node Assay in the Mouse)
GM8048-REG SYN
GLP: Y, published: N 2309245 / ASB2012-11449
Y
SYN
KIIA 5.2.6 (OECD)
1989
Glyphosate technical: Magnusson-Kligman maximisation test in guinea pigs
5887 ! IRI 243268
TOX9552343
N

KIIA 5.2.6 (OECD)
1996
Glyphosate Acid: Skin Sensitisation to the Guinea Pig
CTL/P/4699 SYN
GLP: Y, published: N 2309243 / TOX2000-1987
Y
SYN
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.6
1994
Glyphosate premix: Magnusson & Kligman

N

(OECD)
maximisation study in the guinea pig
567-003 ! 545/42
TOX9552345
KIIA 5.2.6
2009
Examination of Glyphosate TC in Skin
Y
HAG
(OECD)
Sensitisation Test in Guinea Pigs according to
Magnusson and Kligman (Maximisation Test)
LPT 23915 HAG
GLP: Y, published: N
2309231 / ASB2012-11443
KIIA 5.2.6
2010
Examination Of Glyphosate TC In The Skin
Y
HAG
(OECD)
Sensitisation Test In Guinea Pigs According
To Magnusson And Kligman (Maximisation
Test)
24879 HEL
GLP: Y, published: N
2309225 / ASB2012-11440
KIIA 5.2.6
2010
Examination of Glyphosate TC in Skin
Y
HAG
(OECD)
Sensitisation Test in Guinea Pigs according to
Magnusson and Kligman (Maximisation Test)
LPT 24607 HAG
GLP: Y, published: N
2309233 / ASB2012-11444
KIIA 5.2.6
1995
HR-001: Dermal sensitisation study in guinea
Y
ALS
(OECD)

pigs
IET 95-0036 ALS
GLP: Y, published: N
2309227 / ASB2012-11441
KIIA 5.2.6
2008
Skin Sensitisation Test for Glyphosate
Y
HAG
(OECD)
.
Technical in Guinea Pigs. Buehler Test
RF-3996.318.431.07 HAG
GLP: Y, published: N
2309239 / ASB2012-11447
KIIA 5.2.6
2005
Glyphosate acid technical - Dermal
Y
HAG
(OECD)
Sensitisation in Guinea Pigs (Buehler Method)
PSL 15279 HAG
GLP: Y, published: N
2309237 / ASB2012-11446
KIIA 5.2.6
1993
Skin sensitisation test in guinea-pigs with
N

(OECD)
glyphosate technical 95 % min of Excel Indus-
tries Ltd., Bombay.
IIT 1230
TOX9650652
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.2.6

2006
Glyphosate Technical: Skin Sensitisation in the
Y
NUF
(OECD)
Guinea Pig - Magnusson and Kligman
Maximisation method
2060/009 (SMK-PH-05- NUF
GLP: Y, published: N
2309241 / ASB2012-11448
KIIA 5.2.6
2009
Glyphosate Technical: Contact
Y
EXC
(OECD)
Hypersensitivity in albino guinea pigs -
Maximisation-Test
C22908 EXC
GLP: Y, published: N
2309229 / ASB2012-11442
KIIA 5.2.6
1994
Glyphosate: Magnusson & Kligman maximisa-
N

(OECD)
tion study in the guinea pig
710/19
TOX9500250
KIIA 5.2.6
2007
Glyphosate Technical (NUP 05068): Contact
Y
NUF
(OECD)
Hypersensitivity in Albino Guinea Pigs,
Maximisation Test
B02316 NUF
GLP: Y, published: N
2309223 / ASB2012-11439
KIIA 5.2.6
,
2011
Glyphosate technical - Local lymph node assay
Y

SYN
(OECD)
in the mouse - Final report amendment 2
10/218-037E SYN
GLP: Y, published: N
2309247 / ASB2012-11450
KIIA 5.2.6
1991
Luxan glyphosate techn.: Magnusson & Klig-
N

(OECD)
man maximisation study in the guinea pig
349/11
TOX9551796
KIIA 5.2.6
2009
Glyphosate - Skin Sensitisation Study in
Y
HAG
(OECD)
Guinea Pigs. Buehler Test
12174-08 HAG
GLP: Y, published: N
2309235 / ASB2012-11445
KIIA 5.3.1
1989
Glyphosate: 4 week dietary toxicity study in
N

(OECD)
rats
5626 ! IRI 437462
TOX9552351
KIIA 5.3.1
1989
Glyphosate: Oral maximum tolerated dose
N

(OECD)
study in dogs
O.
5660 ! IRI 640683
TOX9552352
Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.3.1
KIIIA1 7.6.2
2012
Glyphosate acid - In Vitro absorption through
abraded rabbit skin using [14C]-glyphosate
Y
EGT
(OECD)
JV2182-REG GTF
GLP: Y, published: N
2309282 / ASB2012-11459
KIIA 5.3.1
1993
Glyphosate: 3 week toxicity study in rats with
N

(OECD)
dermal administration
7839 ! IRI 450881
TOX9552367
KIIA 5.3.1
1982
21-Day dermal toxicity study in rabbits
N
MON
KIIA 5.3.7
IR-81-195 MON
KIIIA1 7.6.2
GLP: N, published: N
(OECD)
2309280 / TOX9552366
KIIA 5.3.1
1982
Range finding study of MON 0139 and iso-
N

(OECD)
propylamine administered orally to dogs

ML-81-032/810036 ! MSL-2155
TOX9552349
KIIA 5.3.1
1996
Glyphosate acid: 21-day dermal toxicity study
Y
SYN
(OECD)
in rats
CTL/P/4985 SYN
GLP: Y, published: N
2309288 / ASB2012-11461
KIIA 5.3.1
1991
28-day dietary study in rats on glyphosate
N

(OECD)
technical
ES.881.28 DDR ! TOXI-881/1991 ! ES-GPT-
28 DDR
TOX9551095
KIIA 5.3.1
1994
28-day dietary study in rats on glyphosate
N

(OECD)
technical –Amendment
ES.881.28 DDR ! TOXI-881/1991 ! ES-GPT-
28 DDR
Z102035
KIIA 5.3.1
1994
28-day dietary study in rats on glyphosate
N

(OECD)
technical –Amendment
ES.881.28 DDR ! TOXI-881/1991 ! ES-GPT-
28 DDR
Z102035
KIIA 5.3.1
1994
28-day dietary study in rats on glyphosate

N

(OECD)
technical - Second Amendment
ES.881.28 DDR ! TOXI-881/1991 ! ES-GPT-
28 DDR
Z102043
KIIA 5.3.1
1994
GGlyphosate technical (Alkaloida,
N
MON
KIIA 5.3.7
Tiszavasvári): Repeated dose twenty-eight-
(OECD)
Day dermal toxicity study in rabbits
MÜF 214/94 MON
GLP: Y, published: N
2309284 / TOX9650151
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.3.1
KIIIA1 7.1.3 (OECD)
1983
Four-week study of 33-1/3 % use-dilution of Roundup in water administered to male and female
Sprague-Dawley rats by inhalation 830025 ! ML-83-015
TOX2002-694
N

KIIA 5.3.2 (OECD)
1981
Glyphosate: Subchronic toxicological study 90-day rats
TOX9650152
N

KIIA 5.3.2 (OECD)
1996
First Revision to Glyphosate Acid: 90 Day Oral Feeding Study in Rats

CTL/P/1599 SYN
GLP: Y, published: N 2309249 / TOX2000-1990
Y
SYN
KIIA 5.3.2 (OECD)
1990
Glyphosate technical: 90 day oral toxicity study in the rat
AGC-900914 ! AGC-401 ! R230
TOX9500266
N

KIIA 5.3.2 (OECD)
1996
Technical Glyphosate: Ninety Day Sub- Chronic Oral (Dietary) Toxicity Study In The Rat
434/016 NUF
GLP: Y, published: N 2309256 / ASB2012-11451
Y
NUF
KIIA 5.3.2 (OECD)
1989
Glyphosate technical: 90 day oral toxicity study in the rats - incl. Amendment to Protocol BY-401
BY-891002 ! BY-401
TOX9551821
N

KIIA 5.3.2 (OECD)
1995
HR-001: 13-week Subchronic Oral Toxicity Study in Rats
IET 94-0138 ALS
GLP: Y, published: N 2309258 / ASB2012-11452
Y
ALS
KIIA 5.3.2 (OECD)
1995
HR-001: 13-week Oral Subchronic Toxicity Study in Mice
IET 94-0136 ALS
GLP: Y, published: N 2309260 / ASB2012-11453
N
ALS
KIIA 5.3.2 (OECD)
1993
90 day range finding study of glyphosate in rats
011-0001 ALK
GLP: Y, published: N 2309252 / TOX9650149
N
ALK

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.3.2
1991
Glyphosate: 13-week dietary toxicity study in
N

(OECD)
rats
7136 ! IRI 437876
TOX9552364
KIIA 5.3.2
1991
Glyphosate: 13-week dietary toxicity study in
N

(OECD)
mice
7024 ! IRI 437918
TOX9552363
KIIA 5.3.2
1987
90-day study of glyphosate administered in
N

(OECD)
W.
feed to Sprague-Dawley rats
MSL 7375 ! ML-86-351 ! EHL 86128
TOX9552362
KIIA 5.3.2
1992
Glyphosat techn. (FSG 03090 H/05 March
N

(OECD)
1990): 90 day oral toxicity study in wistar rats
TOXI-882/1991 ! ES-GPT-90 OR ! ES-882 90

OR
TOX9551096
KIIA 5.3.3
2007
Glyphosate Technical: 13-Week Toxicity
Y
NUF
(OECD)
Study By Oral Route (Capsule) In Beagle
Dogs
29646 TCC NUF
GLP: Y, published: N
2309262 / ASB2012-11454
KIIA 5.3.3
1996
First Revision to Glyphosate Acid: 90-Day
Y
SYN
(OECD)
Oral Toxicity Study in Dogs
CTL/P/1802 SYN
GLP: Y, published: N
2309271 / TOX2000-1991
KIIA 5.3.3
1999
Subchronic (90 Day) Oral Toxicity Study With
Y
ADM
(OECD)
Glyphosate Technical In Beagle Dogs AND
Test compound stability in experimental diet
(dog feed)
1816 / 1817-R.FST FSG
GLP: Y, published: N
2309264 / ASB2012-11455
KIIA 5.3.3
1985
Twelve month study of glyphosate adminis-
N

(OECD)
tered by gelatin capsule to beagle dogs
MSL-5069 ! 636
Z35385
KIIA 5.3.3
1983

Six month study of MON 0139 administered
N

(OECD)
by gelatin capsule to beagle dogs
810166 ! ML-81-368
TOX9552361
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.3.3
1996
HR-001: 13-week Oral Subchronic Toxicity
Y
ALS
(OECD)
Study in Dogs
IET 94-0158 ALS
GLP: Y, published: N
2309269 / ASB2012-11456
KIIA 5.3.4
1996
Glyphosate Acid: 1 Year Dietary Toxicity
Y
SYN
(OECD)
Study in Dogs
CTL/P/5079 SYN
GLP: Y, published: N
2309278 / TOX2000-1992
KIIA 5.3.4
1990
Glyphosate: 52-week oral toxicity study in
N

(OECD)
dogs
7502 ! IRI 642675
TOX9552384

KIIA 5.3.4
2007
Glyphosate technical: 52-week Toxicity Study
Y
NUF
(OECD)
by Oral Route (Capsule)in Beagle Dogs
29647 TCC NUF
GLP: Y, published: N
2309274 / ASB2012-11457
KIIA 5.3.4
1997
HR-001: 12-Month Oral Chronic Toxicity
Y
ALS
(OECD)
Study in Dogs
IET 94-0157 ALS
GLP: Y, published: N
2309276 / ASB2012-11458
KIIA 5.4.1
1995
HR-001: Reverse Mutation Test
Y
ALS
(OECD)
IET 94-0142 ALS
GLP: Y, published: N
2309291 / ASB2012-11462
KIIA 5.4.1
Callander, R.D.
1996
Glyphosate acid: An evaluation of mutagenic
Y
SYN
(OECD)
potential using S. typhimurium and E. coli
CTL/P/4874 SYN
GLP: Y, published: N
2309313 / ASB2012-11473
KIIA 5.4.1
Flügge, C.
2009
Mutagenicity Study of Glyphosate TC in the
Y
HAG

(OECD)
Salmonella typhimurium Reverse Mutation
Assay (in vitro)
LPT 23916 HAG
GLP: Y, published: N
2309303 / ASB2012-11468
KIIA 5.4.1
Flügge, C.
2010
Mutagenicity Study of Glyphosate TC in the
Y
HAG
(OECD)
Salmonella typhimurium Reverse Mutation
Assay (in vitro)
LPT 24880 HAG
GLP: Y, published: N
2309305 / ASB2012-11469
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.1 (OECD)
Jensen, J. C.
1991
Mutagenicity test: Ames salmonella assay with glyphosate, batch 206-JaK-25-1
Report: 12323,
TOX9552371
Y

KIIA 5.4.1
KIIIA1 7.6.3 (OECD)
Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.
1992
Ames/salmonella mutagenicity assay of MON 2139 (Roundup herbicide formulation)
EHL 91183 ! ML-91-440 ! MSL-11729 TOX1999-239
N

KIIA 5.4.1 (OECD)
Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.

1992
Ames/salmonella mutagenicity assay of MON 14445 (DIRECT Herbicide formulation)
MSL-11731 ! EHL 91185/ML-91-442 TOX1999-320
N

KIIA 5.4.1
KIIA 5.4.4 (OECD)
Kier, L. D.; Stegeman, S. D.; Costello, J. G.; Schermes, S.
1992
Ames/Salmonella mutagenicity assay of Rodeo MSL-11730 ! EHL 91184/ML-91-441 TOX9552373
N

KIIA 5.4.1 (OECD)
Li, A. P.;
Long, T. J.
1988
An evaluation of the genotoxic potential of glyphosate, Fundamental and Applied Toxi- cology 10 (1988)537 – 546
published: Y,
TOX9500253
N

KIIA 5.4.1
KIIA 5.4.4 (OECD)
Rank, J.;
Jensen, A. G.; Skov, B.
1993
Genotoxicity testing of the herbicide roundup and its active ingredient glyphosate isopropyl- amine using the mouse bone marrow micronu- cleus test, Salmonella mutagenicity test, and Allium anaphase-telephase test
Z82234
Y

KIIA 5.4.1
KIIA 5.4.4 (OECD)
Rasmussen, E. S.
1997
Genotoxicity of Roundup/Glyphosate, Danish Environmental Protection Agency, AA036753, 7042-0110
ASB2013-9671
N

KIIA 5.4.1 (OECD)
Riberri do Val, R.
2007
Bacterial reverse mutation test (Ames Test) for Glifosato Técnico Helm

3393/2007-2.0AM-B HAG
GLP: Y, published: N 2309299 / ASB2012-11466
Y
HAG
KIIA 5.4.1 (OECD)
Schreib, G.
2012
Reverse mutation assay using Bacteria (Sal- monella typhimurium) with Glyphosate tech. 126159
ASB2014-9133
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.1 (OECD)
Shirasu, Y.; Moriya, M.; Ota, T.;
Ohta, T.
1978
Glyphosate: The report of mutagenic study with bacteria for CP 67573 - Microbial muta- genicity testing on CP67573
Report: ET-78-241,
TOX9552368
N

KIIA 5.4.1 (OECD)
Sokolowski, A.
2007
Salmonella typhimurium and Escherichia coli Reverse mutation assay with glyphosate technical (NUP-05068)
1061401 NUF
GLP: Y, published: N 2309293 / ASB2012-11463
Y
NUF
KIIA 5.4.1 (OECD)
Sokolowski, A.
2007
Salmonella typhimurium and Escherichia coli Reverse mutation assay with glyphosate technical (NUP-05070)
1061402 NUF
GLP: Y, published: N 2309295 / ASB2012-11464
Y

NUF
KIIA 5.4.1 (OECD)
Sokolowski, A.
2007
Salmonella typhimurium and Escherichia coli Reverse mutation assay with glyphosate technical (NUP-05067)
1061403 NUF
GLP: Y, published: N 2309297 / ASB2012-11465
Y
NUF
KIIA 5.4.1 (OECD)
Sokolowski, A.
2009
Glyphosate technical - Salmonella typhimurium and Escherichia coli Reverse Mutation Assay
1264500 SYN
GLP: Y, published: N 2309315 / ASB2012-11474
Y
SYN
KIIA 5.4.1 (OECD)
Sokolowski, A.
2010
Salmonella typhimurium and Escherichia coli Reverse Mutation Assay with Solution of Glyphosate TC spiked with Glyphosine 1332300 HAG
GLP: Y, published: N
2309307 / ASB2012-11470
Y
HAG
KIIA 5.4.1 (OECD)
Thompson, P.W.
1996
Technical glyphosate: Reverse mutation assay "Ames test" using Salmonella typhimurium and Escherichia coli
434/014 NUF
GLP: Y, published: N 2309311 / ASB2012-11472
Y
NUF
KIIA 5.4.1 (OECD)
Thompson, P.
2014
Glyphosate: Reverse mutation assay 'Ames test' using Salmonella typhimurium and Esche- richia coli
41401854
ASB2014-9148
Y
Annex point/ reference number
Author(s)
Year

Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.1 (OECD)
Vargas, A. A. T.; Bonetti, R.
1996
The Salmonella typhimurium reverse mutation by Glifos
G.1.1 - 050/96
TOX1999-884
N

KIIA 5.4.1 (OECD)
Wallner, B.
2010
Reverse Mutation Assay using Bacteria (Salmonella typhimurium) with Glyphosate TC BSL 101268
HAG
GLP: Y, published: N
2309309 / ASB2012-11471
Y
HAG
KIIA 5.4.2 (OECD)
Fox, V.
1998
Glyphosate acid: In vitro cytogenetic assay in human lymphocytes
CTL/P/6050 SYN
GLP: Y, published: N 2309321 / TOX2000-1995
Y
SYN
KIIA 5.4.2 (OECD)
Jensen, J. C.
1991
Mutagenicity test: In vitro mammalian cell gene mutation test with glyphosate, batch 206- JaK-25-1,
Report: 12325, published: N,
TOX9552372
N

KIIA 5.4.2 (OECD)
Kyomu, M.
1995
HR-001: In vitro cytogenetics test IET 94-0143 ALS
GLP: Y, published: N
2309317 / ASB2012-11475

Y
ALS
KIIA 5.4.2
KIIA 5.4.3
KIIA 4.4.4 (OECD)
Li, A. P.
1983
CHO/HGPRT gene mutation assay with glyphosate, Report ML-83-155 ! 830079, pub- lished: N, TOX9552369
N

KIIA 5.4.2 (OECD)
Rossberger, S.
1994
Glyphosate: DNA repair test with primary rat hepatocytes, Report: 931564 ! 94-03-28 ro, published: N,
TOX9400697/ TOX9551099
N
ADM
KIIA 5.4.2 (OECD)
van de Waart,
E. J.
1995
Evaluation of the ability of glyphosate to in- duce chromosome aberrations in cultured pe- ripheral human lymphocytes (with independent repeat)
Report: 141918, published: N, TOX9651525
N

KIIA 5.4.2 (OECD)
Wright, N.P.
1996
Technical glyphosate: Chromosome aberration test in CHL cells in vitro
434/015 NUF
GLP: Y, published: N 2309319 / ASB2012-11476
Y
NUF
KIIA 5.4.3 (OECD)
Akanuma, M.
1995
HR-001: DNA Repair Test (Rec-Assay) IET 94-0141 ALS
GLP: Y, published: N
2309325 / ASB2012-11477
N
ALS
Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.3 (OECD)
Clay, P.
1996
Glyphosate acid: L5178 TK+/- mouse lymphoma gene mutation assay CTL/P/4991 SYN
GLP: Y, published: N
2309323 / TOX2000-1994
Y
SYN
KIIA 5.4.4
KIIA 5.10 (OECD)
Alvarez-Moya, C., Silva, M.R.,
Arambula, A.R.V.,
Sandoval, A.I., Vasquez, H.C.,
Montes, R.M.G.
2011
Evaluation of genetic damage induced by glyphosate isopropylamine salt using Tradescantia bioassays
Genetics and Molecular Biology 34 (1):127-
130 34, 127-130
GLP: N, published: Y 2309560 / ASB2012-11538
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Amer, S.M.,
Aly, F.A.E.,
Farghaly, A.A., Ibrahim, A.A.E.
2006
In vitro and in vivo evaluation of the genotoxicity of the herbicide glyphosate in mice
Bulletin of the National Research Centre (Egypt) 31, 427-446
GLP: N, published: Y
2309562 / ASB2012-11539
N
MOD
KIIA 5.4.4
KIIA 5.10 (OECD)
Andre, V., Goff, J.L., Pottier, D., Lebailly, P., Peluso, M., Munnia, A., Gauduchon, P.
2007

Evaluation of bulky DNA adduct levels after pesticide use: Comparison between open-field farmers and fruit growers
Toxicological & Environmental Chemistry 89, 125-139
GLP: N, published: Y
2309570 / ASB2012-11543
N
LIT
KIIA 5.4.4
KIIA 5.5.3
KIIA 5.6
KIIA 5..7.2
KIIA 5.10
KIIIA1 7.6.3 (OECD)
Anonym.
2004
WORLD HEALTH ORGANIZATION and FOOD AND AGRICULTURE ORGANIZA- TION OF THE UNITED NATIONS, Rome:
Pesticide residues in food – 2004; Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Envi- ronment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–
29 September 2004, ASB2008-6266
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Benachour, N., Seralini, G.E.
2009
Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic, and placental cells
Chem Res Toxicol 22, 97-105 GLP: N, published: Y
2309606 / ASB2012-11561
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
Bolognesi, C., Bonatti, S., Degan, P., Gallerani, E., Peluso, M., Rabboni, R., Roggieri, P., Abbondandolo,

A.
1997
Genotoxic activity of glyphosate and its technical formulation roundup
Journal of Agricultural and Food Chemistry 45, 1957-1962
GLP: N, published: Y 2309628 / Z59299
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Bolognesi, C., Carrasquilla, G., Volpi, S.,
Solomon, K.R., Marshall, E.J.
2009
Biomonitoring of genotoxic risk in agricultural workers from five colombian regions: association to occupational exposure to glyphosate
J Toxicol Environ Health A 72, 986-997 GLP: N, published: Y
2309630 / ASB2012-11570
N
JCC
KIIA 5.4.4
KIIA 5.10 (OECD)
Bolognesi, C., Landini, E., Perrone, E., Roggieri, P.
2004
Cytogenetic biomonitoring of a floriculturist population in Italy: micronucleus analysis by fluorescence in situ hybridization (FISH) with an all-chromosome centromeric probe Mutation Research-Genetic Toxicology and Environmental Mutagenesis 557, 109-117 GLP: N, published: Y
2309634 / ASB2012-11572
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Bolognesi, C., Perrone, E., Landini, E.
2002
Micronucleus monitoring of a floriculturist population from western Liguria, Italy Mutagenesis 175, 391-397
GLP: N, published: Y
2309636 / ASB2012-11573
N
LIT
KIIA 5.4.4 (OECD)
1999
A micronucleus study in mice for glifosate técnico Nufarm
RF-G12.79/99 NUF
GLP: Y, published: N 2309335 / ASB2012-11482
Y
NUF
KIIA 5.4.4

KIIA 5.10
KIIIA1 7.6.3 (OECD)
Cavalcante, D.G.S.M.,
Martinez, C.B.R., Sofia, S.H.
2008
Genotoxic effects of Roundup (R) on the fish
Prochilodus lineatus
Mutation Research-Genetic Toxicology and Environmental Mutagenesis 655, 41-46 GLP: N, published: Y
2309662 / ASB2012-11586
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
Cavas, T., Konen, S.
2007
Detection of cytogenetic and DNA damage in peripheral erythrocytes of goldfish (Carassius auratus) exposed to a glyphosate formulation using the micronucleus test and the comet assay
Mutagenesis 22, 263-268 GLP: N, published: Y
2309664 / ASB2012-11587
N
LIT
KIIA 5.4.4
Chruscielska,
2000
Glyphosate: Evaluation of chronic activity and
N

KIIA 5.10
K.; Brzezinski,
possible far -reaching effects - Part 2. Studies
(OECD)
J.;
on mutagenic activity
Grafstein, B.
Pestycydy, 2000, (3-4), 21-25

ASB2013-9830
KIIA 5.4.4
Clements, C.;
1997
Glyphosate: Genotoxicity of select herbicides
N

KIIA 5.10
Ralph, S.; Pe-
in Rana catesbeiana tadpoles using the alka-
KIIIA1 7.6.3
tras, M.
line single-cell gel DNA electrophoresis (com-
(OECD)
et) assay
Environ. Molec. Mutagen., 29, 277-288
Z101728
KIIA 5.4.4
KIIA 5.10 (OECD)
2000
Comparative analysis between micronuclei tests in mice and in peripheral erythrocytes of Oreochromis niloticus in evaluation ofmutagenic potential ofthe agrotoxins deltamethrin, dicofol, glyphosate, and lmazapyr
ASB2013-11477
N

KIIA 5.4.4 (OECD)
2010
Amendment No. 1 to report: Evaluation of the mutagenic potential of Glyphosate technical by micronucleus assay in mice
3996.402.395.07
ASB2014-9284
KIIA 5.4.4 (OECD)
2008
Evaluation of the mutagenic potential of Glyphosate Technical Micronucleus assay in mice
Bioagri Laboratories Ltda., Brazil
Data owner: HAG (original sponsor: Jingma Chemicals, Longyou Zhejian, China)
Report No.: RF - 3996.402.395.07 Date: 2008-09-29
Unpublished; ASB2012-11481
KIIA 5.4.4
2000
Glyphosate: Evaluation of chronic activity and
N

KIIA 5.5.3

possible far - reaching effects - Part 1. Studies
KIIA 5.10
on chronic toxicity
(OECD)
Pestycydy, 2000, (3 -4), 11-20
ASB2013-9829
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
2000
Glyphosate: Evaluation of chronic activity and possible far - reaching effects - Part 3. Prenatal toxicity
Pestycydy, 2000, (3-4), 27-31
ASB2013-9831
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Dimitrov, B.D., Gadeva, P.G.,
Benova, D.K., Bineva, M.V.
2006
Comparative genotoxicity of the herbicides Roundup, Stomp and Reglone in plant and mammalian test systems
Mutagenesis 21, 375-382 GLP: N, published: Y
2309708 / ASB2012-11607
N
LIT
KIIA 5.4.4 (OECD)
2006
Glyphosate Technical: Micronucleus Test In The Mouse
2060/014 NUF
GLP: Y, published: N 2309327 / ASB2012-11478
Y
NUF
KIIA 5.4.4 (OECD)
Flowers, L. J.
1981
Ames/salmonella mutagenicity assay of MON 8080

MSL 1538 ! ML-80-294/800281
TOX1999-319
N

KIIA 5.4.4 (OECD)
2009
Micronucleus Test of Glyphosate TC in Bone Marrow Cells of the CD Rat by oral administration
LPT 23917 HAG
GLP: Y, published: N 2309329 / ASB2012-11479
Y
HAG
KIIA 5.4.4 (OECD)
1996
Glyphosate acid: mouse bone marrow micronucleus test
CTL/P/4954 SYN
GLP: Y, published: N 2309337 / TOX2000-1996
N
SYN
KIIA 5.4.4
KIIA 5.10 (OECD)
2002
A comparison between mouse and fish micronucleus test using cyclophosphamide, mitomycin C and various pesticides Mutation Research-Genetic Toxicology and Environmental Mutagenesis 518, 145-150 GLP: N, published: Y
2309776 / ASB2012-11834
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Guilherme, S., Gaivão, I., Santos, M.A., Pacheco, M.
2010
European eel (Anguilla anguilla) genotoxic and pro-oxidant responses following short- term exposure to Roundup®a glyphosate- based herbicide
Mutagenesis 25, 523-530
GLP: N, published: Y 2309780 / ASB2012-11836
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N

Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
Helal, A.D., Moussa, H.M.
2005
Chromosomal aberrations induced by glyphosate isopropylamine herbicide and trials for diminuting its toxicity using some chemical inactivators and antioxidant
Veterinary Medical Journal Giza 53, 169-187 GLP: N, published: Y
2309794 / ASB2012-11841
N
LIT
KIIA 5.4.4
Heydens, W.F.,
2008
Genotoxic potential of glyphosate formulations: Mode-of-action investigations Journal of Agricultural and Food Chemistry 56, 1517-1523
GLP: N, published: Y 2309802 / ASB2012-11845
N
LIT
KIIA 5.10
Healy, C.E.,
KIIIA1 7.6.3
Hotz, K.J., Kier,
(OECD)
L.D., Martens,
M.A., Wilson,
A.G.E, Farmer,
D.R.
KIIA 5.4.4
KIIA 5.10 (OECD)
Holeckova, B.
2006
Evaluation of the in vitro effect of glyphosate- based herbicide on bovine lymphocytes using chromosome painting
Bulletin of the Veterinary Research Institute in Pulawy 50, 533-536
GLP: N, published: Y
2309806 / ASB2012-11847
N
LIT
KIIA 5.4.4
2008
Glyphosate Technical - Micronucleus Assay in
Y
SYN
(OECD)
Bone Marrow Cells of the Mouse

1158500 SYN
GLP: Y, published: N
2309339 / ASB2012-11483
KIIA 5.4.4
1991
Mutagenicity test: Micronucleus test with
N

(OECD)
glyphosate, batch 206-JaK-25-1, Report:
12324, published: N,
TOX9552374
KIIA 5.4.4
Kale, P.G.,
1995
Mutagenicity testing of 9 herbicides and pesticides currently used in agriculture Environmental and Molecular Mutagenesis 25, 148-153
GLP: N, published: Y
2309834 / Z73986, ASB2012-11860
N
LIT
KIIA 5.10
Petty, B.T.,
(OECD)
Walker, S.,
Ford, J.B.,
Dehkordi, N.,
Tarasia, S.,
Tasie, B.O.,
Kale, R., Sohni,
Y.R.
KIIA 5.4.4
KIIA 5.10 (OECD)
Kaya, B.: Creus, A.; Yanikoglu, A.; et al.;
2000
Use of the Drosophila wing spot
test in the genotoxicity testing of different herbicides
N

ASB2013-9832
KIIA 5.4.4
1992
Mouse micronucleus study of Rodeo herbicide
N

(OECD)

formulation
MSL-11772 ! EHL 91201/91205/ML-91-438
TOX9552376
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIIA1 7.6.3 (OECD)
1992
Mouse micronucleus study of Roundup herbi- cide formulation
MSL-11771 ! EHL 91200/91204 ! ML-91- 434/ML-91-437
TOX1999-242
N

KIIA 5.4 .4 (OECD)
1992
Glyphosate: Mouse micronucleus study of DIRECT Herbicide formulation
MSL-11773 ! EHL 91202/91206 ! ML-91- 436/ML-91-439
TOX1999-322
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Knopper, L.D.,
Lean, D.R.S.
2004
Carcinogenic and genotoxic potential of turf pesticides commonly used on golf courses Journal of Toxicology and Environmental Health-Part B-Critical Reviews 7, 267-279 GLP: N, published: Y
2309864 / ASB2012-11871
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Lebailly, P., Devaux, A., Pottier, D., De Meo, M.,
Andre, V.,
Baldi, I., Severin, F., Bernaud, J., Durand, B., Henry-Amar, M., Gauduchon,
P.
2003
Urine mutagenicity and lymphocyte DNA damage in fruit growers occupationally exposed to the

fungicide captan
Occupational & Environmental Medicine 60, 910-917
GLP: N, published: Y 2309878 / ASB2012-11878
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Levine, S.L., Han, Z., Liu, J.,
Farmer, D.R., Papadopoulos, V.
2007
Disrupting mitochondrial function with surfactants inhibits MA-10 Leydig cell steroidogenesis
Cell Biol Toxicol 23, 385-400 GLP: N, published: Y
2309890 / ASB2009-9030
N
LIT
KIIA 5.4.4 (OECD)
1983
In vivo bone marrow cytogenetics study of glyphosate in Sprague-Dawley rats, Report: ML-83-236 !
830083, published: N,
TOX9552375
N

KIIA 5.4.4
KIIA 5.10 (OECD)
1998
Genotoxicity and oxidative stress induced by pesticide exposure in bovine lymphocyte cul- tures in vitro
Mutation Research 403 (1998) 13-20
ASB2013-9836
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
1998
Cytogenetic damage and induction of pro- oxidant state in human lymphocytes exposed in vitro to glyphosate, vinclozolin,aAtrazine and DPX-E9636

Environmental and Molecular Mutagenesis 32: 39-46 (1998)
ASB2013-9837
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Manas, F., Peralta, L., Raviolo, J., Ovandoa, H.G., Weyers, A., Ugnia, L., Cid,
M.G., Larripa,
I., Gorla, N.
2009
Genotoxicity of glyphosate assessed by the comet assay and cytogenetic tests Environmental Toxicology and Pharmacology 28, 37-41
GLP: N, published: Y 2309908 / ASB2012-11892
N
LIT
KIIA 5.4.4
KIIA 5.10
KIIIA1 7.6.3 (OECD
1991
Glyphosate: Oral and pulmonary toxicology of the surfactant used in Roundup herbicide Z80636
N

KIIA 5.4.4
KIIA 5.11 (OECD)
1994
Environmental health criteria 159, Glyphosate TOX9500301
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Mladinic, M., Berend, S., Vrdoljak, A.L., Kopjar, N., Radic, B., Zeljezic, D.
2009
Evaluation of genome damage and its relation to oxidative stress induced by glyphosate in human lymphocytes in vitro
Environmental and Molecular Mutagenesis 50, 800-807
GLP: N, published: Y
2309942 / ASB2012-11906
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Mladinic, M., Perkovic, P., Zeljezic, D.
2009
Characterization of chromatin instabilities induced by glyphosate, terbuthylazine and carbofuran using cytome FISH assay Toxicol Lett 189, 130-137
GLP: N, published: Y

2309944 / ASB2012-11907
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Monroy, C., Cortes, A., Sicard, D., de Restrepo, H.
2005
Cytotoxicity and genotoxicity of human cells exposed in vitro to glyphosate
Biomedica 25, 335-345 GLP: N, published: Y
2309950 / ASB2012-11910
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
Pastor, S., Creus, A., Parron, T., Cebulska- Wasilewska, A., Siffel, C., Piperakis, S.,
Marcos, R.
2003
Biomonitoring of four European populations occupationally exposed to pesticides: use of micronuclei as biomarkers
Mutagenesis 18, 249-258 GLP: N, published: Y 2310004 / ASB2012-11991
N
LIT
KIIA 5.4.4 (OECD)
Patel, N. N.
2012
Micronucleus test of Glyphosate TGAI in mice 120709 ! 485-1-06-4696 ! DR-0112-6927-003
! 10001701-27-1
ASB2014-9277
KIIA 5.4.4
KIIA 5.10 (OECD)
Paz-Y-Mino, C.,
Sanchez, M.E., Arevalo, M., Munoz, M.J.,
Witte, T., De- La-Carrera, G.O., Leone,
P.E.
2007
Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate

Genetics and Molecular Biology 30, 456-460 GLP: N, published: Y
2310006 / ASB2012-11992
N
LIT
KIIA 5.4.4
KIIA 5.10
KIIIA1 7.6.3 (OECD)
Peluso, M., Munnia, A., Bolognesi, C., Parodi, S.
1998
32P-postlabeling detection of DNA adducts in mice treated with the herbicide Roundup
Environmental and Molecular Mutagenesis 31, 55-59
GLP: N, published: Y
2310014 / TOX1999-318
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Piesova, E.
2004
The Influence Of Different Treatment Length On the Induction Of Micronuclei In Bovine Lymphocytes After Exposure To Glyphosate Folia Veterinaria 48, 130-134
GLP: N, published: Y
2310026 / ASB2012-12001
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Piesova, E.
2005
The effect of glyphosate on the frequency of micronuclei in bovine lymphocytes in vitro Acta Veterinaria-Beograd 55, 101-109 GLP: N, published: Y
2310024 / ASB2012-12000
N
MOD
KIIA 5.4.4
KIIA 5.10 (OECD)
Poletta, G.L., Larriera, A., Kleinsorge, E., Mudry, M.D.
2009
Genotoxicity of the herbicide formulation Roundup (R) (glyphosate) in broad-snouted caiman (Caiman latirostris) evidenced by the Comet assay and the Micronucleus test Mutation Research-Genetic Toxicology and Environmental Mutagenesis 672, 95-102 GLP: N, published: Y
2310028 / ASB2012-12002
N
LIT
Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4
KIIA 5.10 (OECD)
Prasad, S., Srivastava, S., Singh, M., Shukla, Y.
2009
Clastogenic effects of glyphosate in bone marrow cells of swiss albino mice
J Toxicol
GLP: N, published: Y 2310034 / ASB2012-12005
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Raipulis, J., Toma, M., Balode, M.
2009
Toxicity and genotoxicity testing of Roundup Proceedings of the Latvian Academy of Sciences. Section B. Natural, Exact, and Applied Sciences. 63, 29-32
GLP: N, published: Y
2310040 / ASB2012-12008
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Rodrigues, H.G., Penha-
Silva, N.,
Araujo, M.F.P, Nishijo, H., Aversi-Ferreira,
T.A.
2011
Effects of Roundup Pesticide on the Stability of Human Erythrocyte Membranes and Micronuclei Frequency in Bone Marrow Cells of Swiss Mice
Open Biology Journal 54-59 GLP: N, published: Y
2310046 / ASB2012-12010
N
LIT
KIIA 5.4.4 (OECD)
Roth, M.
Glyphosate technical - Micronucleus assay in bone marrow cells of the mouse
1479200 ! TK0112981
ASB2014-9333
KIIA 5.4.4

KIIA 5.10 (OECD)
Salvagni, J., Ternus, R., Fuentefria, A.
2011
Assessment of the genotoxic impact of pesticides on farming communities in the countryside of Santa Catarina State, Brazil Genetics and Molecular Biology 34, 122-126 GLP: N, published: Y
2310060 / ASB2012-12017
N
LIT
KIIA 5.4.4
KIIA 5.9
KIIIA1 7.6.3 (OECD)
Sawada, Y., Nagai, Y.
1987
Roundup® poisoning - its clinical observation possible involvement - englische Version Journal of Clinical and Experimental Medicine (paper) 143, 25-27
GLP: N, published: Y
2309502 / Z35531
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Shaham, J., Kaufman, Z., Gurvich, R., Levi, Z.
2001
Frequency of sister-chromatid exchange among greenhouse farmers exposed to pesticides Mutat Res 491-, 71-80 GLP: N, published: Y
2310076 / ASB2012-12025
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Sivikova, K., Dianovsky, J.
2006
Cytogenetic effect of technical glyphosate on cultivated bovine peripheral lymphocytes Int J Hyg Environ Health 209, 15-20 GLP: N, published: Y
2310084 / ASB2012-12029
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N

Owner5
KIIA 5.4.4
KIIA 5.8.1 (OECD)
1992
Dodigen 4022: Chromosome aberrations in vitro in V79 chinese hamster cells
92.1024 ! 92.0337
TOX1999-325
N

KIIA 5.4.4
KIIA 5.8.1 (OECD)
Stammberger, I.; Mayer, D.
1992
Dodigen 4022: Study of the mutagenic poten- tial in strains of Salmonella typhimurium (ames test) and Escherichia coli
92.0487 ! 92.0336
TOX1999-324
N

KIIA 5.4.4
KIIA 5.10
KIIIA1 7.6.3 (OECD)
1998
Mouse micronucleus screening assay of MON 0818
ML-89-463 ! EHL 89182
TOX1999-240
N

KIIA 5.4.4
KIIIA1 7.6.3 (OECD)
Stegeman, S. D.; Li, A. P.
1990
Ames/salmonella mutagenicity assay of MON 0818
EHL 89178 ! ML-89-461 ! MSL-10625
TOX1999-241

N

KIIA 5.4.4 (OECD)
1993
Glyphosate technical (FSG 03090 H/05 March 1990): Mutagenicity-micronucleus test in swiss albino mice, Report: 889-MUT.MN ! TOXI- 889/1993 ! ES-GPT-MUT-MN, published: N,
TOX9551100
N

KIIA 5.4.4 (OECD)

1994
Glyphosate technical (FSG 03090 H/05 March 1990): Genetic toxicology - In vivo mammali- an bone marrow cytogenetic test, Report: 890- MUT-CH.AB ! TOXI-890/1993 ! ES-GPT-
MUT-CH.AB, published: N,
TOX9400323 / TOX9551101
N

KIIA 5.4.4
KIIA 5.10 (OECD)
Vigfusson, N.V.,
Vyse, E.R.
1980
The effect of the pesticides Dexon, Captan and Roundup on sister chromatid exchanges in human lymphocytes in vitro
Mutation Research 79, 53-57 GLP: N, published: Y
2310114 / TOX970056 / ASB2012-12044
N
LIT
KIIA 5.4.4
KIIA 5.10 (OECD)
Vlastos, D., Stivaktakis, P., Matthopoulos, D.P.
2006
Pesticide exposure and genotoxicity correlations within a Greek farmers' group International Journal of Environmental Analytical Chemistry 86, 215-223
GLP: N, published: Y
2310116 / ASB2012-12045
N
LIT
KIIA 5.4.4
KIIA 5.5.3
KIIA 5.10
KIIIA1 7.6.3 (OECD)
Williams, G.M., Kroes, R., Munro, I.C.
2000
Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans
Regulatory Toxicology and Pharmacology 31, 117-165
GLP: N, published: Y
2310132 / ASB2012-12053
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.

GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.4.4 (OECD)
1996
A micronucleus study in mice for the product GILFOS
G1206096 ! G.1.2 - 60/96
TOX1999-253
N

KIIA 5.4.4 (OECD)
2007
Mammalian Erythrocyte Micronucleus Test for Glifosato Técnico Helm
3393/2007-3.0MN-B
ASB2012-11480
KIIA 5.4.6 (OECD)
1992
Glyphosate technical (FSG 03090 H/05, March 1990): Dominant lethal test in wistar rats Report: 888-DLT ! TOXI-888/1992 ! ES-GPT-
DLT, published: N, TOX9551102
N

KIIA 5.4.6 (OECD)
C.
1980
Dominant lethal mutagenicity assay with tech- nical Glyphosate in mice, Report: 401-064 ! IR-79-014, published: N,
TOX9552377
N

KIIA 5.5
(OECD)
Anon.
2015
Lesion-related incidence data. RITA database
ASB2015-2532
KIIA 5.5 (OECD)
Eaton, G.; John- son, F. N.; Cus-
ter, R. P.;
Crane, A. R.;
1980
The Icr:Ha(ICR) mouse: a current account of breeding, mutations, diseases and mortality Lab. Animals 14(1980)17-24
ASB2015-2537

LIT
KIIA 5.5 (OECD)
Giknis, M. L. A.; Clifford, C. B.;
2010
Spontaneous neoplastic lesions in the Crl:CD1 (ICR) mouse in control groups from 18 month to 2 year studies
Selected pages
ASB2015-2529
KIIA 5.5 (OECD)
Greim, H.; Saltmiras, D.; Mostert, V.; Strupp, C.;
2015
Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor inci- dence data from fourteen chron- ic/carcinogenicity rodent studies
Crit Rev Toxicol, 2015; 45(3): 185–208
ASB2015-2287
LIT
KIIA 5.5 (OECD)
Roe, F. J. C.;
Tucker, M. J.;
1974
Recent developments in the design of carcino- genicity tests on laboratory animals Proc. Europ. Soc. Stud. Drug Tox., 15:171-177 (1974)
ASB2015-2534
LIT
KIIA 5.5 (OECD)
Sher, S. P.
1974
Review article - Tumors in control mice: Liter- ature tabulation
Toxicol. Appl. Pharmacol. 30(1974)337-359
Z22020
LIT
KIIA 5.5 (OECD)
Son, W.-C.;
Gopinath, C.;
2004
Early occurrence of spontaneous tumors in CD-1 mice and Sprague–Dawley rats Toxicologic Pathology, 32:371–374, 2004
ASB2015-2533
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number

Data protection claimed
Y/N
Owner5
KIIA 5.5 (OECD)
Taddesse- Heath, L.; Chat- topadhyay, S. K.; Dillehay, D.
L.; et al.;
2000
Lymphomas and high-level expression of mu- rine leukemia viruses in CFW mice
J. Virol. 74(2000)15:6832-6837 ASB2015-2535
LIT
KIIA 5.5 (OECD)
Toth, B.; Rap- paport, H.; Shubik, P.;
1963
Influence of dose and age on the induction of malignant lymphomas and other tumors by 7,12-Dimethylbenz(α)anthracene in Swiss mice
J. Nat. Cancer Institute, 30(1963)4:723-732
ASB2015-2536
LIT
KIIA 5.5 (OECD)
Tucker, M. J.
1979
The effect of long-term food restriction on tumours in rodents
Int. J. Cancer: 23, 803-807 (1979)
Z83266
LIT
KIIA 5.5 (OECD)
Wood, E.;
2010
Historical Incidence of Malignant lymphoma in CD-1 Mouse
ASB2015-2531
KIIA 5.5.1
KIIA 5.10 (OECD)
1996
Glyphosate Acid: One Year Dietary Toxicity Study in Rats
CTL/P/5143 SYN
GLP: Y, published: N 2309341 / TOX2000-1998
N
SYN
KIIA 5.5.2 (OECD)
1993
Glyphosate - 104 week combined chronic feeding / oncogenicity study in rats with 52 week interim kill (results after 104 weeks) 7867 CHE
GLP: Y, published: N
2309374 / TOX9750499
N
CHE

KIIA 5.5.2
KIIA 5.10 (OECD)
2001
Glyphosate Acid: Two Year Dietary Toxicity and Oncogenicity Study in Rats CTL/PR1111 SYN
GLP: Y, published: N
2309368 / ASB2012-11488
N
SYN
KIIA 5.5.2 (OECD)
1974
2-year chronic oral toxicity study with CP 67573 in albino rats
B564 ! BTL-71-32
Z35230
N

KIIA 5.5.2 (OECD)
1997
HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 1 (Seite 1- 500)
IET 94-0150 Vol.1 ALS
GLP: Y, published: N 2309360 / ASB2012-11484
N
ALS
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.2 (OECD)
1997
HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 2 (Seite 501- 1000)
IET 94-0150 Vol. 2 ALS
GLP: Y, published: N 2309362 / ASB2012-11485
N
ALS
KIIA 5.5.2 (OECD)
1997
HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol.3 (Seite 1001- 1500)
IET 94-0150 Vol. 3 ALS
GLP: Y, published: N 2309364 / ASB2012-11486
N
ALS

KIIA 5.5.2 (OECD)
1997
HR-001: 24-Month Oral Chronic Toxicity and Oncogenicity Study in Rats, Vol. 4 (Seite 1501-2051)
IET 94-0150 Vol. 4 ALS
GLP: Y, published: N 2309366 / ASB2012-11487
N
ALS
KIIA 5.5.2 (OECD)
1990
Chronic study of glyphosate administered in feed to Albino rats
MSL-10495 MON
GLP: Y, published: N 2309384 / TOX9300244
N
MON
KIIA 5.5.2 (OECD)
1996
Combined Chronic Toxicity and Carcinogenicity Study with Glyphosate Technical in Wistar Rats
TOXI:886.C.C-R FSG
GLP: Y, published: N
2309343 / TOX9651587 / TOX9600015
N
ADM
KIIA 5.5.2 (OECD)
2009
Glyphosate Technical: Dietary combined chronic toxicity / carcinogenicity study in the rat
SPL2060-0012 NUF
GLP: Y, published: N 2309391 / ASB2012-11490
Y
NUF
KIIA 5.5.3
KIIA 5.10 (OECD)
Acquavella, J.F., Gustin, C., Alexander, B.H., Mandel, J.S.
2005
Implications for epidemiologic research on variation by pesticide in studies of farmers and their families
Scandinavian Journal of Work Environment & Health 31, 105-109
GLP: N, published: Y
2309540 / ASB2012-11530
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not

BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Alavanja, M.C., Samanic, C., Dosemeci, M., Lubin, J., Tarone, R., Lynch, C.F.,
Knott, C., Thomas, K., Hoppin, J.A., Barker, J., Coble, J.,
Sandler, D.P.,
Blair, A.
2003
Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study cohort
Am J Epidemiol 157, 800-814 GLP: N, published: Y
2309554 / ASB2012-11535
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Andreotti, G., Freeman, L.E.B., Hou, L.,
Coble, J., Rusiecki, J., Hoppin, J.A., Silverman, D.T., Alavanja,
M.C.R.
2009
Agricultural pesticide use and pancreatic cancer risk in the Agricultural Health Study Cohort
International Journal of Cancer 124, 2495-
2500
GLP: N, published: Y 2309572 / ASB2012-11544
N
LIT
KIIA 5.5.3 (OECD)
1993
Glyphosate: 104-week dietary carcinogenicity study in mice
7793 ! IRI 438618
TOX9552382
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Band, P.R., Abanto, Z., Bert, J., Lang,
B., Fang, R.,
Gallagher, R.P., Le, N.D.
2011
Prostate Cancer Risk and Exposure to Pesticides in British Columbia Farmers Prostate 71, 168-183
GLP: N, published: Y 2309594 / ASB2012-11555
N
LIT
KIIA 5.5.3

KIIA 5.10 (OECD)
Barale-Thomas, E.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
473–474
ASB2013-10998
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Berry, C.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
445–446
ASB2013-10988
N
--
KIIA 5.5.3
KIIA 5.10 (OECD)
Blair, A., Freeman, L.B.
2009
Epidemiologic Studies in Agricultural Populations: Observations and Future Directions
Journal of Agromedicine 14, 125-131 GLP: N, published: Y
2309618 / ASB2012-11566
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Carreon, T., Butler, M.A.,
Ruder, A.M.,
Waters, M.A., Davis-King, K.E., Calvert,
G.M., Schulte, P.A., Connally, B., Ward, E.M.,
Sanderson, W.T.,
Heinemann, E.F., Mandel,

J.S., Morten,
R.F., Reding,
D.J.,
Rosenmann, K.D.,
Talaska, G.
2005
Gliomas and farm pesticide exposure in women: The Upper Midwest Health Study Environmental Health Perspectives 113, 546-
551
GLP: N, published: Y 2309660 / ASB2012-11585
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
McDuffie, H.H., Pahwa, P., McLaughlin, J.R., Spinelli, J.J., Fincham, S., Dosman, J.A., Robson, D., Skinnider, L.F., Choi,
N.W.
2001
Non-Hodgkin's lymphoma and specific pesticide exposures in men: cross-Canada study of pesticides and health
Cancer Epidemiol Biomarkers Prev 10, 1155-
1163
GLP: N, published: Y 2309924 / ASB2011-364
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Engel, L.S.,
Hill, D.A.,
Hoppin, J.A.,
Lubin, J.H.,
Lynch, C.F., Pierce, J., Samanic, C., Sandler, D.P.,
Blair, A.,
Alavanja, M.C.
2005
Pesticide use and breast cancer risk among farmers' wives in the agricultural health study American Journal of Epidemiology 161, 121-
135
GLP: N, published: Y 2309720 / ASB2012-11613
N
MOD
KIIA 5.5.3
KIIA 5.10 (OECD)
Eriksson, M., Hardell, L., Carlberg, M., Akerman, M.
2008
Pesticide exposure as risk factor for non- Hodgkin lymphoma including histopathological subgroup

analysis
Int J Cancer 123, 1657-1663 GLP: N, published: Y
2309722 / ASB2012-11614
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Farmer, D.R.,
Lash, T.L., Acquavella, J.F.
2005
Glyphosate Results Revisited Environmental Health Perspectives 113, A365-A366
GLP: N, published: Y
2309726 / ASB2012-11616
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Flower, K.B.,
Hoppin, J.A.,
Lynch, C.F., Blair, A., Knott, C., Shore, D.L.,
Sandler, D.P.
2004
Cancer risk and parental pesticide application in children of agricultural health study participants
Environmental Health Perspectives 112, 361-
635
GLP: N, published: Y 2309734 / ASB2012-11620
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Freeman,L.B.
2009
Evaluation of agricultural exposures: the agricultural health study and the agricultural cohort consortium
Reviews on Environmental Health 24, 311-
318

GLP: N, published: Y 2309740 / ASB2012-11623
N
MOD
KIIA 5.5.3
KIIA 5.10 (OECD)
Fritschi, L., Benke, G.,
Hughes, A.M., Kricker, A..,Turner, J., Vajdic, C.M., Grulich, A., Milliken, S., Kaldor, J., Armstrong, B.K.
2005
Occupational exposure to pesticides and risk of non-Hodgkin's lymphoma
American Journal of Epidemiology 162, 849-
857
GLP: N, published: Y 2309746 / ASB2012-11624
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
George, J., Prasad, S., Mahmood, Z., Shukla, Y.
2010
Studies on glyphosate-induced carcinogenicity in mouse skin: a proteomic approach
J Proteomics 73, 951-964 GLP: N, published: Y
2309766 / ASB2012-11829
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Grunewald, W.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
447–448
ASB2013-11001
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Hammond, B.; Goldstein, D. A.; Saltmiras,
D.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
459–464
ASB2013-10995
N

Annex point/ reference number

Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Hardell, L., Eriksson, M.
1999
A case-control study of non-Hodgkin lymphoma and exposure to pesticides Cancer 85, 1353-1360
GLP: N, published: Y
2309788 / ASB2012-11838
N
MOD
KIIA 5.5.3
KIIA 5.10 (OECD)
Hardell, L., Eriksson, M., Nordstrom, M.
2002
Exposure to pesticides as risk factor for non- Hodgkin's lymphoma and hairy cell leukemia: Pooled analysis of two Swedish case-control studies
Leukemia & Lymphoma 43, 1043-1049 GLP: N, published: Y
2309790 / ASB2012-11839
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Heinemann, J. A.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 442 ASB2013-10987
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Karunanayake, C.P., Spinelli, J.J.,
McLaughlin, J.R., Dosman, J.A., Pahwa, P.,
McDuffie, H.H.
2011
Hodgkin Lymphoma and Pesticides Exposure in Men: A Canadian Case-Control Study Journal of Agromedicine 17, 30-39
GLP: N, published: Y 2309844 / ASB2012-11865
N

LIT
KIIA 5.5.3 (OECD)
1983
A chronic feeding study of glyphosate (Roundup technical) in mice
77-2061 ! (BDN-77-420)
TOX9552381
N

KIIA 5.5.3 (OECD)
2001
Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice TOXI: 1559.CARCI-M FSG
GLP: Y, published: N
2309396 / ASB2012-11491
Y
ADM
KIIA 5.5.3
KIIA 5.10 (OECD)
Landgren, O., Kyle, R.A.,
Hoppin, J.A., Freeman, L.E.B., Cerhan, J.R., Katzmann, J.A., Rajkumar, S.V., Alavanja,
M.C.
2009

Pesticide exposure and risk of monoclonal gammopathy of undetermined significance in the
Agricultural Health Study
Blood 113, 6386-6391
GLP: N, published: Y 2309874 / ASB2012-11875
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Langridge, P.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 441 ASB2013-10986
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5

KIIA 5.5.3
KIIA 5.10 (OECD)
Lash, T.L.
2007
Bias analysis applied to Agricultural Health Study publications to estimate non-random sources of uncertainty
J Occup Med Toxicol 2, 1-9
GLP: N, published: Y 2309876 / ASB2012-11877
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Lee, W.J.,
Lijinsky, W., Heineman, E.F., Markin, R.S., Weisenburger, D.D., Ward,
M.H.
2004
Agricultural pesticide use and adenocarcinomas of the stomach and oesophagus
Occupational and Environmental Medicine 61 (9):743-749 61, 743-749
GLP: N, published: Y
2309888 / ASB2012-11883
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Lee, W.J., Colt, J.S., Heineman, E.F., McComb, R.,
Weisenburger,
D.D., Lijinsky, W., Ward, M.H.
2005
Agricultural pesticide use and risk of glioma in Nebraska, United States
Occupational and Environmental Medicine 62, 786-792
GLP: N, published: Y 2309886 / ASB2012-11882
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Monge, P., Wesseling, C., Guardado, J., Lundberg, I., Ahlbom, A., Cantor, K.P., Weideroass, E., Partanen, T.
2007
Parental occupational exposure to pesticides and the risk of childhood leukemia in Costa Rica
Scandinavian Journal of Work Environment & Health 33, 293-303
GLP: N, published: Y 2309948 / ASB2012-11909
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Multigner, L., Ndong, J.R.,

Oliva, A., Blanchet, P.
2008
Environmental pollutants and prostate cancer: epidemiological data
Gynecol Obstet Fertil 36, 848-856 GLP: N, published: Y
2309964 / ASB2012-11917
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Ndong, J.R., Blanchet, P., Multigner, L.
2009
Pesticides and prostate cancer: epidemiological data
Bulletin Du Cancer 96, 171-180 GLP: N, published: Y
2309974 / ASB2012-11922
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Nordström, M.; Hardell, L.; Magnuson, A.; Hagberg, H.; Rask-Andersen,
A.
1998
Occupational exposures, animal exposure and smoking as risk factors for hairy cell leukae- mia evaluated in a case-control study TOX1999-687
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Ollivier, L.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 458 ASB2013-11000
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Pahwa, P., Karunanayake, C.P., Dosman, J.A., Spinelli, J.J., McDuffie, H.H.,

McLaughlin,
J.R.
2011
Multiple Myeloma and Exposure to Pesticides: A Canadian Case-Control Study
Journal of Agromedicine 17, 40-50 GLP: N, published: Y
2309996 / ASB2012-11987
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Panchin, A. Y.;
2013
Toxicity of roundup-tolerant genetically modi- fied maize is not supported by statistical tests Food and Chemical Toxicology 53 (2013) 475
ASB2013-10937
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Pilu, R.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 454 ASB2013-10992
N

KIIA 5.5.3
KIIA 5.10 (OECD)
De Roos, A.J.,
Blair, A., Rusiecki, J.A., Hoppin, J.A.,
Svec, M., Dosemeci, M., Sandler, D.P.,
Alavanja, M.C.
2005
Cancer incidence among glyphosate-exposed pesticide applicators in the agricultural health study
Environmental Health Perspectives 113, 49-
54
GLP: N, published: Y 2309704 / ASB2012-11605
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
De Roos, A.J.,
Zahm, S.H.,
Cantor, K.P., Weisenburger, D.D., Holmes,
F.F.,
Burmeister, L.F., Blair, A.
2003

Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men
Occupational and Environmental Medicine 60 GLP: N, published: Y
2309706 / ASB2012-11606
N
LIT
KIIA 5.5.3
KIIA 5.10 (OECD)
Schorsch, F.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
465–466
ASB2013-10996
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Séralini, G.-E.;
Clair, E.; Mes- nage, R.; Gress, S.; Defarge, N.; Malatesta, M.; Hennequin, D.; Spiroux de Vendômois, J.;
2012
Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize.
Food and Chem Toxicol., in Press, ASB2012-15514
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3
KIIA 5.10 (OECD)
Séralini, G. E.; Mesnage, R.; Defarge, N.; Gress, S.; Hen- nequin, D.; Clair, E.; Mala- testa, M.; Spi- roux de Ven-
dômois, J.;
2013
Answers to critics: Why there is a long term toxicity due to a Rounduptolerant genetically modified maize and to a Roundup herbicide Food and Chemical Toxicology 53 (2013)
476–483
ASB2013-10985
N

KIIA 5.5.3
KIIA 5.10 (OECD)
de Souza, L.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 440 ASB2013-10999
N

KIIA 5.5.3 (OECD)
1997
HR-001: 18-Month Oral Oncogenicity Study in Mice
IET 940151 ALS
GLP: Y, published: N 2309415 / ASB2012-11493
Y
ALS
KIIA 5.5.3
KIIA 5.10 (OECD)
Tester, M.;
2012
Letter to the Editor
Food and Chemical Toxicology 53 (2013) 457 ASB2013-10994
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Tien, D. L.;
Huy, H. L.;
2012
Comments on ‘‘Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize’’
Food and Chemical Toxicology 53 (2013)
443–444
ASB2013-10984
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Trewavas, A.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013) 449 ASB2013-10989
N

KIIA 5.5.3
KIIA 5.10 (OECD)

Tribe, D.;
2012
Letter to the editor
Food and Chemical Toxicology 53 (2013)
467–472
ASB2013-10997
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Wager, R.;
2013
Letter to the editor
Food and Chemical Toxicology 53 (2013)
455–456
ASB2013-10993
N

KIIA 5.5.3
KIIA 5.10 (OECD)
Weichenthal, S., Moase, C., Chan, P.
2010
A review of pesticide exposure and cancer incidence in the Agricultural Health Study cohort
Environ Health Perspect 118, 1117-1125 GLP: N, published: Y
2310122 / ASB2012-12048
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.5.3 (OECD)
2009
Glyphosate Technical: Dietary carcinogenicity study in the mouse
SPL 2060-0011 NUF
GLP: Y, published: N 2309412 / ASB2012-11492
Y
NUF
KIIA 5.6.1 (OECD)
1985

Three-generation reproduction study in rats with the oral administration of glyphosate
TOX9650161
N

KIIA 5.6.1 (OECD)
1988
Report on effect of glyphosate technical of Excel Industries Ltd., Bombay, on fertility and general reproductive performance (Segment I)
TOX9551832
N

KIIA 5.6.1 (OECD)
1988
Report on effect of pesticides on reproductive process - Segment IV - three generation repro- duction study with albino rats using glyphosate technical of Excel Industries Ltd., Bombay
TOX9551965
N

KIIA 5.6.1 (OECD)
1991
Dietary range finding study of glyphosate in pregnant rats and their juvenile offspring CHV 42/90619
TOX9552388
N

KIIA 5.6.1 (OECD)
1992
The Effect of Dietary Administration of Glyphosate on Reproductive Function of Two Generations in the Rat
CHV 47/911129 CHE
GLP: Y, published: N 2309436 / TOX9552389
N
CHE
KIIA 5.6.1 (OECD)
2007
Glyphosate technical: Dietary Two Generation Reproduction Study in the Rat
2060/0013 NUF
GLP: Y, published: N 2309418 / ASB2012-11494
Y
NUF
KIIA 5.6.1 (OECD)
2000
Glyphosate acid: Multigeneration reproduction toxicity study in rats
CTL/P/6332 SYN / MON
GLP: Y, published: N 2309423 / TOX2000-2000
Y
SYN

KIIA 5.6.1 (OECD)
1990
Two Generation Reproduction Feeding Study with Glyphosate in Sprague-Dawley Rats MSL-10387
MON
GLP: Y, published: N
2309439 / ASB2012-11496 / TOX9552387
N
MON
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.6.1 (OECD)
1993
Two Generation Reproduction Study in Wistar Rats
TOXI: 885-RP-G2
GLP: Y, published: N
2309427 / TOX9300009 / TOX9551104
N
ADM
KIIA 5.6.1 (OECD)
1997
HR-001: A two-generation reproduction study in rats
IET 96-0031 ALS
GLP: Y, published: N 2309425 / ASB2012-11495
N
ALS
KIIA 5.6.10 (OECD
Antoniou, M.; Habib, M.E.M;
Howard, C.V.; Jennings, R.C.; Leifert, C.; Nodari, R.O.; Robinson, C.J.;
Fagan, J.
2012
Teratogenic Effects of Glyphosate-Based Herbicides: Divergence of Regulatory Deci- sions from Scientific Evidence
J Environ Anal Toxicol 2012, S:4, ASB2012-15927
N

KIIA 5.6.10 (OECD)
1991
The effect of glyphosate on pregnancy of the rat (incorporates preliminary investigation) CHV 43 u.

41/90716
TOX9552393
N

KIIA 5.6.10 (OECD)
1995
HR-001: Teratogenicity Study in Rats IET 94-0152 ALS
GLP: Y, published: N
2309444 / ASB2012-11497
Y
ALS
KIIA 5.6.10 (OECD)
2012
Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity
Toxicology, in Press
ASB2012-13917
N

KIIA 5.6.10 (OECD)
2002
Amendment 001 to glyphosate acid: Develop- mental toxicity study in the rat
CTL/P/4819 ! RR0690
ASB2012-10080
N

KIIA 5.6.10 (OECD)
1991
Glyphosate techn. (FSG 03090 H/05 March 1990): Teratogenicity study in Wistar rats ES.883.TER-R !
TOXI-883/1991 ! ES-GPT- TER-R
TOX9551105
N

KIIA 5.6.10 (OECD)
1980
Glyphosate: Teratology study in rats 401-054 ! IR-79-016
TOX9552392
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed

Y/N
Owner5
KIIA 5.6.11 (OECD)
2013
No evidence of endocrine disruption by glyphosate in male and female pubertal assays. Abstract
ASB2013-3464
N

KIIA 5.6.11
1989
Rabbit Teratology Study with Glyphosate
N
EXC
(OECD)
Technical
IIT Project No. 1086 EXC
GLP: Y, published: N
2309462 / TOX9551960
KIIA 5.6.11
1991
The Effect of Glyphosate on Pregnancy of the
N
CHE
(OECD)
Rabbit (Incorporates Preliminary
Investigations)
CHV 45 & 39 & 40/901 CHE
GLP: Y, published: N
2309454 / TOX9552391
KIIA 5.6.11
1996
Glyphosate technical: Oral gavage teratology
Y
NUF
(OECD)
study in the rabbit
434/020 NUF
GLP: Y, published: N
2309448 / ASB2012-11499
KIIA 5.6.11
1995
HR-001: A Teratogenicity Study in Rabbits
N
ALS
(OECD)
IET 94-0153 ALS

GLP: Y, published: N
2309446 / ASB2012-11498
KIIA 5.6.11
Kimmel, G.L.;
2013
Evaluation of developmental toxicity studies of
N

(OECD)
Kimmel, C.A.;
glyphosate with attention to cardiovascular
Williams, A.L.;
development
DeSesso, J.M.;
Critical Reviews in Toxicology 43(2013)2: 79-
95, ASB2013-3462
KIIA 5.6.11
1996
Glyphosate acid: Developmental toxicity study
N
SYN
(OECD)
in the rabbit
CTL/P/5009 SYN
GLP: Y, published: N
2309450 / TOX2000-2002
KIIA 5.6.11
1993
Teratogenicity study in rabbits – Tets

N
ADM
(OECD)
compound: Glyphosate technical
TOXI: 884-TER-RB
GLP: Y, published: N
2309457 / TOX9551106
KIIA 5.6.11
1980
Technical Glyphosate: Teratology study in
N
MON
(OECD)
rabbits
IR-79-018 MON
GLP: N, published: N

2309452 / TOX9552390
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.6.2 (OECD)
1996
Glyphosate acid: Developmental toxicity study in the rat
29.03.1996 CTL/P/4819 ! RR 0690
TOX2000-2001
N

KIIA 5.6.2 (OECD)
2011
Glyphosate Technical: Dietary carcinogenicity study in the mouse – Amendment
SPL 2060-0011
ASB2014-9149
KIIA 5.6.2 (OECD)
2011
Assessment and further discussion on rele- vance of perceived elevation in testicular atro- phy for SafePharm project number 2060/0011 (Glyphosate technical: mouse oncogenicity study)
SPL 2060-0011
ASB2014-9150
KIIA 5.7. (OECD
1996
Glyphosat Acid: Acute delayed neurotoxicity study with in the domestic hen
CTL/C/3122 ! C2.8/01 ! ISN 361
ASB2013-9828
N

KIIA 5.7.1 (OECD)
1996
Glyphosate acid: Acute neurotoxicity study in rats
CTL/P/4866 SYN
GLP: Y, published: N 2309464 / ASB2012-11500
N
SYN
KIIA 5.7.4
KIIA 5.10 (OECD)
Astiz, M., de Alaniz, M.J., Marra, C.A.

2009
Effect of pesticides on cell survival in liver and brain rat tissues
Ecotoxicol Environ Saf 72, 2025-2032 GLP: N, published: Y
2309582 / ASB2012-11549
N
LIT
KIIA 5.7.4
KIIA 5.9
KIIA 5.10 (OECD)
Barbosa, E.R., da Costa, M.D.L.,
Bacheschi, L.A., Scaff, M.,
Leite, C.C.
2001
Parkinsonism after glycine-derivate exposure Movement Disorders 16, 565-568
GLP: N, published: Y 2309598 / ASB2012-11557
N
LIT
KIIA 5.7.4
KIIA 5.10 (OECD)
Cole, R.D., Anderson, G.L., Williams, P.L.
2004
The nematode Caenorhabditis elegans as a model of organophosphate-induced mammalian neurotoxicity
Toxicology and Applied Pharmacology 194, 248-256
GLP: N, published: Y
2309680 / ASB2012-11594
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.7.4
KIIA 5.10 (OECD)
da Costa, M.D.L.,
Goncalves, L.R., Barbosa, E.R., Bacheschi,
L.A.
2003
Neuroimaging abnormalities in parkinsonism: study of five cases
Arquivos De Neuro-Psiquiatria 61, 381-386 GLP: N, published: Y

2309688 / ASB2012-11598
N
LIT
KIIIA 5.7.4
KIIA 5.10 (OECD)
Engel, L.S., Checkoway, H., Keifer, M.C.,
Seixas, N.S., Longstreth, W.T., Jr., Scott, K.C., Hudnell,
K., Anger,
W.K.,
Camicioli, R.
2001
Parkinsonism and occupational exposure to pesticides
Occup Environ Med 28, 582-589 GLP: N, published: Y
2309718 / ASB2012-11612
N
LIT
KIIA 5.7.4
KIIA 5.10 (OECD)
Gui, Y.-x., Fan,
X.-n., Wang,
H.-m., Wang,
G., Chen, S.-d.
2012
Glyphosate induced cell death through apoptotic and autophagic mechanisms Neurotoxicology and Teratology GLP: N, published: Y
2309778 / ASB2012-11835
N
LIT
KIIA 5.7.4
KIIA 5.10 (OECD)
Heu, C., Elie- Caille, C., Mougey, V., Launay, S., Nicod, L.
2012
A step further toward glyphosate-induced epidermal cell death: Involvement of mitochondrial and oxidative mechanisms Environmental Toxicology and Pharmacology 34, 144-153
GLP: N, published: Y
2309800 / ASB2012-11844
N
LIT
KIIA 5.7.4 (OECD)
1996
Glyphosate Acid: Subchronic Neurotoxicity Study In Rats
CTL/P/4867 SYN
GLP: Y, published: N 2309466 / ASB2012-11501
N
SYN
KIIA 5.7.4

KIIA 5.10 (OECD)
Kamel, F.,
Tanner, C.M.,
Umbach, D.M.,
Hoppin, J.A., Alavanja, M.C.R., Blair,
A., Comyns, K.,
Goldman, S.M., Korell, M., Langston, J.W., Ross G.W.,
Sandler, D.P.
2007
Pesticide exposure and self-reported Parkinson's disease in the agricultural health study
American Journal of Epidemiology 165, 364-
374
GLP: N, published: Y 2309838 / ASB2012-11862
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.7.4
KIIA 5.10 (OECD)
Mink, P.J.,
Mandel, J.S.,
Lundin, J.I., Sceurman, B.K.
2011
Epidemiologic studies of glyphosate and non- cancer health outcomes: A review
Regulatory Toxicology and Pharmacology 61, 172-184
GLP: N, published: Y
2309938 / ASB2012-11904
N
LIT
KIIA 5.7.4
KIIA 5.10 (OECD)
Negga, R.,
Rudd, D.A.,
Davis, N.S.,
Justice, A.N., Hatfield, H.E., Valente, A.L.,
Fields, A.S.,
Fitsanakis, V.A.
2011

Exposure to Mn/Zn ethylene-bis- dithiocarbamate and glyphosate pesticides leads to neurodegeneration in Caenorhabditis elegans
NeuroToxicology 32, 331-341 GLP: N, published: Y
2309976 / ASB2012-11923
N
LIT
KIIA 5.7.4
KIIA 5.9
KIIA 5.10 (OECD)
Wang, G., Fan,
X.N., Tan,
Y.Y., Cheng,
Q., Chen, S.D.
2011
Parkinsonism after chronic occupational exposure to glyphosate
Parkinsonism & Related Disorders 17, 486-
487
GLP: N, published: Y 2310120 / ASB2012-12047
N
LIT
KIIA 5.8 (OECD)
1996
AMPA, Reverse Mutation Test IET 96-0076 ALS
GLP: Y, published: N
2309478 / ASB2012-11507
Y
ALS
KIIA 5.9 (OECD)
Bakke, J. P.
1991
Evaluation of the potential of AMPA to induce unscheduled DNA synthesis in the in vitro hepatocyte DNA repair assay using the male F- 344 rats
2495-V01-91 ! SR-91-234
TOX9552409
N

KIIA 5.8 (OECD)
Callander, R.D.
1988
Aminomethyl Phosphonic Acid: An Evaluation of Mutagenic Potential Using S. typhimurium and E. coli
CTL/P/2206 SYN
GLP: Y, published: N 2309476 / TOX9500043
N
SYN
KIIA 5.8 (OECD)

1993
AMPA: Acute oral toxicity (limit) test in rats 8763 ! IRI 552409
TOX9552395
N

KIIA 5.8 (OECD)
1993
AMPA: Acute dermal toxicity (limit) test in rats
8764 ! IRI 552409
TOX9552396
N

KIIA 5.8 (OECD)
1993
AMPA: Magnusson-Kligman maximisation test in guinea pigs
8765 ! IRI 552409
TOX9300374
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.8 (OECD)
1979
CP 50435: 90-day subacute rat toxicity study 401-050 ! IRD-78-174
TOX9552401
N

KIIA 5.8 (OECD)
1992
AMPA: Teratogenicity study in rats 7891 ! IRI 490421
TOX9300348
N

KIIA 5.8 (OECD)
1993
AMPA: 4 week dose range finding study in rats with administration by gavage
7803 ! IRI 450860
TOX9300349

N

KIIA 5.8 (OECD)
1991
A developmental toxicity study of AMPA in rats
WIL-50159 ! WI-90-266
TOX9552414
N

KIIA 5.8 (OECD)
1991
Assessment of acute oral toxicity of (N- methyl-N-phosphonomethyl)glycine to rats 12837
TOX9552398
N

KIIA 5.8 (OECD)
1993
Mutagenicity test: Ames salmonella test with AMPA, batch 286-JRJ-73-4,
13269
TOX9300378
N

KIIA 5.8 (OECD)
1993
AMPA, batch 286-JRJ-73-4: Mutagenicity test: In vitro mammalian cell gene mutation test performed with mouse lymphoma cells (L5178Y)
13270
TOX9300380
N

KIIA 5.8 (OECD)
1993
Mutagenicity test: Micronucleus test with AMPA, batch 286-JRJ-73-4
13268
TOX9300379
N

KIIA 5.8 (OECD)
1993
Mouse micronucleus study of AMPA EHL-90170/ML-90-404 ! MSL 13243 TOX9552413
N

KIIA 5.8 (OECD)
1996
AMPA: Acute Oral Toxicity Study In Mice IET 96-0075 ALS
GLP: Y, published: N

2309468 / ASB2012-11502
Y
ALS
KIIA 5.8 (OECD)
1988
Aminomethyl Phosphonic Acid: Acute Oral Toxicity to the Rat

CTL/P/2266 SYN
GLP: Y, published: N 2309470 / TOX9500044
N
SYN
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.8 (OECD)
2002
Acute Toxicity Study of AMPA (Aminomethyl Phosphonic Acid) in CD Rats by Dermal Administration - LIMIT TEST
16168/02
GLP: Y, published: N 2309472 / ASB2012-11503
Y
ADM
KIIA 5.8 (OECD)
2002
Examination of AMPA (Aminomethyl Phosphonic Acid) in the Skin Sensitisation Test in Guinea Pigs according to Magnusson And Kligman (Maximisation Test)
16169/02
GLP: Y, published: N 2309474 / ASB2012-11506
Y
ADM
KIIA 5.8 (OECD)
2002
Measurement of unscheduled DNA synthesis (UDS) in rat hepatocytes in vitro procedure with AMPA (Amino methyl phosphonic acid) IPL-R 020625 ALS
GLP: Y, published: N
2309480 / ASB2012-11508
Y
ALS
KIIA 5.8 (OECD)

1993
AMPA: 13-week toxicity study in rats with administration by gavage
7866 ! IRI 450876
TOX9300377
N

KIIA 5.8 (OECD)
1991
90-day oral (capsule) toxicity study in dogs with AMPA
WIL-50173 ! WI-90-354
TOX9552406
N

KIIA 5.9 (OECD)
Acquavella, J.F., Weber,
J.A., Cullen,
M.R., Cruz,
O.A., Martens,
M.A., Holden,
L.R., Riordan, S., Thompsen,
M., Farmer, D.
1999
Human ocular effects from self-reported exposures to Round-up herbicides
Human & Experimental Toxicology (paper) 18, 479-486
GLP: N, published: Y 2309482 / TOX2002-699
N
LIT
KIIA 5.9 (OECD)
Bando, H.,
Murao, Y., Aoyagi, U., Hirakawa, A., Iwase, M.,
Nakatani, T.
2010
[Extreme hyperkalemia in a patient with a new glyphosate potassium herbicide poisoning: report of a case]
Chudoku Kenkyu 23, 246-249 GLP: N, published: Y
2309596 / ASB2012-11556
N
LIT
KIIA 5.9 (OECD)
BfR
2011
Frauenmilch: Dioxingehalte sinken kontinuier- lich. Information Nr. 011/2011 des BfR vom
23.03.2011
ASB2014-8171
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.9
KIIIA1 7.6.3 (OECD)
Bradberry, S.M., Proutfoot, A.T., Vale, J.A.
2004
Glyphosate poisoning
Toxicological reviews (paper), 23, 159-167 GLP: N, published: Y
2309484 / ASB2012-11509
N
LIT
KIIA 5.9 (OECD)
Bradberry, S.M.,
Proudfoot, A.T.,
Vale, J.A.
2004
Glyphosate poisoning Toxicol Rev 23, 159-167 GLP: N, published: Y
2309642 / ASB2012-11576
N
LIT
KIIA 5.9 (OECD)
Burger, R.; Begemann, K.; Meyer, H.;
Hahn, A.;
2009
Severe dyspnoea after spraying of a pesticide containing glyphosate. Lung damage histologi- cally confirmed
Clinical Toxicology (2009) 47, 506
ASB2013-11831
N

KIIA 5.9 (OECD)
Chang, C.-J.,
Peng, Y.-C.,
Hung, W.-H.,
Yang, D.-Y.,
Lin, T.-J.
1999
Clinical impact of upper gastrointestinal tract injuries in glyphosate-surfactant oral intoxication

Human & Experimental Toxicology (paper), 18, 475-478
GLP: N, published: Y
2309486 / ASB2012-11510
N
LIT
KIIA 5.9 (OECD)
Fromme, H.; Gruber, L.; Seckin, E.; et al.;
2011
Phthalates and their metabolites in breast milk
— Results from the Bavarian Monitoring of Breast Milk (BAMBI)
Environment International 37 (2011) 715–722
ASB2014-8169
N
LIT
KIIA 5.9 (OECD)
Fürst, P.
2006
Dioxins, polychlorinated biphenyls and other organohalogen compounds in human milk Mol. Nutr. Food Res. 2006, 50, 922 – 933
ASB2014-8168
N
LIT
KIIA 5.9 (OECD)
Goldstein, D.A., Johnson, G., Farmer, D.R.,
Martens, M.A.
1999
Pneumonitis and herbicide exposure Chest (paper), 16, 1139-1140
GLP: N, published: Y
2309490 / ASB2012-11511
N
LIT
KIIA 5.9 (OECD)
Goldstein, D.A., Acquavella, J.F., Mannion,
R.M., Farmer, D.R.
2002
An analysis of glyphosate data from the California Environmental Protection Agency Pesticide Illness Surveillance Program
Journal of Toxicology-Clinical Toxicology 40, 885-892
GLP: N, published: Y
2309770 / ASB2012-11831
N
LIT
KIIA 5.9 (OECD)
Kamijo, Y., Mekari, M., Yoshimura, K., Kano, T., Soma, K.
2012
Glyphosate-surfactant herbicide products containing glyphosate potassium salt can cause fatal

hyperkalemia if ingested in massive amounts
Clinical Toxicology 50, 159
GLP: N, published: Y 2309840 / ASB2012-11863
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.9 (OECD)
Lee, H-L.,
Chen, K.-W.,
Chi, C.-H.,
Huang, J.-J.,
Tsai, L.-M.
2000
Clinical presentations and prognostic factors of a glyphosate-surfactant herbicide intoxication: a review of 131 cases
Academic Emergency Medicine (paper) 7, 906-910
GLP: N, published: Y
2309492 / ASB2012-11512
N
LIT
KIIA 5.9 (OECD)
Lee, C.H.,
Shih, C.P.,
Hsu, K.H.,
Hung, D.Z.,
Lin, C.C.
2008
The early prognostic factors of glyphosate- surfactant intoxication
Am J Emerg Med 26, 275-281 GLP: N, published: Y
2309880 / ASB2012-11879
N
LIT
KIIA 5.9
KIIA 5.10
KIIIA1 7.6.3 (OECD)
1987
Irritating effect of glyphosate, surfactant and roundup on stomach and small intestine in dogs

MON
GLP: N, published: N 2309496 / TOX9552430
N
MON
KIIA 5.9 (OECD)
Paumgartten, F.J.R.
2012
ANVISA - Glyphosate Intoxications 2010 to 2012 in Brasil;
ASB2013-13413
N

KIIA 5.9 (OECD)
Pushnoy, L.A.,
Avnon, L.S., Carel, R.S.
1998
Herbicide (Roundup) Pneumonitis Chest (paper), 114, 1769-1771 GLP: N, published: Y
2309498 / ASB2012-11513
N
LIT
KIIA 5.9 (OECD)
Raab, U.; Alb-
recht, M.; Preiss, U.; et al.;
2013
Organochlorine compounds, nitro musks and perfluorinated substances in breast milk – Results from Bavarian Monitoring of Breast Milk 2007/8
Chemosphere 93 (2013) 461–467
ASB2014-8170
N
LIT
KIIA 5.9 (OECD)
Sawada, Y., Nagai, Y., Ueyama, M., Yamamoto, I.
1988
Probable toxicity of surface-active agent in commercial herbicide containing glyphosate The Lancet (paper) 1, 299-301
GLP: N, published: Y
2309504 / Z35532
N
LIT
KIIA 5.9 (OECD)
Tominack, R., Conner, P., Yamashita, M.
1989
Clinical Management of Roundup® herbicide exposure
The Japanese Journal of Toxicology (paper) 2, 187-192
GLP: N, published: Y
2309506 / TOX9552426
N

LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.9 (OECD)
UBA
2008
Aktualisierung der Referenzwerte für HCB, β-HCH, DDT und PCB in Frauenmilch. Stellungnahme der Kommission Human- Biomonitoring des Umweltbundesamtes
BfR Stillkommission
Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2008 · 51:1239–1242
ASB2014-8167
N

KIIA 5.9 (OECD)
Verdugo-Raab, U.;
2012
Ergebnisse der Muttermilchuntersuchungen 1984–2010
Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit
ASB2014-8173
N

KIIA 5.10 (OECD)
AFSSA
2009
Avis de l'Agence française de sécurité sanitaire des aliments relatif au glyphosate et aux préparations phytopharmaceutiques à base de cette substance active
GLP: N, published: Y
2309546 / ASB2012-11532
N
LIT
KIIA 5.10 (OECD)
1996
Glyphosate Acid: Comparison of Salivary Gland Effects in Three Strains of Rat CTL/P/5160 SYN
GLP: Y, published: N
2309518 / ASB2012-11520
N
SYN
KIIA 5.10 (OECD)

1996
Glyphosate Acid: Comparison of Salivary Gland Effects in Three Strains of Rat CTL/P/5160 SYN
GLP: Y, published: N
2309558 / ASB2012-11537
Y
MOD
KIIA 5.10 (OECD)
Alavanja, M. C. R.; Ross, M. K.;
Bonner, M. R.
2013
Increased cancer burden among pesticide ap- plicators and others due to pesticide exposure CA: A Cancer Journal for Clinicians, 2013;63:120–142
ASB2014-9174
N
LIT
KIIA 5.10 (OECD)
Alavanja, M. C. R.; Bonner, M. R.
2012
Occupational pesticide exposures and cancer risk: a review
Journal of Toxicology and Environmental
Health, Part B, 15:238–263, 2012 ASB2014-9173
N
LIT
KIIA 5.10 (OECD)
Alvarez-Moya, C.; Reynoso Silva, M.; Val- dez Ramírez, C.; et al.;
2014
Comparison of the in vivo and in vitro geno- toxicity of Glyphosate Isopropylamine salt in three different organisms
Genetics and Molecular Biology, 37, 1, 105-
110 (2014) ASB2014-6902
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Altenburger, R.; Scholz, S.; Schmitt-Jansen, M.; Busch, W.; Escher B. I.
2012
Mixture toxicity revisited from a toxicoge- nomic perspective

Environ. Sci. Technol. 2012, 46, 2508−2522 ASB2014-9176
N
LIT
KIIA 5.10 (OECD)
Andreotti, G.; Koutros, S.; Berndt, S. I. et al.
2012
The Interaction between pesticide use and genetic variants involved in lipid metabolism on prostate cancer risk
Journal of Cancer Epidemiology
Volume 2012, Article ID 358076, ASB2014-9198
N
LIT
KIIA 5.10 (OECD)
Anonymous
2009
Final List of Initial Pesticide Active Ingredients and Pesticide Inert Ingredients to be Screened Under the Federal Food, Drug, and Cosmetic Act
Federal Register /Vol. 74, No. 71
/Wednesday, April 15, 2009 /Notices, 17579-
17585 74, 17579-17585
GLP: N, published: Y 2310108 / ASB2012-12041
N
LIT
KIIA 5.10 (OECD)
Anonymous
2012
GM Soy linked to health damage in pigs -- a Danish Dossier
ASB2013-11007
N

KIIA 5.10 (OECD)
Anonymous
2013
Effects on ruminants and other herbivores (livestock and wild life)
ASB2013-11007
N

KIIA 5.10 (OECD)
Antoniou, M.; Brack, P.; Car- rasco, A. et al.
2010
GV-SOYA - Nachhaltig? - Verantwortungs- bewusst? - Zusammenfassung der wichtigsten Ergebnisse
ASB2012-803
N

KIIA 5.10 (OECD)
Arbuckle, T.E., Lin, Z.Q., Mery, L.S.

2001
An exploratory analysis of the effect of pesticide exposure on the risk of spontaneous abortion in an Ontario farm population Environmental Health Perspectives 109, 851-
857
GLP: N, published: Y 2309574 / ASB2012-11545
N
LIT
KIIA 5.10 (OECD)
Aris, A., Leblanc, S.
2011
Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada Reproductive Toxicology 31, 528-533 GLP: N, published: Y
2309578 / ASB2012-11547
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Astiz, M.; de Catalfo, G.; Garcia, M.
2013
Pesticide-induced decrease in rat testicular steroidogenesisis differentially prevented by lipoate and tocopherol
Ecotoxicology and Environmental Safety 91 (2013) 129–138
ASB2014-7493
N
LIT
KIIA 5.10 (OECD)
Astiz, M.; de Alaniz, M. J. T.; Marra, C. A.
2012
The oxidative damage and inflammation caused by pesticides are reverted by lipoic acid in rat brain Neurochemistry International 61 (2012) 1231–
1241
ASB2014-9201
N
LIT
KIIA 5.10 (OECD)
Axelrad, J.C.,
Howard, C.V., McLean, W.G.

2003
The effects of acute pesticide exposure on neuroblastoma cells chronically exposed to diazinon
Toxicology 185, 67-78 GLP: N, published: Y
2309590 / ASB2012-11553
N
LIT
KIIA 5.10 (OECD)
Bailey, J.; Hauswirth, J.; Stump, D.;
2013
No evidence of endocrine disruption by glyphosate in male and female pubertal assays. Abstract
SOT 2013 Annual Meeting, PS 1937: p 412
ASB2013-3464
N

KIIA 5.10 (OECD)
Basrur, P. K.;
2006
Disrupted sex differentiation and feminization of man and domestic animals
Environmental Research 100 (2006) 18–38
ASB2014-7492
N
LIT
KIIA 5.10 (OECD)
Bates, N.; Ed- wards, N.
2013
Letter to the editor: Glyphosate toxicity in animals
Clinical Toxicology (2013), 51, 1243
ASB2014-9249
N
LIT
KIIA 5.10 (OECD)
Bell, E.M., Hertz-Picciotto, I., Beaumont, J.J.
2001
A case-control study of pesticides and fetal death due to congenital anomalies Epidemiology 12, 148-156
GLP: N, published: Y
2309602 / ASB2012-11559
N
LIT
KIIA 5.10 (OECD)
Belle, R., Le Bouffant, R., Morales, J., Cosson, B., Cormier, P., Mulner-
Lorillon, O.
2007
Sea urchin embryo, DNA-damaged cell cycle checkpoint and the mechanisms initiating cancer development
J Soc Biol 201, 317-327

GLP: N, published: Y 2309604 / ASB2012-11560
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed

Y/N
Owner5
KIIA 5.10 (OECD)
Bellé, R.; Mo-
rales, J.; Cor-
mier, P.; Mul- ner-Lorillon, O.
2012
Letter to the editor: Toxicity of Roundup and Glyphosate
Journal of Toxicology and Environmental Health, Part B, 15:233–237, 2012
ASB2014-9251
N
LIT
KIIA 5.10 (OECD)
Benachour, N., Sipahutar, H., Moslerni, S., Gasnier, C., Travert, C.,
Seralini, G.E.
2007
Time- and dose-dependent effects of roundup on human embryonic and placental cells Archives of Environmental Contamination and Toxicology 53, 126-133
GLP: N, published: Y
2309608 / ASB2009-9018
N
LIT
KIIA 5.10 (OECD)
Benedetti, A.L., Vituri, C.D., Trentin, A.G, Domingues, M.A.C.,
Alvarez-Silva,
M.
2004
The effects of sub-chronic exposure of Wistar rats to the herbicide Glyphosate-Biocarb (R) Toxicology Letters 153, 227-232
GLP: N, published: Y 2309610 / ASB2012-11562
N
LIT
KIIA 5.10 (OECD)
Benitez-Leite, S., Macchi, M., Acosta, M.

2009
Malformaciones congénitas asociadas a agrotóxicos
Archives of Pediatrics 80 (3):377-378. 80,
377-378
GLP: N, published: Y 2309612 / ASB2012-11563
N
LIT
KIIA 5.10 (OECD)
Barry, K.; Koutros, S.; Berndt, S. et al.
2011
Genetic variation in base excision repair path- way genes, pesticide exposure, and prostate cancer risk
Environmental Health Perspectives, 119(2011)12
ASB2014-9247
N
LIT
KIIA 5.10 (OECD)
Benedettia, D.; Nunesa, E.; Sarmentoa, M. et al.
2013
Genetic damage in soybean workers exposed to pesticides: Evaluation with the comet and buccal micronucleus cytome assays Mutation Research 752 (2013) 28– 33
ASB2014-9279
N
LIT
KIIA 5.10 (OECD)
Beuret, C.J., Zirulnik, F., Gimenez, M.S.
2005
Effect of the herbicide glyphosate on liver lipoperoxidation in pregnant rats and their fetuses
Reproductive Toxicology 19, 501-504 GLP: N, published: Y
2309614 / ASB2012-11564
N
LIT
KIIA 5.10 (OECD)
Beswick, E.; Millo, J.
2011
Fatal poisoning with Glyphosate - surfactant herbicide
JICS Volume 12, Number 1, January 2011
ASB2014-9283
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not

BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
BfR
2009
BfR-Bewertung der Studie "Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines" vom 06.08.2009
GLP: N, published: Y
2309616 / ASB2012-11565
N
LIT
KIIA 5.10
1987
Synergism and potentiation in rats of Glypho-
N

(OECD)
sate (tech.) of Excel Industries Ltd., Bombay
TOX9551964
KIIA 5.10 (OECD)
Blair, A.,
Zahm, S.H.
1993
Patterns of pesticide use among farmers: implications for epidemiologic research Epidemiology 4, 55-62
GLP: N, published: Y
2309620 / ASB2012-11567
N
LIT
KIIA 5.10 (OECD)
Bleeke, M.S., Kurtzweil, M.L.,
Saltmiras, D.A.
2010
Dietary Exposure Assessment of Polyoxyethylenealkylamines (POEA) Surfactants
MON
GLP: N, published: Y 2309622 / ASB2010-6123
N
LIT
KIIA 5.10 (OECD)
Borgert, C. J.;
Baker, S. P.; Matthews, J. C.
2013
Potency matters: Thresholds govern endocrine activity
Regulatory Toxicology and Pharmacology 67 (2013) 83–88

ASB2014-9292
N
LIT
KIIA 5.10 (OECD)
Brändli, D.; Reinacher, S.
2011
Herbizide im Urin
Ithaka Journal 1 | 2012:1–4 ASB2012-804
N
LIT
KIIA 5.10 (OECD)
BVL
2010
Glyphosate - Comments from Germany on the paper by Paganelli, A. et al. (2010): "Glyphosate-based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling"
GLP: N, published: Y
2309648 / ASB2012-11579
N
LIT
KIIA 5.10 (OECD)
Caglar, S., Ko- lankaya, D.
2008
The effect of sub-acute and sub-chronic expo- sure of rats to the glyphosate-based herbicide Roundup
Environmental Toxicology and Pharmacology 25 (2008) 57–62
ASB2012-11580
N
LIT
KIIA 5.10 (OECD)
Campaña, H.; Pawluk, M. S.; López Camelo,
J. S.; Grupo de Estudio del ECLAMC
2010
Prevalencia al nacimiento de 27 anomalías congénitas seleccionadas, en 7 regiones geo- gráficas de la Argentina. Births prevalence of 27 selected congenital anomalies in 7 geo- graphic regions of Argentina
Arch Argent Pediatr 2010;108(5):409-417
ASB2013-10559
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number

Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Campo, N. B.-
C.; Zarate, D.
H. V.; Hernandez, E.
D. R.
2009
Toxicity of the main pesticides used in Popayán Valley with Bacillus subtillis Facultad de Ciencias Agropecuarias 16 Vol 7 No. 1 Enero - Junio 2009 ASB2014-9281
N

KIIA 5.10 (OECD)
Carmichael, S. L.; Yang, W.;
Roberts, E. M.
et al.
2013
Hypospadias and residential proximity to pes- ticide applications
Pediatrics 2013;132(5)e1216–e1226
ASB2014-9307
N
LIT
KIIA 5.10 (OECD)
Carroll, R.; Metcalfe, C.; Gunnell, D. et al.
2012
Diurnal variation in probability of death fol- lowing self-poisoning in Sri Lanka—evidence for chronotoxicity in humans
International Journal of Epidemiology 2012;41:1821–182
ASB2014-9308
N
LIT
KIIA 5.10 (OECD)
Cassault-Meyer, E.; Gress, S.; Seralini, G. E.; Galeraud-Denis, I.;
2014
An acute exposure to glyphosate-based herbi- cide alters aromatase levels in testis and sperm nuclear quality
Environ Toxicol. Pharmacol 38 (2014) 131–
140
ASB2014-5615
N
LIT
KIIA 5.10 (OECD)
Cattani, D.; de Liz Oliveira Cavalli, V. L.; Heinz Rieg, C.
E. et al.
2014

Mechanisms underlying the neurotoxicity induced by Glyphosate-based herbicide in immature rat hippocampus: Involvement of glutamate excitotoxicity
Toxicology 320 (2014) 34–45
ASB2014-3919
N
LIT
KIIA 5.10 (OECD)
Chaufan, G.; Coalova, I.; Molina, M.
2014
Glyphosate commercial formulation causes cytotoxicity, oxidative effects, and apoptosis on human cells: Differences with its active ingredient
International Journal of Toxicology 2014, Vol. 33(1) 29-38
ASB2014-9314 / ASB2014-7616
N
LIT
KIIA 5.10 (OECD)
Chen, Y. J.;
Wu, M.-L.;
Deng, J.-F.;
Yang, C.-C.
2009
The epidemiology of Glyphosate-surfactant herbicide poisoning in Taiwan, 1986–2007: a poison center study
Clinical Toxicology (2009) 47, 670–677
ASB2014-9318
N
LIT
KIIA 5.10 (OECD)
Chen, H.-H.;
Lin, J.-L.;
Huang, W-H. et al.
2013
Spectrum of corrosive esophageal injury after intentional paraquat or Glyphosate-surfactant herbicide ingestion
International Journal of General Medicine 2013:6 677–683
ASB2014-9321
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed

Y/N
Owner5
KIIA 5.10 (OECD)
Chien, W.-C.;
Chung, C.-H.; Jaakkola, J. J.
K. et al.
2012
Risk and prognostic factors of inpatient mortal- ity associated with unintentional insecticide and herbicide poisonings: A retrospective cohort study
PLOS one September 2012 Volume 7 Issue 9 e45627
ASB2014-9326
N
LIT
KIIA 5.10 (OECD)
Chorfa, A.; Bétemps, D.; Morignat, E. et al.
2013
Specific pesticide-dependent increases in al- pha-synuclein levels in human neuroblastoma (SH-SY5Y) and melanoma (SK-MEL-2) cell lines
Toxicological Sciences 133(2), 289–297 2013
ASB2014-9328
N
LIT
KIIA 5.10 (OECD)
Clair, E., Linn, L., Travert, C., Amiel, C., Seralini, G.-E.,
Panoff, J.-M.
2012
Effects of Roundup and Glyphosate on Three Food Microorganisms: Geotrichum candidum, Lactococcus lactis subsp. cremoris and Lactobacillus delbrueckii subsp. bulgaricus Current Microbiology 64, 486-491
GLP: N, published: Y
2309674 / ASB2012-11592
N
LIT
KIIA 5.10 (OECD)
Clair, E., Mesnage, R., Travert, C., Séralini, G.-E.
2012
A glyphosate-based herbicide induces necrosis and apoptosis in mature rat testicular cells in vitro, and testosterone decrease at lower levels Toxicology in Vitro 26, 269-279
GLP: N, published: Y
2309678 / ASB2012-1628
N
LIT
KIIA 5.10 (OECD)
Coalova, I.; Ríos de Molina,
M. C.; Chaufan, G.;
2014

Influence of the spray adjuvant on the toxicity effects of a Glyphosate formulation Toxicology in Vitro 28 (2014) 1306–1311 ASB2014-7615
N
LIT
KIIA 5.10 (OECD)
Cocco, P.; Satta, G.;
2014
Lymphoma risk and occupational exposure to pesticides: results of the Epilymph study Occup Environ Med 2012;0:1–7
ASB2014-7523
N
LIT
KIIA 5.10 (OECD)
Corsini, E.; Sokooti, M.; Galli, C. L.; Moretto, A.; Colosio, C.
2012
Pesticide induced immunotoxicity in humans: A comprehensive review of the existing evi- dence Toxicology (2012) ASB2014-9352
N
LIT
KIIA 5.10 (OECD)
Culbreth, M. E.; Harrill, J. A.; Freudenrich, T.
M. et al.
2012
Comparison of chemical-induced changes in proliferation and apoptosis in human and mouse neuroprogenitor cells NeuroToxicology 33 (2012) 1499–1510
ASB2014-9355
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Curwin, B.D.,
Hein, M.J., Sanderson, W.T., Striley, C., Heederik, D., Kromhout, H., Reynolds, S.J., Alavanja, M.C.
2006
Urinary pesticide concentrations among chil- dren, mothers and fathers living in farm and non-farm households in iowa
Ann. Occup. Hyg. 2006, 1-33 ASB2012-11597
N

LIT
KIIA 5.10
KIIIA1 7.6.3 (OECD)
Dallegrave, E., Mantese, F.D.,
Coelho, R.S.,
Pereira, J.D., Dalsenter, P.R., Langeloh, A.
2003
The teratogenic potential of the herbicide glyphosate-Roundup (R) in Wistar rats Toxicology Letters 142, 45-52
GLP: N, published: Y 2309692 / ASB2012-11600
N
LIT
KIIA 5.10
KIIIA1 7.6.3 (OECD)
Dallegrave, E., Mantese, F.D., Oliveira, R.T., Andrade, A.J.M.,
Dalsenter, P.R.,
Langeloh, A.
2007
Pre- and postnatal toxicity of the commercial glyphosate formulation in Wistar rats Archives of Toxicology 81, 665-673
GLP: N, published: Y 2309694 / ASB2012-2721
N
LIT
KIIA 5.10 (OECD)
de Liz Oliveira Cavalli, V. L.; Cattani, D.; Rieg, C. E. H. et al.
2013
Roundup disrupts male reproductive functions by triggering calcium-mediated cell death in rat testis and Sertoli cells FreeRadicalBiologyandMedicine65(2013)335– 346
ASB2014-7495
N
LIT
KIIA 5.10 (OECD)
Daruich, J., Zirulnik, F., Gimenez, M.S.
2001
Effect of the herbicide glyphosate on enzymatic activity in pregnant rats and their fetuses Environmental Research 85, 226-231 GLP: N, published: Y
2309696 / ASB2012-11601
N
LIT
KIIA 5.10 (OECD)
Da Silva, F. R.; Kvitko, K.; Rohr, P. et al.
2014
Genotoxic assessment in tobacco farmers at different crop times
Science of the Total Environment 490 (2014) 334–341
ASB2014-9358
N

LIT
KIIA 5.10 (OECD)
DeSesso, J. M.; Williams, A.
2012
Comment on ‘‘Glyphosate impairs male off- spring reproductive development by disrupting gonadotropin expression" by Romano et al.
2012
Arch Toxicol (2012) 86:1791–1793 ASB2014-9369
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
De Souza Filho, J.; Neves Sousa,
C. C.; Da Silva,
C. C. et al.
2013
Mutagenicity and genotoxicity in gill erythro- cyte cells of Poecilia reticulata exposed to a Glyphosate formulation
Bull Environ Contam Toxicol (2013) 91:583–587
ASB2014-7617
N
LIT
KIIA 5.10 (OECD)
El-Shenawy, N.S.
2009
Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate
Environmental Toxicology and Pharmacology 28 (2009) 379–385
ASB2012-11611
N
LIT
KIIA 5.10 (OECD)
El-Zaemey, S.; Heyworth, J.
2013
Noticing pesticide spray drift from agricultural pesticide application areas and breast cancer: a case-control study
Aust NZ J Public Health. 2013; Online
ASB2014-9473

N
LIT
KIIA 5.10 (OECD)
European Commission
2011
Standing Committee on the Food Chain and Animal Health, Section Phytopharmaceuticals
- Plant Protection Products - Legislation - 22- 23 November 2010
GLP: N, published: Y 2309724 / ASB2012-11615
N
LIT
KIIA 5.10 (OECD)
Faria, N. M. X.;
Fassa, A. G.; Meucci, R. D. et al.
2014
Occupational exposure to pesticides, nicotine and minor psychiatric disorders among tobacco farmers in southern Brazil
NeuroToxicology (2014) in Press
ASB2014-9477
N

KIIA 5.10 (OECD)
Folta, K.
2014
Letter to the editor
Food and Chemical Toxicology: 65 (2014) 392 ASB2014-9478
N
LIT
KIIA 5.10 (OECD)
Forgacs, A.L.,
Ding, Q.,
Jaremba, R.G., Huhtaniemi, I.T., Rahman,
N.A.,
Zacharewski, T.R.
2012
BLTK1 Murine Leydig Cells: A Novel Steroidogenic Model for Evaluating the Effects of Reproductive and Developmental Toxicants Toxicological Sciences
GLP: N, published: Y 2309736 / ASB2012-11621
N
LIT
KIIA 5.10 (OECD)
Freire, C.; Koifman, S.
2012
Pesticide exposure and Parkinson’s disease: Epidemiological evidence of association NeuroToxicology 33 (2012) 947–971
ASB2014-9479
N

LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
French Committee for the Study of Toxicity
2005
Enquiry into the referral of the Committee for the Study of Toxicity by the DGAL regarding the article "Differential effects of glyphosate and Roundup on human placental cells and aromatase." Richard S., Moslemi S., Sipahutar H., Benachour
GLP: N, published: Y
2309742 / ASB2009-9025
N
LIT
KIIA 5.10 (OECD)
Garlich, F. M.; Goldman, M.; Pepe, J. et al.
2014
Hemodialysis clearance of glyphosate follow- ing a life-threatening ingestion of glyphosate-surfactant herbicide
Clinical Toxicology (2014), 52, 66–71
ASB2014-9480
N
LIT
KIIA 5.10 (OECD)
Garry, V.F.,

Harkins, M.E., Erickson, L.L., Long-Simpson, L.K., Holland, S.E., Burroughs,
B.L.
2002
Birth defects, season of conception, and sex of children born to pesticide applicators living in the Red River Valley of Minnesota, USA Environmental Health Perspectives 110:441- 449 110, 441-449
GLP: N, published: Y
2309750 / ASB2012-11626
N
LIT
KIIA 5.10 (OECD)
Garry, V.F.,
Holland, S.E., Erickson, L.L., Burroughs, B.L.
2003

Male reproductive hormones and thyroid function in pesticide applicators in the Red River Valley of Minnesota
Journal of Toxicology and Environmental Health-Part A 66, 965-986
GLP: N, published: Y
2309752 / ASB2012-11627
N
LIT
KIIA 5.10 (OECD)
Gasnier, C., Benachour, N., Clair, E., Travert, C., Langlois, F., Laurant, C., Decroix- Laporte, C.,
Seralini, G.E.
2010
Dig1 protects against cell death provoked by glyphosate-based herbicides in human liver cell lines
J Occup Med Toxicol 5 GLP: N, published: Y 2309754 / ASB2012-11628
N
LIT
KIIA 5.10 (OECD)
Gasnier, C., Dumont, C., Benachour, N., Clair, E.,
Chagnon, M.C.,
Seralini, G.E.
2009
Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines Toxicology 262, 184-191
GLP: N, published: Y 2309756 / ASB2012-11629
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Gasnier, C., Laurant, C., Decroix- Laporte, C., Mesnage, R., Clair, E., Travert, C.,
Seralini, G.E.
2011
Defined plant extracts can protect human cells against combined xenobiotic effects
J Occup Med Toxicol 6, 3 GLP: N, published: Y 2309758 / ASB2012-11630
N
LIT
KIIA 5.10 (OECD)
Gencer, N.; Ergün, A.; De- mir, D.
2012

In vitro effects of some herbicides and fungi- cides on human erythrocyte carbonic anhy- drase activity
Fresenius Environmental Bulletin, Volume 21
- No 3. 2012 ASB2014-9481
N
LIT
KIIA 5.10 (OECD)
Gentile, N.; Manas, F.; Bo- sch, B.; Peralta, L.; Gorla, N.; Aiassa, D.
2012
Micronucleus assay as a biomarker of genotox- icity in the occupational exposure to agro- chemicals in rural workers
Bull Environ Contam Toxicol (2012) 88:816–822
ASB2014-9482
N
LIT
KIIA 5.10 (OECD)
George, J.; Shukla, Y.;
2013
Emptying of intracellular calcium pool and oxidative stress imbalance are associated with the Glyphosate-induced proliferation in human skin keratinocytes HaCaT cells
ISRN Dermatology, Volume 2013, Article ID 825180
ASB2014-8034
N
LIT
KIIA 5.10 (OECD)
Gil, H. W.;
Park, J. S.;
Hong; S. Y.
2013
Effect of intravenous lipid emulsion in patients with acute Glyphosate intoxication
Clinical Toxicology (2013), 51, 767–771
ASB2014-9488
N
LIT
KIIA 5.10 (OECD)
Glyphosat task force
2014
Response to EFSA non-confidential comment 48 (EFSA non-confidential letter page 9, in reference to public comment 2(78
ASB2014-9624
N
LIT
KIIA 5.10 (OECD)
Goldner, W. S.;
Sandler, D. P.; Yu, F. et al.
2013

Hypothyroidism and pesticide use among male private pesticide applicators in the agricultural health study
JOEM Volume 55, Number 10, October 2013
ASB2014-9492
N
LIT
KIIA 5.10 (OECD)
Goldstein, D. A.; Saltmiras,
D. A
2014
Neurodevelopmental toxicity: still more ques- tions than answers
neurology Vol 13 July 2014
ASB2014-9493
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10
Grandjean, P.;
2014
Neurobehavioural effects of developmental
N
LIT
(OECD)
Landrigan, P. J.
toxicity
Lancet Neurol 2014; 13: 330–38
ASB2014-9494
KIIA 5.10
Greenpeace
2011
Herbicide tolerance and GM cropsfedd - Why
N

(OECD)
the world should be ready to round up Glypho-
sate
ASB2012-810

KIIA 5.10
Gress, S.; Le-
2014
Cardiotoxic electrophysiological effects of the
N
LIT
(OECD)
moine, S.; Pud-
herbicide Roundup in rat and rabbit ventricular
du, P.-E.; Sera-
myocardium in vitro
lini, G.-E.;
Cardiovasc Toxicol
Rouet, R.;
ASB2014-12161
KIIA 5.10 (OECD)
Guilherme, S.; Santos, M. A.; Barroso, C.; et al.;
2012
Differential genotoxicity of Roundupformula- tion and its constituents in blood cells of fish (Anguilla anguilla): considerations on chemi- cal interactions and DNA damaging mecha-
nisms
N
LIT
Ecotoxicology (2012) 21:1381–1390
ASB2014-7619
KIIA 5.10
2010
An 8-Week Oral (Diet and Gavage) Toxicity
Y
MOD
(OECD)
Study of Citric Acid in Male Rats
WIL-50361 GTF
GLP: Y, published: N
2309782 / ASB2012-11519
KIIA 5.10
2012
Glyphosate - A 28-Day Oral (Dietary)
Y
EGT
(OECD)
Immunotoxicity Study in Female B6C3F1
Mice
WIL-50393 MON
GLP: Y, published: N
2309522 / ASB2012-11521

KIIA 5.10
Harrill, J. A.;
2011
Comparative sensitivity of human and rat neu-
N
LIT
(OECD)
Freudenich, T.
ral cultures to chemical-induced inhibition of
M.; Robinette,
neurite outgrowth
B. L.; Mundy,
Toxicology and Applied Pharmacology 256
W. R.
(2011) 268–280
ASB2014-9558
KIIA 5.10
Hayes; A. W.
2014
Reply to letter to the editor
N
LIT
(OECD)
Food and Chemical Toxicology: 65 (2014)
394–395
ASB2014-9559
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Hecker, M., Hollert, H., Cooper, R., Vinggaard, A.M., Akahori,
Y., Murphy, M., Nellemann, C., Higley, E., Newsted, J., Laskey, J.,
Buckalew, A.
2011
The OECD validation program of the H295R steroidogenesis assay: Phase 3. Final inter- laboratory validation study
Environmental Science and Pollution Research 18, 503-515
GLP: N, published: Y 2309792 / ASB2012-11840
N

LIT
KIIA 5.10 (OECD)
Hedberg, D.; Wallin, M.;
2010
Effects of Roundup and glyphosate formula- tions on intracellular transport, microtubules and actin filaments in Xenopus laevis melano- phores
Toxicology in Vitro 24 (2010) 795–802
ASB2014-7494
N
LIT
KIIA 5.10 (OECD)
Heu, C.,
Berquand, A., Elie-Caille, C., Nicod, L.
2012
Glyphosate-induced stiffening of HaCaT keratinocytes, a Peak Force Tapping study on living cells
Journal of structural biology 178, 1-7 GLP: N, published: Y
2309798 / ASB2012-11843
N
LIT
KIIA 5.10 (OECD)
Hinojosa, R.; Baud, F.; Marque, S.; Barreteau, H.
2013
Severe poisonings in intensive care unit: Study of announced substances in 2011
Annales Pharmaceutiques Françaises (2013) 71, 174—185
ASB2014-9566
N
LIT
KIIA 5.10 (OECD)
Hoare, A.
2014
QSAR assessment on the toxicological proper- ties of Glyphosate and its impurities
Report EE/14/002, Battelle UK Limited
ASB2014-9157
KIIA 5.10 (OECD)
Hokanson, R., Fudge, R., Chowdhary, R., Busbee, D.
2007
Alteration of estrogen-regulated gene expression in human cells induced by the agricultural and horticultural herbicide glyphosate
Hum Exp Toxicol 26, 747-752 GLP: N, published: Y
2309804 / ASB2012-11846
N
LIT
KIIA 5.10 (OECD)
Honeycutt, Z.; Rowlands, H.;
2014
Glyphosate Testing Report: Findings in Amer- ican Mothers' Breast Milk, Urine and Water. "Moms

Across America” and ”Sustainable Pulse”
ASB2014-6793
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Horiuchi, N.; Oguchi, S.; Nagami, H. et al.
2007
Pesticide-related dermatitis in Saku District, Japan, 1975-2000
Int. J Occup. Environ Health 2007;14:25-34 ASB2014-9570
N
LIT
KIIA 5.10 (OECD)
Hour, B. T.;
Belen, C.; Zar,
T. et al.
2012
Herbicide Roundup intoxication: Successful treatment with continuous renal replacement therapy
The American Journal of Medicine, Vol 125, No 8, August 2012
ASB2014-9571
N
LIT
KIIA 5.10 (OECD)
Jamkhande, P. G.; Chintawar,
K. D.; Chandak,
P. G.
2014
Teratogenicity: A mechanism based short review on common teratogenic agents Asian Pac J Trop Dis 2014; 4(6): 421-432 ASB2014-9573
N
LIT
KIIA 5.10 (OECD)
Jany, K.-D.
2013
Die Langzeitfütterungsstudie von Seralini et al. (2012) - eine kritische Replik
Ernährungs Umschau 8/2013
ASB2014-9580

N
LIT
KIIA 5.10 (OECD)
Jasper, R.; Lo-
catelli, G. O.; Pilati, C. et al.
2012
Evaluation of biochemical, hematological and oxidative parameters in mice exposed to the herbicide Glyphosate-Roundup
Interdiscip Toxicol. 2012; Vol. 5(3): 133–140.
ASB2014-9583
N
LIT
KIIA 5.10 (OECD)
Jayasumana, C.; Gunatilake, S.; Senanayake, P.;
2014
Glyphosate, hard water and nephrotoxic met- als: Are they the culprits behind the epidemic of chronic kidney disease of unknown etiology in Sri Lanka?
Int. J. Environ. Res. Public Health 2014, 11, 2125-2147
ASB2014-3085
N
LIT
KIIA 5.10 (OECD)
John, B.
2014
Letter to the editor
Food and Chemical Toxicology:65 (2014) 391 ASB2014-9584
N
LIT
KIIA 5.10 (OECD)
Kachuri, L.; Demers, P. A.; Blair, A. et al.
2013
Multiple pesticide exposures and the risk of multiple myeloma in Canadian men
Int. J. Cancer: 133, 1846–1858 (2013)
ASB2014-8030
N
LIT
KIIA 5.10 (OECD)
Kamel, F.; Um-
bach, D. M.; Bedlack, R. S. et al.
2012
Pesticide exposure and amyotrophic lateral sclerosis
NeuroToxicology 33 (2012) 457–462 ASB2014-9586
N
LIT
Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Kelce, W.R.,
Lamb, J.C., DeSesso, J.M.
2010
A Critique of prepubertal exposur eto commer- cial formulation of the herbicide glyphosate
N
LIT
GLP: N, published: Y
2309848 / ASB2012-11867
KIIA 5.10 (OECD)
Kier, L. D.; Kirkland, D. J.
2013
Review of genotoxicity studies of Glyphosate and Glyphosate-based formulations
Crit Rev Toxicol, 2013; 43(4): 283–315
ASB2014-9587
N
LIT
KIIA 5.10 (OECD)
Kilinc, N.; Isgör, M. M.; Sengül, B. et al.
2013
Influence of pesticide exposure on carbonic anhydrase II from sheep stomach Toxicology and Industrial Health 1–8
ASB2014-9588
N
LIT
KIIA 5.10 (OECD)
Kim, J.; Ko, W.; Lee, W. J.
2013
Depressive symptoms and severity of acute occupational pesticide poisoning among male farmers
Occup Environ Med 2013;0:1–7
ASB2014-9592

N
LIT
KIIA 5.10 (OECD)
Kim, Y.; Hong,
J.; Gil, H. et al.
2013

Mixtures of Glyphosate and surfactant TN20 accelerate cell death via mitochondrial dam- age-
induced apoptosis and necrosis Toxicology in Vitro 27 (2013) 191–197
ASB2014-9591
N
LIT
KIIA 5.10
Kitazawa, T.
IET historical control data on milignant lym-
(OECD)
phoma incidence in control ICR (Crj:CD-1)
mice HR-001: Carcinogenicity study in mice
(IET 94-0151)
13-C015
ASB2014-9146
KIIA 5.10
Knezevic, V.;
2012
Early continuous dialysis in acute Glyphosate-
N
LIT
(OECD)
Bozic, D.; Bu-
surfactant poisoning
dosan, I. et al.
Srp Arh Celok Lek. 2012 Sep-Oct;140(9-
10):648-652
ASB2014-9593
KIIA 5.10 (OECD)
Koller, V. J.; Fürhacker, M.; Nersesyan, A. et al.
2012
Cytotoxic and DNA-damaging properties of Glyphosate and Roundup in human-derived buccal
epithelial cells
Arch Toxicol (2012) 86:805–813
ASB2014-7618
N
LIT
KIIA 5.10
Koureas, M.;
2014
Increased levels of oxidxative DNA damage in
N
LIT
(OECD)
Tsezou, A.;
pesticide sprayers in Thessaly Region
Tsakalof, A. et

(Greece). Implications of pesticide exposure
al.
Science of the Total Environment 496 (2014)
358–364
ASB2014-9724
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Koutros, S.; Andreotti, G.; Berndt, S. I. et al.
2011
Xenobiotic-metabolizing gene variants, pesti- cide use, and the risk of prostate cancer
Pharmacogenetics and Genomics 2011, Vol 21
No 10
ASB2014-9594
N
LIT
KIIA 5.10 (OECD)
Krüger, M.; Schrödl, W.; Neuhaus, J.;
Shehata, A. A.;
2013
Field investigations of glyphosate in urine of Danish dairy cows
J Environ Anal Toxicol, 3:5
ASB2013-11599
N

KIIA 5.10 (OECD)
Krüger, M.; Shehata, A. A.; Schrödl, W.;
Rodloff, A.;
2013
Glyphosate suppresses the antagonistic effect of Enterococcus spp. on Clostridium botulinum in
Press, Anaerobe 20: 74-78 (2013)
ASB2013-8527
N

KIIA 5.10 (OECD)
Krüger, M.; Schledorn, P.; Schrödl, W.; Hoppe, H. W.;
Lutz, W.;
Shehata, A. A.;

2014
Detection of Glyphosate residues in animals and humans
J Environ Anal Toxicol 2014, 4:2 ASB2014-5024
N
LIT
KIIA 5.10 (OECD)
Krüger, M.;Große- Herrenthey, A.; Schrödl, W.; Gerlach, A.;
Rodloff, A.;
2012
Visceral botulism at dairy farms in Schleswig Holstein, Germany - Prevalence of Clostridium botulinum in feces of cows, in animal feeds, in feces of the farmers, and in house dust Anaerobe 18 (2012) 221-223
ASB2013-13312
N

KIIA 5.10 (OECD)
Krüger, M.; Schrödl, W.; Pedersen, I; Shehata, A. A.
2014
Detection of Glyphosate in malformed piglets J Environ Anal Toxicol 2014, 4:5
ASB2014-8935
N
LIT
KIIA 5.10 (OECD)
Kumar, S.
2011
Occupational, environmental and lifestyle factors associated with spontaneous abortion Reproductive Sciences 18(10) 915-930
ASB2014-9725
N
LIT
KIIA 5.10 (OECD)
Kwiatkowska, M.; Huras, B.; Bukowska, B.
2014
The effect of metabolites and impurities of Glyphosate on human erythrocytes (in vitro) Pesticide Biochemistry and Physiology 109 (2014) 34–43
ASB2014-9603
N
LIT
KIIA 5.10 (OECD)
Kwiatkowska, M.; Nowacka- Krukowska, H.; Bukowska, B.
2014
The effect of Glyphosate, its metabolites and impurities on erythrocyte acetylcholinesterase activity Environ. Toxicol. Pharmacol. 37 (2014) 1101–
1108
ASB2014-8085
N

LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Labite, H.; Cummins, E.
2012
A quantitative approach for ranking human health risks from pesticides in Irish groundwa- ter
Human and Ecological Risk Assessment, 18: 1156– 1185, 2012
ASB2014-9604
N
LIT
KIIA 5.10 (OECD)
Lamb, J. C.; Bofetta, P.; Foster, W. G. et al.
2014
Critical comments on the WHO-UNEP state of the science of endocrine disrupting chemicals – 2012
Regulatory Toxicology and Pharmacology 69 (2014) 22–40
ASB2014-9605
N
LIT
KIIA 5.10 (OECD)
Larsen, K.; Najle, R.; Lifschitz, A.; Virkel, G.
2012
Effects of sub-lethal exposure of rats to the herbicide Glyphosate in drinking water: Gluta- thione transferase enzyme activities, levels of reduced Glutathione and lipid peroxidation in liver, kidneys and small intestine
Environ. Toxicol. Pharmacol. 34(2012)811- 818
ASB2014-6905
N
LIT
KIIA 5.10 (OECD)
Larsen, K.; Najle, R.; Lifschitz, A. et al.
2014
Effects of sublethal exposure to a Glyphosate- based herbicide formulation on metabolic activities of different xenobiotic-metabolizing enzymes in rats
International Journal of Toxicology 2014, Vol. 33(4) 307-318
ASB2014-9606
N
LIT

KIIA 5.10 (OECD)
Lee, B. K.; Lee,
H. K.; Ryu, H.
H. et al.
2012
Continuous renal replacement therapy in a patient with cardiac arrest after Glyphosate- surfactant herbicide poisoning
Hong Kong Journal of Emergency Medicine
ASB2014-9607
N
LIT
KIIA 5.10 (OECD)
LeFew, W. R.;
McConnell, E. R.; Crooks, J. L. et al.
2013
Evaluation of microelectrode array data using Bayesian modeling as an approach to screening and prioritization for neurotoxicity testing NeuroToxicology 36 (2013) 34–41
ASB2014-9608
N
LIT
KIIA 5.10 (OECD)
Lesmes-Fabian, C.; García- Santos, G.; Leuenberger, F. et al.
2012
Dermal exposure assessment of pesticide use: The case of sprayers in potato farms in the Colombian highlands
Science of the Total Environment 430 (2012) 202–208
ASB2014-9726
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Levine, S.
2012
EDSP assays and regulatory safety studies provide a weight of evidence that Glyphosate is not an endocrine disruptor
SETAC North America 33rd Annual Meeting
ASB2014-9609

N
LIT
KIIA 5.10 (OECD)
Lopez, S. L.; Aiassa, D.; Benitez-Leite, S.; Lajmano- vich, R.; Manas, F.; Poletta, G.; Sanchez, N.; Simoniello, M. F.; Carrasco, A.
E.;
2012
Pesticides used in South American GMO- based agriculture: A review of their effects on humans and animal models
Advances in Molecular Toxicology, Volume 6, 41-75
doi.org/10.1016/B978-0-444-59389-4.00002-1 ASB2013-10534
N

KIIA 5.10 (OECD)
Malhotra, R.C., Ghia, D.K.,
Cordato, D.J., Beran, R.G.
2010
Glyphosate-surfactant herbicide-induced re- versible encephalopathy
Case Reports / Journal of Clinical Neurosci- ence 17 (2010) 1472–1473
ASB2012-11890
N
LIT
KIIA 5.10 (OECD)
Manas, F., Peralta, L., Raviolo, J., Ovando, H.G., Weyers, A., Ugnia, L., Cid,
M.G., Larripa,
I., Gorla, N.
2009
Genotoxicity of AMPA, the environmental metabolite of glyphosate, assessed by the Comet assay and cytogenetic tests Ecotoxicology and Environmental Safety 72, 834-837
GLP: N, published: Y 2309906 / ASB2012-11891
N
LIT
KIIA 5.10 (OECD)
Mandel, J.S., Alexander, B.H., Baker,
B.A.,
Acquavella, J.F., Chapman, P., Honeycutt,
R.
2005
Biomonitoring for farm families in the farm family exposure study
Scand J Work Environ Health 31, 98-104 GLP: N, published: Y
2309910 / ASB2012-11893
N
LIT
KIIA 5.10 (OECD)
Mañas, F.; Pe- ralta, L.; Ugnia,
L. et al.

2013
Oxidative stress and comet assay in tissues of mice administered Glyphosate and Ampa in drinking water for 14 days
Journal of Basic & Applied Genetics | 2013 | Vol- ume 24 | Issue 2 | Article 7
ASB2014-6909
KIIA 5.10 (OECD)
Manfo, F. P. T.; Moundipa, P. F.; Déchaud, H. et al.
2010
Effect of agropesticides use on male reproduc- tive function: A study on farmers in Djutitsa (Cameroon)
Environmental Toxicology
ASB2014-9611
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Markard, C.;
2014
Umweltprobenbank des Bundes. Ergebnisse der Vorstudie "HBM von Glyphosat"
II 1.2-93404/21
ASB2014-2057
KIIA 5.10 (OECD)
Marc, J.; Mul- ner-Lorillon, O.; Boulben, S. et al.
2002
Pesticide Roundup provokes cell division dys- function at the level of CDK1/Cyclin B activa- tion
Chemical Research in Toxicology 15:326-331 (2002)
ASB2013-9838 / ASB2009-9012
N

KIIA 5.10 (OECD)
Marc, J., Belle, R., Morales, J., Cormier, P., Mulner- Lorillon, O.
2004
Formulated glyphosate activates the DNA- response checkpoint of the cell cycle leading to the prevention of G2/M transition Toxicological Sciences 82, 436-442
GLP: N, published: Y
2309912 / ASB2012-11894
N
LIT
KIIA 5.10 (OECD)

Marc, J., Mulner- Lorillon, O., Belle, R.
2004
Glyphosate-based pesticides affect cell cycle regulation
Biology of the Cell 96, 245-249 GLP: N, published: Y
2309914 / ASB2009-9014
N
LIT
KIIA 5.10 (OECD)
Marc, J., Mulner- Lorillon, O., Durand, G.,
Belle, R.
2003
Embryonic cell cycle for risk assessment of pesticides at the molecular level Environmental Chemistry Letters 1, 8-12 GLP: N, published: Y
2309916 / ASB2009-9013
N
LIT
KIIA 5.10 (OECD)
Mariager, T. P.; Madsen, P. V.; Ebbehoj, N. E. et al.
2013
Severe adverse effects related to dermal expo- sure to a Glyphosate-surfactant herbicide Clinical Toxicology (2013), 51, 111–113 ASB2014-9612
KIIA 5.10 (OECD)
Martini, C. M.; Gabrielli, M.
2012
A commercial formulation of Glyphosate in- hibits proliferation and differentiation to adi- pocytes and induces apoptosis in 3T3-L1 fi- broblasts
Toxicology in Vitro 26 (2012) 1007–1013
ASB2014-9613
KIIA 5.10 (OECD)
McConnell, E. R.; McClain, M.
A.; Ross, J. et al.
2012
Evaluation of multi-well microelectrode arrays for neurotoxicity screening using a chemical training set
NeuroToxicology 33 (2012) 1048–1057
ASB2014-9615
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5

KIIA 5.10 (OECD)
McQueen, H., Callan, A.C., Hinwood, A.L.
2012
Estimating maternal and prenatal exposure to glyphosate in the community setting.
International Journal of Hygiene and Environmental Health
GLP: N, published: Y
2309926 / ASB2012-11898
N
LIT
KIIA 5.10 (OECD)
Mesnage, R., Clair, E., Gress, S., Then, C.,
Székács, A., Séralini, G.E.
2012
Cytotoxicity on human cells of Cry1Ab and Cry1Ac Bt insecticidal toxins alone or with a glyphosate-based herbicide
Journal of Applied Toxicology:n/a-n/a GLP: N, published: Y
2309930 / ASB2012-11900
N
LIT
KIIA 5.10 (OECD)
Mesnage, R.; Moesch, C.; Le Grand, R. et al.
2012
Glyphosate exposure in a farmer's family Journal of Environmental Protection, 2012, 3, 1001-1003
ASB2014-3846
KIIA 5.10 (OECD)
Mesnage R.; Defarge N.; Spiroux de Vendômois et al.
2014
Major pesticides are more toxic to human cells than their declared active principles
Hindawi Publishing Corporation, BioMed Reserch International Vol 2014
ASB2014-1755
KIIA 5.10 (OECD)
Mesnage, R.; Séralini, G.-E.
2014
The need for a closer look at pesticide toxicity during GMO assessment
Practical Food Safety: Contemporary Issues and Future Directions, First Edition.
Edited by Rajeev Bhat and Vicente M. Gómez- López.
ASB2014-9616
KIIA 5.10 (OECD)
Mink, P. J.;
Mandel, J. S.; Sceurman, B. K. et al.
2012
Epidemiologic studies of Gyphosate and can- cer: A review
Regulatory Toxicology and Pharmacology 63 (2012) 440–452
ASB2014-9617
KIIA 5.10 (OECD)

Modesto, K. A.; Martinez, C. B. R.
2010
Effects of roundup transorb on fish: Hematolo- gy, antioxidant defenses and acetylcholinester- ase activity
Chemosphere 81 (2010) 781–787
ASB2012-811
KIIA 5.10 (OECD)
Moreno, N. C.;
Sofia, S. H.; Martinez, C. B. R.;
2014
Genotoxic effects of the herbicide Round- upTransorb®and its active ingredient glypho- sate onthe fish Prochilodus lineatus
Environ. Toxicol. Pharmacol. 37 (2014) 448–
454
ASB2014-7522
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Mose, T., Kjaerstad, M.B., Mathiesen, L., Nielsen, J.B., Edelfors, Sn., Knudsen L.E.
2008
Placental passage of benzoic acid, caffeine, and glyphosate in an ex vivo human perfusion system
Journal of Toxicology and Environmental Health-Part a-Current Issues 71, 984-991 GLP: N, published: Y
2309958 / ASB2012-11914
N
LIT
KIIA 5.10 (OECD)
Mostafalou, S.; Abdollahi, M.
2013
Pesticides and human chronic diseases: Evi- dences, mechanisms, and perspectives Toxicology and Applied Pharmacology 268 (2013) 157–177
ASB2014-9618
KIIA 5.10 (OECD)
Mulet, J.M.
2011
Letter to the Editor Regarding the Article by Paganelli et al.
Chemical Research in Toxicology 24, 609 GLP: N, published: Y
2309962 / ASB2012-11916

N
MOD
KIIA 5.10 (OECD)
NABU
2011
Glyphosat & Ag rogentechnik - Risiken des Anbaus herbizidresistenter Pflanzen für Mensch und Umwelt
Ausgabe: 04/2011
ASB2012-8016
KIIA 5.10 (OECD)
Narayan, S.; Liew, Z.; Paul,
K. et al.
2013
Household organophosphorus pesticide use and Parkinson's disease
International Journal of Epidemiology 2013;1– 10
ASB2014-9620
KIIA 5.10 (OECD)
Niemann, L.; Sieke, C.; Pfeil, R.; Solecki, R.;
2014
A critical review of glyphosate findings in human urine samples and comparison with the exposure of operators and consumers
in Press J. Verbr. Lebensm., (2015) 10:3-12
ASB2014-11029
KIIA 5.10 (OECD)
Omran, N. E.;
Salama, W. M.;
2013
The endocrine disrupter effect of atrazine and glyphosate on Biomphalaria alexandrina snails
Toxicology and Industrial Health 1–10
ASB2014-7614
KIIA 5.10 (OECD)
Paumgartten, F.J.R.
Cremonese, C. Freiere, C. Meyer, A. Koiman, S.
2012
Pesticide exposure and poor pregnancy outcomes: weaknesses of the evidence // Exposição a agrotóxicos e resultados adversos da gravidez: a fragilidade da evidência
Cad. Saúde Pública, Rio de Janeiro, 28(10):2009-2012, out, 2012
ASB2013-10538
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not

BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Paganelli, A., Gnazzo, V., Acosta, H., Lopez, S.L., Carrasco, A.E.
2010
Glyphosate-Based Herbicides Produce Teratogenic Effects on Vertebrates by Impairing Retinoic Acid Signaling Chem Res Toxicol 23, 1586-1595 GLP: N, published: Y
2309994 / ASB2012-11986, ASB2010-11410
N
LIT
KIIA 5.10 (OECD)
Pahwa, P. P.; Karunanayak,
C. P.; Dosman,
J. A. et al.
2011
Soft-tissue sarcoma and pesticides exposure in men results of a canadian case-control study JOEM _ Volume 53, Number 11, November 2011
ASB2014-9625
KIIA 5.10 (OECD)
Palma, G.
2011
Letter to the Editor Regarding the Article by Paganelli et al.
Chemical Research in Toxicology 24, 775-
776
GLP: N, published: Y 2310000 / ASB2012-11989
N
LIT
KIIA 5.10
(OECD)
PANAP
2009
Glyphosate - Summary
ASB2012-8017
KIIA 5.10 (OECD)
Perry, L.; Ad-
ams, R. D.; Benett, A. R. et al.
2014
National toxicovigilance for pesticide expo- sures resulting in health care contact – An example from the UK's National poisons in- formation service
Clinical Toxicology (2014), 52, 549–555
ASB2014-9626
KIIA 5.10 (OECD)
Quassinti, L., Maccari, E., Murri, O., Bramucci, M.
2009

Effects of paraquat and glyphosate on steroidogenesis in gonads of the frog Rana esculenta in vitro
Pesticide Biochemistry and Physiology 93, 91-95
GLP: N, published: Y
2310038 / ASB2012-12007
N
MOD
KIIA 5.10 (OECD)
Razi, M.; Najaft, G.; Feyzi, S. et al.
2012
Histological and histochemical effects of Glyphosate on testicular tissue and function Iran J Reprod Med Vol. 10. No. 3. pp: 181- 192, May 2012
ASB2014-9390
KIIA 5.10 (OECD)
Relyea, A.R.
2005
The impact of insecticides and herbicides on the biodiversity and productivity of aquatic communities Ecological Applications, 15(2), 2005, pp. 618–
627
ASB2012-204
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Relyea, A.R.
2012
New effects of Roundup on amphibians: Predators reduce herbicide mortality; herbi- cides induce antipredator morphology Ecological Applications, 22(2), 2012, pp. 634–
647
ASB2012-2791
KIIA 5.10 (OECD)
Rhomberg, L. R.; Goodman, J. E.
2012
Low-dose effects and nonmonotonic dose– responses of endocrine disrupting chemicals: Has the case been made?
Regulatory Toxicology and Pharmacology 64 (2012) 130–133
ASB2014-9391
KIIA 5.10 (OECD)
Richard, S., Moslemi, S., Sipahutar, H., Benachour, N., Seralini, G.E.
2005

Differential effects of glyphosate and roundup on human placental cells and aromatase
Environmental Health Perspectives 113, 716-
720
GLP: N, published: Y
2310042 / ASB2009-9024 / TOX2005-1743
N
LIT
KIIA 5.10 (OECD)
Riede, S.; Schafft, H.; Lahrssen- Wiederholt, M.; Breves, G.;
2014
Effects of a glyphosate-based herbicide on in vitro ruminal fermentation and microbial community with special attention to clostridia. Proc. Soc. Nutr. Physiol. ; VOL 23 2014; 23;
34
Gesellschaft fur Ernahrungsphysiologie Conference; 68th, Gesellschaft fur Ernah- rungsphysiologie
ASB2013-14684
KIIA 5.10 (OECD)
Roberts, J. R.;
Karr, C. J.
2012
Pesticide exposure in children PEDIATRICS Volume 130, Number 6, De-
cember 2012
ASB2014-9394
KIIA 5.10 (OECD)
Rodloff, A. C.; Krüger, M.;
2012
Chronic Clostridium botulinum infections in farmers
Anaerobe 18 (2012) 226-228
ASB2013-13311
N

KIIA 5.10 (OECD)
Romano, M., Romano, R., Santos, L., Wisniewski, P., Campos, D., de Souza, P., Viau, P., Bernardi, M., Nunes, M.,
de Oliveira, C.
2012
Glyphosate impairs male offspring reproductive development by disrupting gonadotropin expression
Archives of Toxicology 86, 663-673 GLP: N, published: Y
2310048 / ASB2012-12011
N
LIT
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not

BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Romano, R.M.,
Romano, M.A., Bernardi, M.M., Furtado, P.V., Oliveira, C.A.
2010
Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology Arch Toxicol 84, 309317
GLP: N, published: Y
2310050 / ASB2012-12012
N
LIT
KIIA 5.10 (OECD)
Romano, M. A.; Romano, R. M.
2012
Reply to comment of John M. DeSesso and Amy L. Williams regarding "Glyphosate im- pairs male offspring reproductive development by disrupting gonadotropin expression" by Romano et al. 2012 Arch Toxicol (2012) 86:1795–1797
ASB2014-9396
KIIA 5.10 (OECD)
Rosanoff, A.
2014
Letter to the editor
Food and Chemical Toxicology: 65 (2014) 389 ASB2014-9397
KIIA 5.10 (OECD)
Roberfroid, M.
2014
Letter to the editor
Food and Chemical Toxicology: 65 (2014) 390 ASB2014-9393
KIIA 5.10 (OECD)
Roberfroid, M.
2014
Letter to the editor
Food and Chemical Toxicology: 66 (2014) 385 ASB2014-9392
KIIA 5.10 (OECD)
Roustan, A.; Aye, M.; De
Meo, M.; Di Giorgio, C.;
2014
Genotoxicity of mixtures of glyphosate and atrazine and their environmental transfor- mation products before and after photoactiva- tion
Chemosphere 108 (2014) 93–100
ASB2014-8086
KIIA 5.10 (OECD)
1987

The subacute oral toxicity of the isopropyla- mine salt of glyphosate (MON 0139) in female cattle
82002 ! VT-82-003 TOX9552424
N

KIIA 5.10 (OECD)
1987
The subacute toxicity of Roundup herbicide (MON-2139) in female cattle
82001 ! VT-82-002 ASB2010-8131
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
1987
The acute toxicity of glyphosate in female goats
80006 ! VT-80-450 TOX9552422
N

KIIA 5.10 (OECD)
1987
The acute oral toxicity of the isopropylamine salt of glyphosate (MON 0139) in female goats 80007 !
VT-80-451
TOX9552423
N

KIIA 5.10 (OECD)
Saltmiras, D., Bus, J.S.,
Spanogle, T., Hauswirth, J., Tobia, A., Hill,
S.
2011
Letter to the Editor Regarding the Article by Paganelli et al.
Chemical Research in Toxicology 24, 607-
608
GLP: N, published: Y 2310056 / ASB2012-12015
N
LIT
KIIA 5.10 (OECD)
Saltmiras, D.A., Tobia, A.

2012
No Evlidence of Endocrine Disruption by Glyphosate in Hershberger and Uterotrophic Assays.
Abstract PS 2198
The Toxicologist (supplement to Toxicological Sciences) 126, 474 GLP: N, published: Y
2310058 / ASB2012-12016
N
LIT
KIIA 5.10 (OECD)
Samsel, A.; Seneff, S.
2013
Glyphosate's suppression of Cytochrome P450 enzymes and amino acid biosynthesis by the Gut Microbiome: Pathways to modern diseases Entropy 2013, 15, 1416-1463
ASB2013-8535
KIIA 5.10 (OECD)
Savitz, D.A., Arbuckle, T., Kaczor, D., Curtis, K.M.
1997
Male pesticide exposure and pregnancy outcome
American Journal of Epidemiology 146, 1025-1036
GLP: N, published: Y
2310070 / ASB2012-12022
N
LIT
KIIA 5.10 (OECD)
Schinasi, L.; Leon, M. E.;
2014
Non-Hodgkin lymphoma and occupational exposure to agricultural pesticide chemical groups and active ingredients: A systematic review and meta-analysis
Int. J. Environ. Res. Public Health 2014, 11, 4449-4527
ASB2014-4819
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Seneff, S.; Lau- ritzen, A.; Da- vidson, R. M. et al.
2013
Is encephalopathy a mechanism to renew sul- fate in autism?
Entropy 2013, 15, 372-406 ASB2014-9729
KIIA 5.10 (OECD)
Sengupta, P.; Banerjee, R.

2013
Environmental toxins: Alarming impacts of pesticides on male fertility
Human and Experimental Toxicology 1-23
ASB2014-9730
KIIA 5.10 (OECD)
Séralini, G. E.
2014
Conclusiveness of toxicity data and double standards
Food and Chemical Toxicology 69 (2014)
357–359
ASB2014-9632
KIIA 5.10 (OECD)
Seyboldt, C.; Hoedemaker, M.;
2014
Bedeutung von Clostridium botulinum bei chronischem Krankheitsgeschehen und Teil- projekt: Mikrobiologisches Risikopotenzial von Biogasanlagen unter besonderer Berück- sichtigung von Hühnertrockenkot als Gärsub- strat. Abschlussbericht
Projekt: 2810HS005
Tierärztliche Hochschule Hannover ASB2014-10736
KIIA 5.10 (OECD)
Shehata, A. A.; Schrödl, W.; Aldin, A. A.;
Hafez, H. M.;
Krüger, M.;
2012
The effect of glyphosate on potential patho- gens and beneficial members of poultry micro- biota in vitro
Curr Microbiol, published online 09.12.2012
ASB2012-16301
N

KIIA 5.10 (OECD)
Shehata, A.; Schrödl, W.; Neuhaus, J.; Krüger, M.;
2012
Antagonistic effect of different bacteria on Clostridium botulinum types A, B, D and E in vitro
Downloaded from veterinaryrecord.bmj.com on December 19, 2012
ASB2013-8529
N

KIIA 5.10 (OECD)
Sirinathsinghji, E.;
2014
Sri Lanka Partially Bans Glyphosate for Dead- ly Kidney Disease Epidemic
ISIS Report 09/04/14
ASB2014-10742
KIIA 5.10 (OECD)
Sørensen, M. T.; Damgaard Poulsen, H.; Højberg, O.

2014
Memorandum on "The feeding of genetically modified Glyphosate resistant soy products to livestock"
ASB2014-5761
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Song, H. Y.;
Kim, J. H.;
Seok, S. J.;
Gil, H. W.;
Hong, S, Y.;
2012
In vitro cytotoxic effect of glyphosate mixture containing surfactants
J Korean Med Sci 2012; 27: 711-715 ASB2013-10531
N

KIIA 5.10 (OECD)
Sribanditmong- kol, P.; Jutavijit- tum, P.; Pon- graveevongsa, P.; Wunnapuk, K.; Durongka- dech, P.
2012
Pathological and toxicological findings in Glyphosate-surfactant herbicide fatality Am J Forensic Med Pathol & Volume 33, Number 3, September 2012
ASB2014-9731
KIIA 5.10 (OECD)
Sugeng, A. J.;
Beamer, P. I.; Lutz, E. A. et al.
2013
Hazard-ranking of agricultural pesticides for chronic health effects in Yuma County, Arizo- na
Science of the Total Environment 463-464 (2013) 35–41
ASB2014-9733
KIIA 5.10 (OECD)
Takahashi, H.; Kakinuma, Y.

1992
Ammonium salt of glyphosate (MON 8750) general pharmacology study
IET 90-0149/ET-92-15
TOX9552421
N

KIIA 5.10 (OECD)
Thongprakai- sang, S.; Thi- antanawat, A.; Rangkadilok, N.; Suriyo, T.; Satayavivad, J.;
2013
Glyphosate induces human breast cancer cells growth via estrogen receptors
Food and Chemical Toxicology, 59(2013)129–136
ASB2013-11991
N

KIIA 5.10 (OECD)
Tizhe, E. V.; Ibrahim, N. D. G.; Fatihu, M.
Y. et al.
2013
Haematogical changes induced by subchronic Glyphosate exposure: Ameliorative effect of zinc in Wistar rats
Sokoto Journal of Veterinary Sciences, Vol- ume 11 (Number 2). December, 2013
ASB2014-6963
KIIA 5.10 (OECD)
Tizhe, E. V.; Ibrahim, N. D. G.; Fatihu, M.
Y. et al.
2013
Influence of zinc supplementation on histo- pathological changes in the stomach, liver, kidney, brain, pancreas and spleen during sub- chronic exposure of Wistar rats to Glyphosate Comp Clin Pathol (2013)
ASB2014-6965
KIIA 5.10 (OECD)
Tizhe, E. V.; Ibrahim, N. D. G.; Fatihu, M.
Y. et al.
2013
Serum biochemical assessment of hepatic and renal functions of rats during oral exposure to Glyphosate with zinc
Comp Clin Pathol (2014) 23:1043–1050
ASB2014-6964
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Vandenberg, L. N.; Colborn, T.; Hayer, T. B. et al.
2012

Hormones and endocrine-disrupting chemicals: Low-dose effects and nonmonotonic dose responses
Endocrine Reviews, June 2012, 33(3):378–455
ASB2014-9635
KIIA 5.10 (OECD)
Walsh, L.P., McCormick, C., Martin, C., Stocco, D.M.
2000
Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory (StAR) protein expression
Environmental Health Perspectives 108, 769-
776
GLP: N, published: Y 2310118 / ASB2012-12046
N
LIT
KIIA 5.10 (OECD)
Wigle, D. T.; Arbuckle, T. E.; Turner, M. C.; Bérube, A.; Yang, Q.; Liu,
S.; Krewski, D.
2008
Epidemiologic evidence of relationships be- tween reproductive and child health outcomes and environmental chemical contaminants Journal of Toxicology and Environmental Health, Part B, 11:373–517, 2008
ASB2014-9637
KIIA 5.10 (OECD)
Williams, A.L., Watson, R.E., DeSesso, J.M.
2012
Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis
Journal of Toxicology and Environmental Health, Part B 15, 39-96
GLP: N, published: Y
2310130 / ASB2012-12052
N
LIT
KIIA 5.10 (OECD)
1996
Glyphosate Technical: Pharmacology Screening Study in the Rat
434/021 NUF
GLP: Y, published: N 2310134 / ASB2012-12054
Y
NUF
KIIA 5.10 (OECD)
Wunnapuk, K.; Gobe, G.; Endre
Z. et al.
2013
Use of a glyphosate-based herbicide-induced nephrotoxicity model toinvestigate a panel of kidney injury biomarkers
Toxicology Letters 225 (2014) 192– 200
ASB2014-9638

KIIA 5.10 (OECD)
Xia, S.; Zhao,
Y.-B.; Yang,
M.-Q. et al.
2013
Induction of vitellogenin gene expression in medaka exposed to Glyphosate and potential molecular mechanism
China Environmental Science 2013, 33(9):
1656-1663
ASB2014-9642
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIA 5.10 (OECD)
Yang, W.; Car-
michael, S. L.; Roberts, E. M. et al.
2013
Residential agricultural pesticide exposures and risk of neural tube defects and orofacial clefts among offspring in the San Joaquin Valley of California
American Journal of Epidemiology
ASB2014-9644
KIIA 5.10 (OECD)
Yousef, M.I.,
Salem, M.H.,
Ibrahim, H.Z.,
Helmi, S.,
Seehy, M.A., Bertheussen, K.
1995
Toxic effects of carbofuran and glyphosate on semen characteristics in rabbits
Journal of Environmental Science and Health Part B-Pesticides Food Contaminants and Agricultural Wastes 30, 513-534
GLP: N, published: Y
2310142 / ASB2012-12058
N
LIT
KIIA 5.10 (OECD)
Zhang, Z.-L.;
Yang, Z.-F.
2013

Research Progress on Rep roductive and De- velopmental Toxicity of Glyphosate
J Environ o.:.:up Med. reb.2013 Vol.30 "",,.2
ASB2014-9643
KIIA 5.10 (OECD)
Zhao, W.; Yu,
H.; Zhang, J. et al.
2013
Effects of Glyphosate on apoptosis and expres- sions of androgen-binding protein and vi- mentin mRNA in mouse Sertoli cells
J South Med Univ, 2013, 33(11): 1709-1712
ASB2014-9645
KIIA 5.10 (OECD)
Zouaoui, K.; Dulaurent, S.; Gaulier, J. M. et al.
2012
Determination of Glyphosate and AMPA in blood and urine from humans: About 13 cases of acute intoxication
Forensic Science International (2012)
ASB2014-9734
KIIIA1 7.1.1 (OECD)
1991
Acute Oral Toxicity Study In Rats BD-91-261 MON
GLP: Y, published: N
2315976 / TOX9552438
N
MOD
KIIIA1 7.1.2 (OECD)
1991
Acute Dermal Toxicity Study In Rats BD-91-262 MON
GLP: Y, published: N
2315978 / TOX9552439
N
MOD
KIIIA1 7.1.3 (OECD)
Polveche, V . Rombaut, M. Bonicelli, B.
1999
Measurements of granulometry and distribution of a spray nozzle - Comparison of different glyphosate formulations
106/Pulv MON
GLP: N, published: N 2315980 / ASB2012-12069
N
MOD
KIIIA1 7.1.3 (OECD)
1982
Acute inhalation toxicity of Roundup formula- tion to male and female Sprague-Dawley rats - incl. Amendment No. 1, Date: 15.12.1982
810093 ! ML-81-201

TOX2002-693
N

Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIIA1 7.1.4
1991
Primary dermal irritation study in rabbits
N
MOD
(OECD)
BD-91-263 MON
GLP: Y, published: N
2315983 / TOX9552440
KIIIA1 7.1.5
1991
Primary eye irritation study in rabbits
N
MOD
(OECD)
BD-91-60 MON
GLP: Y, published: N
2315985 / TOX9552441
KIIIA1 7.1.6
1987
Genamin T-200 BM: A closed-patch repeated
N

(OECD)
insult dermal sensitization study in guinea pigs
- (Buehler method)
6816-86 ! BD-86-290
ASB2010-366
KIIIA1 7.1.6
Griffon, B.
2001
Skin sensitization test in guinea pigs (Modified
N

MOD
(OECD)
Buehler test: 9 applications)
CI-2001-153 MON
GLP: Y, published: N
2315987 / TOX2005-1135
KIIIA1 7.4
Martin, S.;
2008
Guidance for exposure and risk evaluation for
N

(OECD)
Westphal, D.;
bystanders and residents exposed to plant pro-
Erdtmann-
tection products during and after application
Vourliotis, M.;
2008/1070089 ! 1661-5751/00/000001-10 !
Dechet, F.;
DOI 10.1007/s00003-008-0361-5
Schulze-
ASB2009-450
Rosario, C.;
Stauber, F.;
Wicke, H.;
Chester, G.
KIIIA1 7.5
Krebs. B.;
2000
Uniform Principles for safeguarding the health
N

(OECD)
Maasfeld, W.;
of workers re-entering crop-growing areas
Schrader, J.;
after application of plant protection product
Wolf, R.; Hoer-
TOX2004-1971
nicke, E.; Nol-
ting, H. G.;
Backhaus, G.
F.; Westphal, D.
KIIIA1 7.6.2
Davies, D.J.

2003
Glyphosate SL (360 g/L) Formulation
Y
SYN
(OECD)
(A12798Q): in vitro absorption through human
epidermis
CTL JV1732 SYN
GLP: Y, published: N
2309514 / ASB2012-11518
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIIA1 7.6.2 (OECD)
Hadfield, N.
2011
Glyphosate 360 IPA Salt (CA2273): In Vitro Absorption through Human Epidermis using [14C]-glyphosate
JV2147-REG NUF
GLP: Y, published: N 2309512 / ASB2012-11517
Y
NUF
KIIIA1 7.6.2 (OECD)
EFSA
2012
Panel on Plant Protection Products and their Residues (PPR). Guidance on Dermal Absorp- tion. EFSA Journal (2012), 10(4), 2665-2695,
ASB2012-6959
N

KIIIA1 7.6.2 (OECD)
Franz, T.J.
1983
Evaluation of the percutaneous absorption of Roundup formulations in man using an in-vitro technique
MON
GLP: N, published: N 2309488 / TOX9552417
N
MON

KIIIA1 7.6.2 (OECD)
OECD
2011
Guidance notes on dermal absorption. Adopted 18 August 2011. Series on Testing and As- sessment, No. 156. ENV/JM/MONO(2011)36, JT03305971. ASB2013-2
http://www.oecd.org/dataoecd/63/12/48532204
.pdf.
N

KIIIA1 7.6.2 (OECD)
Ward, R.J.
2010
360 g/L Glyphosate SL Formulation (MON 52276) - In vitro absorption of glyphosate through human epidermis
JV2084-REG MON
GLP: Y, published: N 2315989 / ASB2012-5383
Y
MOD
KIIIA1 7.6.2 (OECD)
Ward
2010
450 g/L Glyphosate SL Formulation (MON 79545) - In vitro absorption of glyphosate through human epidermis
JV2083-REG MON
GLP: Y, published: N 2309508 / ASB2012-11515
Y
MON
KIIIA1 7.6.2 (OECD)
Ward
2010
480 g/L Glyphosate SL Formulation (MON 79351) - In vitro absorption of glyphosate through human epidermis
JV2085-REG MON
GLP: Y, published: N 2309510 / ASB2012-11516
Y
MON
KIIIA1 7.6.2 (OECD)
Wester, R. C.; Melendres, J.; Sarason, R.; McMaster, J.;
Maibach, H. I.
1991
Glyphosate skin binding, absorption, residual tissue distribution and skin decontamination
TOX9552418
N

Annex point/ reference number
Author(s)

Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIIA1 7.6.2 (OECD)
Wester, R.C.,
Quan, D.,
Maibach, H.I., Wester, R.M.
2005
Percutaneous Absorption of Hazardous Chemicals from Fabric into and Through Human Skin. In Percutaneous Absorption: Drugs, Cosmetics, Mechanisms, Methods Boca Raton, FL. Taylor and Francis Group, LLC. 22, 303-310
GLP: N, published: Y
2310126 / ASB2012-12050
N
LIT
KIIIA1 7.6.3 (OECD)
EPA
2009
Alkyl Amine Polyalkoxylates; Exemption from the requirement of a tolerance
Fed. Reg. 74(2009)115:28616
ASB2009-9022
N

KIIIA1 7.6.3 (OECD)
1973
G-3780: 14-week oral subacute study in dogs 33372 ! MRD-165 ! XX-95-336 ! MON 0818 ASB2009-9026
N

KIIIA1 7.6.3 (OECD)
Hahn, A.; Be- gemann, K.; Burger, R. Hillebrand, J, Meyer, H. Preußner, K.
Gessener, M
2007
Ärztliche Mitteilungen bei Vergiftungen 2007, BfR
ASB2013-4034
N

KIIIA1 7.6.3 (OECD)
Holson, J.F.
1989
A dose range-finding developmental toxicity study of MON 0818 in rats.

WIL Research Labs., Ashland, Ohio, USA, on behalf of Monsanto.
Project no. WIL-50042, Sponsor no. WI-88- 304, unpublished;
ASB2009-9028
N

KIIIA1 7.6.3 (OECD)
1990
A develomental toxicity study of MON 0818 in rats, Final report: WI-89-388
GLP: N, published: Y
2309808 / ASB2009-9029
N
LIT
KIIIA1 7.6.3 (OECD)
Jauhiainen, A.; Räsänen, K.; Sarantila, R.; Nuutinen, J.;
Kangas, J.
1991
Occupational exposure of forest workers to glyphosate during brush saw spraying work American Industrial Hygiene Association Journal, 52(1991)2:61-64
MET9600092
N

KIIIA1 7.6.3 (OECD)
2007
A ReproductionDevelopmental Toxicity Screening Study of MON 0818 in Rats WIL-50282
GLP: Y, published: N
2309858 / ASB2010-365
Y
MOD
Annex point/ reference number
Author(s)
Year
Title
source (where different from company) report no.
GLP or GEP status (where relevant), published or not
BVL registration number
Data protection claimed
Y/N
Owner5
KIIIA1 7.6.3 (OECD)
2008
A Combined 28-Day Repeated Dose Oral (Dietary) Toxicity Study with the Reproduction/Developmental Toxicity Screening Test of MON 8109 and MON 0818 in Rats
WIL-50337 MON
GLP: N, published: N 2309861 / ASB2010-364
N
MOD

KIIIA1 7.6.3 (OECD)
Martinez, T. T.; Long, W. C.; Hiller, R.
1990
Comparison of the toxicology of the herbicide Roundup by oral and pulmonary routes of exposure
Z44833
N

KIIIA1 7.6.3 (OECD)
Stella, J., Ryan, M.
2004
Glyphosate herbicide formulation: a potentially lethal ingestion
Emerg Med Australas 16, 235-239 GLP: N, published: Y
2310102 / ASB2012-12038
N
LIT
KIIIA1 7.6.3 (OECD)
1990
Ninety-day study of MON 0818 administered in feed to albino rats
MSL-10468 ! ML-89-359/EHL 89161
ASB2009-9027
N

KIIIA1 7.6.3 (OECD)
Tai, T.;
Yamashita, M.; Wakimori, H.
1990
Hemodynamic effects of Roundup, glyphosate and surfactant in dogs
The Japanese Journal of Toxicology, 3, 63-68.
TOX9552419
N

KIIIA1 7.6.3 (OECD)
1991
Subchronic toxicity study in rats with Atmer
163. Hazleton Washington, Inc., Vienna, Vir- ginia, USA, on behalf of ICI Americas, sub- mitted by Monsanto.
HWA 564-162
ASB2009-10488
N

KIIIA1 7.9 (OECD)
BfR; Hahn, A.; Begemann, K.; Burger, R. et al.
2007
Ärztliche Mitteilungen bei Vergiftungen ISBN 3-938163-40-2 ! ISSN 1435-4047 ASB2014-9290
Codes of owner
ALK

Alkaloida Europe
ALS
Alschu-Chemie GmbH
CHE
Cheminova A/S
EGT
European Glyphosate Task Force AIR 2
EXC
ExxonMobile Chemical Belgium
ADM
ADAMA Agan Ltd
HAG
Handelsgesellschaft für Baustoffe mbH & Co. KG
HEL
Helm AG
JCC
Jiangsu Changlong
LIT
Published literature
MAH
Makhteshim-AGAN Group
MOD
Monsanto Europe S.A./N.V.
MON
Montedison (Deutschland) Chemie Handels GmbH
NUF
Nufarm GmbH & Co. KG
SYN
Syntana Handelsgesellschaft
Studies marked in yellow are not part of the dossier for renewal.

B.6.13.3 Further toxicological data for other potential co-formulants

The following toxicological evaluation of surfactants was prepared by the German Federal Institute for Risk Assessment in 2010 but was not discussed on EU level so far. Even though it is not essential for current risk assessment of glyphosate, i.e., re- evaluation under Regulation (EC) 1107/2009, it might facilitate product assessment and authorisation on zonal or MS level. Therefore, it has been included here as an appendix. Some of the references mentioned in this evaluation have been also submitted in the GTF dossier on glyphosate but had been provided on request to the RMS before or were found as result of a separate literature search. New references were not included and the text of the 2010 evaluation itself was not amended for other than editorial reasons (mainly correction of typos and citation of references). In rare cases, references to other parts of the current RAR were made. The only exception from this approach was dermal absorption that is now estimated by using the default values of 25 and 75 % as recommended in the EU guidance (EFSA, 2012, ASB2012-6959). Enumeration of tables was kept.

B.6.13.3.1 Toxicological evaluation of the POE- surfactant (CAS no. 61791- 26-2)

Objective of this evaluation:

Many plant protection products (PPP), in particular a number of (but not all) formulations of the widely used herbicidal active ingredient glyphosate, contain a substance with the CAS no. 61791-26-2 as a surfactant. This substance (sum formula, according to U.S.EPA, C48H97NO15) is also known as "POE- and belongs to the heterogeneous chemical group of polyethoxylated alkylamines (POEA). A huge amount of information from different sources (poisoning incidents in humans; in vitro data obtained in different test systems; studies on short-term, reproductive and developmental toxicity of Roundup® formulations or preparations), even though of different quality and reliability, in the whole suggests a higher toxicity of such PPP as compared to the active compound. Glyphosate itself is generally considered to be of low toxicological concern (Williams et al., 2000, ASB2012-12053; EU, 2001, ASB2009-4191; JMPR, 2004, ASB2008-6266). However, in the DAR on glyphosate (DAR, 1998, ASB2010-10302) that was prepared to support first Annex I listing of the active ingredient, it was already mentioned that surfactants could significantly contribute to the toxicity of glyphosate products.
To facilitate a comprehensive risk assessment of products that contain both glyphosate and the POE- and to ensure sufficient protection of operators, bystanders, workers, residents and consumers, it was necessary to establish reference values (ADI, AOEL, ARfD) for the surfactant with CAS no. 61791-26-2 and to estimate its dermal absorption rate. These values may be applied in future for risk assessment purposes in addition to those of glyphosate.
Another goal of this evaluation was to check if there was enough evidence to conclude that higher toxicity of certain PPP was in fact due to the surfactant of if there were indications of a synergistic mode of action with glyphosate.
Conclusion:
A systemic AOEL, an ADI and an ARfD in the same magnitude of 0.1 mg/kg bw(/day) are proposed for the POE with the CAS no. 61791-26-2 that is contained as a surfactant in many glyphosate-based (and some other) PPP. Furthermore, an inhalative AOEL of 0.0166 mg/kg bw/day was established.
For its dermal absorption rate, in the absence of experimental data, the default values of 25% or 75%, depending on concentration, are proposed.
The substance should be classified and labelled for acute oral toxicity (Xn, R22, corresponding to "Acute tox. 4, H302" according to GHS), for skin and severe eye irritation (Xi, R38-41; corresponding C&L according to the GHS would be "Skin irrit. 2, H315" and "Eye dam. 1, H318) and skin sensitisation (Xi, R43, corresponding to "Skin sens. 1, H302317"). Most likely, classification for inhalative toxicity will be also needed.
With regard to nearly all toxicological endpoints under investigation, the POE
was clearly more toxic than glyphosate. Its primary mode of action was a local effect, i.e., strong mucosal irritation. However, occurrence of systemic effects after ingestion or inhalation is also likely. There is some evidence to assume a higher vulnerability of pups.
Eye or mucosal irritation may be produced by both glyphosate and the surfactant and some additivity seems theoretically possible but, with regard to the very different toxic properties of these substances and the apparent differences in the effect doses and severity of findings, higher toxicity of certain PPP as compared to the active ingredient can be allocated to the surfactant alone. The same holds true for poisoning incidents in humans, Therefore, separate reference values of these products are not needed but risk assessment should include a comparison of the expected exposures to the reference values for both glyphosate and POE-
surfactant.
Justification (detailed evaluation):
The evaluation of and proposed reference values for the POE- surfactant with the CAS no. 61791-26-

2 are mainly based on toxicological studies with the surfactant formulations MON 0818 and G-3780 that were submitted by the company Monsanto on request of the BfR after they had been identified in a recent evaluation of the U.S. Environmental Protection Agency (EPA). Both formulations contain this at an amount of about 70 % and are or were part of various glyphosate-based PPP. The data package consists of subchronic oral studies in rats and dogs and of reproductive and developmental toxicity studies in rats. Furthermore, former evaluations by the EU, the EPA and a number of publications were taken into consideration. With regard to the EPA evaluation (EPA, 2009, ASB2009-9022), it must be emphasised that it was more comprehensive because the whole group of polyethoxylated alkyl amines was addressed with special regard to the need of setting tolerances in crops. The EPA conclusions were drawn under the assumption that the alkyl amine content in herbicidal formulations will not exceed 25 % and will not be higher than 10 % in fungicides and insecticides.

In the following, an overview on the toxicological profile of the POE- surfactant with CAS no. 61791-26-2 is given. (For direct comparison to glyphosate, see Table B.6.13-2.) Subsequently, reference values are proposed, the dermal absorption rate is estimated and the possible impact of the surfactant on the toxicity of Roundup® formulations as an example for glyphosate-based herbicides is discussed.

Toxicokinetics and metabolism

No information is available.

Acute toxicity

The acute oral LD50 of the surfactant in rats was 864 mg/kg bw when the value of ca 1200 mg/kg bw for MON 0818 (EPA, 2009, ASB2009-9022) was corrected for the presumed POE- content of 72 %.This result warrants classification and labelling

for acute oral toxicity as “harmful if swallowed” (Xn), i.e., the risk phrase R22, or H302 (Acute toxicity cat. 4, “Warning”) according to GHS would be appropriate.

The acute dermal toxicity was tested in rabbits. The LD50 was above the highest dose of 907 mg/kg bw when corrected for content. Although the amount applied was below the required limit dose of 2000 mg/kg bw, classification and labelling is not considered necessary because no mortality occurred and no clinical signs were reported up to this dose.

Unfortunately, acute inhalation data for the POE- under consideration or a surfactant formulation such as MON 0818 is not available. This must be in fact regarded as a data gap because there is evidence coming from an acute inhalation study with a Roundup formulation (1982, TOX2002-693) that inhalative toxicity was higher than with glyphosate alone for which an LC50 > 5 mg/L air was determined (see Volume 3, B.6.2.3 of this RAR). In this acute study, an LC50 of 3.18 mg/L air for Roundup was obtained resulting in the classification and labelling of the product with Xn, R20 (H332 according to GHS). It is quite likely that this apparent difference was due to the surfactant. MON 0818 was contained in this product at an amount of approximately 18 % w/v, i.e., the POE- content was ca 14 % w/v. When the strong irritating properties of the POE- surfactant (see below) are taken into consideration, one would expect similar effects in the respiratory tract. A higher inhalative toxicity than for glyphosate was also substantiated by a subacute inhalation study (1983, TOX2002-694) with Roundup and by observations in humans after occupational exposure without protective measures ranging from weak symptoms such as a headache to well-documented systemic poisoning with persistent morphological findings (1991, MET9600092; 2007, ASB2013- 4034).

A high acute inhalative toxicity was experimentally confirmed for other polyethoxylated alkyl amine substances. Armoblen 557 (CAS no. 68219-26-3) had an LC50 of 0.66 mg/L that was established in a study with 4-hour exposure. For Ethomeen C/12 (CAS No. 61791-31-9), an LC50 of 0.98 mg/L was

calculated on the basis of a one-hour trial (EPA, 2009, ASB2009- 9022).
However, acute inhalation data for different products that were submitted to support registration in Germany were partly contradictory although they contain similar amounts of glyphosate (at least 360 g/L) and of the surfactant. Apparently, there is no clear correlation of inhalative toxicity with the surfactant content. In fact, there are PPP with the same surfactant at nearly the same concentration for which classification and labelling for acute inhalation toxicity is not needed. In sum, the available information is not sufficient to conclude on the appropriate classification and labelling of the POE-surfactant itself for acute inhalation toxicity although some classification will be probably needed.
If experimental data for a particular formulation containing this surfactant is not available, according to Directive 1999/45/EEC or the CLP regulation, classification and labelling of the PPP for precautionary reasons might be a reasonable option.
The POE- surfactant was found irritating to the skin (Xi, R38) and strongly irritating to the eyes. The U.S. EPA (EPA, 2009, ASB2009-9022) labelled the substance for eye effects even as “corrosive” (C) but, according to the EU scheme, R41 seems to be more appropriate. Correct classification according to GHS rules difficult because the studies themselves were not submitted and the assessment is based on the EPA evaluation. However, if Annex VII of the CLP regulation (Translation table from classification under Directive 67/548/EEC to classification and assignment of hazard statements under this regulation) is
applied, Cat.2/H315 for skin irritation and Cat.1/H318 (for eye irritation) would be most appropriate. Eye irritation is often considered to provide evidence also of mucosal irritation.
(1987, TOX9552430) studied the irritating effect of the glyphosate isopropylammonium salt, MON 0818 and a Roundup formulation (containing 41% w/v of the IPA salt and 15% of MON 0818) on stomach and small intestine mucosa in dogs. Irritation was more severe with the Roundup formulation than with either the IPA salt or the surfactant alone. The intestine appeared to be more affected than the stomach. The severity of the damage was equivalent to that caused be 0.25 N hydrochloric acid.
Concerning skin sensitisation, the available data is scarce. However, in its 2009 evaluation,
U.S. EPA concluded that the POE- was sensitising because of a positive Buehler test using three applications (EPA, 2009, ASB2009-9022). Therefore, classification and labelling (Xi, R43 or, according to GHS, Skin sensitisation, Cat.1/H317) is proposed.
For setting of reference values, the acute toxicity data is, of course, not appropriate. However, acute oral toxicity supports a need to establish an ARfD and the evidence of inhalative toxicity suggests that an inhalative AOEL should be established.
Short-term toxicity (subacute and subchronic studies)
Rat, oral
A 90-day feeding study was performed on SD rats (1990, ASB2009-9027). Because current standards were basically met, the study may be considered as valid and reliable. Test substance was the surfactant formulation MON 0818. As stated in the study report, this test item contained 71.9 % of “polyoxyethylen (15) tallow amine” (POEA). Groups of 10 male and 10 female rats were fed MON 0818 at nominal concentrations of 0, 500, 1500, or 4500 ppm. In most groups, however, these nominal concentrations were not achieved. The actual concentrations were in the range from 80 to 90 % of the nominal values.
The highest dose level was clearly toxic. This became apparent mainly by a reduced body weight gain in both sexes that achieved statistical significance and resulted in a lower mean body weight over the whole course of the study. Food consumption was diminished and clinical signs (piloerection, soft faeces) occurred. Furthermore, blood glucose and urea levels were decreased.

Some deviations in organ weights are most probably related to the lower body weight at termination and there were no gross pathological findings at necropsy that could be attributed to treatment. In contrast, histological lesions of the intestinal mucosa were certainly treatment-related. These findings comprised hyperplasia and cell vacuolation in the Lamina propria and all animals receiving the high dose were affected.
At the mid dose level of 1500 ppm, 4 out of ten male rats and 5/10 females exhibited the same histopathological changes as described above. In males, there was in addition a statistically significant decrease in food consumption and body weight gain over the first 9 days of treatment.
Feeding of MON 0818 at the low dose level of 500 ppm did not cause any remarkable differences from the control groups and, thus, this dose can be regarded as the NOAEL.
For the nominal dietary concentration of 500 ppm, a mean daily intake of 33.0 mg/kg bw was calculated for the male rats and of 39.9 mg/kg bw for the females. However, to establish the true NOAEL for the POE- these values must be corrected for the actually
achieved concentration of 84% of nominal in both the male and female groups and then for the 71.9 % content of the surfactant in MON 0818. These corrections result in intake calculations of 19.9 mg/kg bw/day for males and 24.1 mg/kg bw/day for females. It seems reasonable to round them to 20 mg/kg bw/day that is considered the NOAEL for the surfactant in this study. For the LOAEL that was established at a three times higher dietary level, hence, an achieved intake of 60 mg/kg bw/day is assumed.
The outcome of this study 90-day was at least partly in line with an additional one-month feeding study with ”POEA surfactant” on Sprague-Dawley rats of which the original report was not made available to the BfR. In this experiment, the NOAEL was claimed to be 800 ppm (ca 40 mg/kg bw/day). At the next higher dose level of 2000 ppm, body weight gain in male rats was reduced. At the high dose level of 5000 ppm, lower body weight gain and irritation and inflammation of the colon mucosa were observed in both sexes (
1989, cited in Williams et al., 2000, ASB2012-12053).
The toxicological findings in these feeding studies in rats point to local irritation in the intestines as the primary mode of action. Because of the known irritating properties of the POE- it was first assumed that this local effect was behind the higher toxicity of PPP containing glyphosate and this surfactant as compared to the active ingredient. However, the subchronic study in dogs, the reproduction and developmental studies in rats, comparative mechanistic data and human experience suggest that systemic effects will be most likely due to a second mechanism of POE-tallowamine toxicity.
Dog, oral
Groups of four male and four female Beagle dogs received three times a day a capsule containing the formulation G-3780 for a total of 14 weeks (1973, ASB2009-9026). According to a claim made by Monsanto, G-3780 was very similar to the formulation MON 0818. However, in the study report itself, no information on the composition of the test substance and the content of the POE- with the CAS no. 61791-26-2 is given. Therefore, it is assumed that the POE-content, as in MON 0818, was about 72% suggesting a need for correction of the NOAEL/LOAEL.
The total daily doses of G-3780 were 0, 30 (i.e., 3 x 10), 60 (3 x 20), or 90 (3 x 30) mg/kg bw. However, because of a rather tricky dosing scheme, these dose levels were achieved not before the third or fourth week of treatment. This is one of the reasons for a compromised reliability of this study. Transiently, high dose animals even received 120 (3 x 40) mg/kg bw/day but, because of enhanced emesis, diarrhoea and subsequent emaciation, the dose was lowered again after 10 days. It seems that the MTD was exceeded when more than 90 mg/kg bw/day was administered.

At the two upper dose levels, dogs did not gain and sometimes even lost weight. At termination, mean body weight were by more than 10% lower than in the control groups. In addition, vomiting and diarrhoea were more frequently observed than in the controls. Clinical chemistry revealed lower blood calcium and total protein concentrations.
There were no remarkable findings at necropsy and histopathological examination. In particular, local effects on intestinal mucosa, as in the rat study, were not reported. The clinical signs might suggest gastrointestinal irritation but, on the other hand, are common and unspecific signs of general toxicity in dogs.
The lowest dose level of 30 mg/kg bw/day was considered the NOAEL. After correction for presumed POE- content, a numeric value of 21 mg/kg bw/day would result that is in the same magnitude as the NOAEL in the subchronic rat study. The LOAEL was 42 mg/kg bw/day.
Despite a wide range of parameters that were investigated, the study design, examination methods and the quality of reporting do not comply with modern standards. Therefore, and because of the uncertainties with regard to the actually applied doses, the study can be considered at best supplementary. However, it can be accepted that the requirement of testing for short-term toxicity in a second species has been fulfilled. The conclusion can be drawn that the sensitivity of rats and dogs in terms of the NOAELs/LOAELs is not that different. In contrast to the studies in rats, however, the findings in dogs suggest rather a systemic effect than local irritation.
Rat, inhalative
In a four-week study on SD rats, 15 male and 15 female animals per group were exposed (whole-body) for 6 hours per day over 5 days per week (total number of treatments 22) to nominal concentrations of 0 (control), 0.37, 0.75, or 2.17 mg/L air of the Roundup formulation MON 2139 (1983, TOX2002-694). However, the analytically determined air concentrations were 0.05 mg/L (low dose), 0.16 mg/L (mid dose), and 0.36 mg/L (high dose). There were no unscheduled deaths in this study. Clinical signs did not occur, and there were no gross pathological changes at necropsy. Body weight and organ weights were not altered but, surprisingly, the lungs had not been weighed.
The only findings that may be attributed to treatment were significantly higher total protein, albumin and globulin serum concentrations in females at the two upper dose levels. Furthermore, the incidence of certain histopathological findings in the lungs (perivascular lymphoid infiltrates or aggregates, interstitial infiltration or pneumonia), in the trachea (mononuclear infiltration and chronic inflammation) and the nasal turbinates (inflammation) was increased in high dose females. Unfortunately, histopathology was performed on control and high dose animals only.
Even though the study author did not mention these findings as adverse or treatment-related, they might be a reaction to Roundup application. Accordingly, the lowest concentration of 0.05 mg/L air is considered the NOAEC.
Under the assumption that the effects were in fact entirely due to the POE- an inhalative NOAEL (expressed in mg/kg bw) for this surfactant may be calculated. Since 180 g/L MON 0818 were contained in the test item, a NOAEC of 0.009 mg/L air for this surfactant formulation can be assumed. Taking into consideration the content in MON 0818, a respiratory rate of 45 L air/kg bw per hour for the rat and an exposure time of 6 hours per day, the calculation would result in a inhalative NOAEL of ca 1.66 mg/kg bw/day.
Mutagenicity
Possible mutagenicity of POE- (s) was addressed in the past by different regulatory bodies as well as in a review article (Germany, 2000, ASB2013-2748; Williams et al., 2000, ASB2012-12053; EPA, 2009, ASB2009-9022). The overall conclusion was that these substances were not mutagenic but might have caused positive findings in a number of test systems due to cytotoxicity when PPP such as

various Roundup formulations were tested. Unfortunately, there are relatively few experiments with formulations in standard test systems available because usually only the active compounds are subject to rigorous testing in a battery of regulatory studies. At least, the Roundup formulation MON 2139 containing the POE- with the CAS no. 61791-26-2 as part of the surfactant formulation MON 0818 proved negative in an Ames test in concentrations of up to 500 µg/plate without and of up to 1500 µg/plate in the presence of metabolic activation by S9 mix (1992, TOX1999-239). In a mouse bone marrow micronucleus assay (1992, TOX1999- 242), no evidence of a clastogenic potential was found up to the highest tested dose of 555
mg/kg bw/day that was already clearly toxic to mice after single intraperitoneal administration. Roundup proved cytotoxic in the bone marrow.
MON 0818 itself was tested in the Ames test by Stegemann and Li (1990, TOX1999-241) and proved negative. However, due to severe cytotoxicity, it could be tested only at rather low concentrations (up to 300 µg/plate) in the various Salmonella typhimurium strains. It proved also negative in a micronucleus assay in mouse bone marrow (Stegemann and Kier, 1998, TOX1999-240) at the dose level of 100 mg/kg bw that was administered by intraperitoneal injection but this latter study was considered supplementary only because no evidence of systemic or bone marrow toxicity was obtained.
There is evidence coming from several studies using the Comet assay or other less validated systems, that products which contain cytotoxic (or other) surfactants might produce, mostly in very high concentrations, DNA damage either by direct contact or by enhanced formation of DNA reactive oxygen species (e.g., 1997, Z101728; 1998, TOX1999-318; 2008, ASB2012-11586). A part of these investigations was made in non-mammalian systems that are more relevant to ecotoxicology. Positive findings are nearly always linked to toxicity as recently confirmed by Heydens et al. (2008, ASB2012-11845). Unfortunately, no UDS assay in, e.g., rat hepatocytes is available that would be most suitable to investigate a potential for DNA damage also at concentrations below overt toxicity. However, for the time being, weight of evidence suggests that the relevance of possible effects on the DNA to humans under practical exposure conditions is very low.
Chronic toxicity and carcinogenicity
No such data is available. Currently, for co-formulants like surfactants, long-term studies are not required and, accordingly, usually not performed. However, based on the toxicological profile of POE- it is not expected that chronic toxicity would be much different from the effects that were noted in the subchronic studies. With regard to carcinogenicity, it should be taken into consideration that, in spite of long-lasting experience and extensive use, there is no convincinig epidemiological evidence in people who had been in frequent occupational contact with glyphosate-based plant protection products (see Vo.lume 3, B.6.5, and Volume 1, 2.6.5 of this RAR). The EPA concluded that the whole group of polyethoxylated alkyl amines was not of concern for carcinogenicity (EPA, 2009, ASB2009-9022).
Reproduction toxicity
Two GLP-compliant studies were performed in rats to investigate possible effects of the surfactant formulation MON 0818 on reproduction (2007, ASB2010-365;
2008, ASB2010-364). Furthermore, a rather new published study on reproductive toxicity of a commercial Roundup® formulation (2007, ASB2012-2721) is available. Unfortunately, the design of all three studies was not in line with usual OECD Guideline requirements. The reproductive/developmental screening studies according OCED testing guidelines 421/422 are less sensitive than the full scale study designs according to testing guidelines 414/416.
MON 0818

In a two-generation study (according to OECD 421), Sprague-Dawley rats (20 per sex and dose group) received the test formulation in the F0 generation at dose levels of 0, 100, 300, or 1000 ppm via their diet (2007, ASB2010-365). A broad range of endpoints was examined including hormone measurements, sperm parameters and extensive histopathology. There was no evidence of parental toxicity but the highest dose tested was lower than the LOAEL in the 90-day rat study. In contrast, administration of the high dose resulted in a reduced implantation rate (with 5 of 15 pregnant dams being affected), lower litter size and also an increase in perinatal mortality. Total loss of two litters immediately after birth or at the beginning of the lactation period was noted. However, further development of the surviving pups was not altered.
To produce the F2 generation, three male and female pups from each litter were selected and reared. Between days 21 and 70 after birth, they received the test item at a dietary concentration that was adjusted to the respective actual body weight. The mean daily doses during this period were 0, 7, 21 or 61 mg/kg bw in male rats and 0, 6, 28 or 72 mg/kg bw in females. Two male and female pups per litter were selected for further breeding but only from the control and high dose groups. From the beginning of this third mating period, the selected high dose F1 animals received again 1000 ppm of MON 0818 in their diet. In the F2 generation, no parental toxicity and no impact of this high dose on reproduction were observed.
Histopathological examination of different parts of the intestinal tract (jeunum, ileum, caecum, colon and rectum) did not reveal indications for mucosal irritation in F0 and F1 animals.
Based on the findings in the F1 generation (i.e., lower implantation rate, litter size and pup survival) 300 ppm was considered the NOAEL for reproduction and offspring effects. For the F0 adults, a mean daily intake of 16.6 (males) or 19.5 mg/kg bw/day of MON 0818 was calculated at this dose level that must be corrected for the surfactant content. A NOAEL of 12 (males) to 14 (females) mg/kg bw/day for the surfactant would result (EPA, 2009). For parental toxicity, the highest dose of 1000 ppm was the NOAEL. The corrected mean daily surfactant intake was about 38 mg/kg bw (lowest value as calculated for F1 males).
In a second study (2008, ASB2010-364); according to OECD 422), groups of 12 male and female rats of the same strain [Crl:CD(SD)] were fed 1000 ppm of MON 0818 for a total period of 69 – 72 days. This dose was equivalent to a mean daily intake of 66 mg/kg bw by the male animals and 95 mg/kg bw/day by females over the whole course of the study. During the individual study periods (pre-mating, pregnancy, lactation), the intake in females varied between 74 and 126 mg/kg bw/day. A control groups of equal size received untreated diet. From administration day 14 onwards, the animals were mated.
There were two unscheduled deaths among the treated dams. One female rat died showing clinical signs of dystocia. Another dam was did not give birth and was killed 30 days after mating in poor clinical state. At necropsy, uterine rupture was established and two implantation sites were recorded of which one was a dead fetus and the other an early resorption. In contrast to the assessment by the study author, it cannot be excluded that these deaths were treatment-related. However, there were no adverse effects in the remaining 10 dams or in any of the 12 males in the treatment group. Furthermore, reproduction was not affected in the remaining dams. A higher incidence of chronic-progressive nephropathy in treated males as compared to the control group (6/12 vs. 3/12) was not allocated to substance administration because it was only unilateral. Thus, a NOAEL for parental and reproduction
toxicity was not established. Offspring effects could not be fully evaluated because all pups were killed on day 4 post partum already. However, if effects on litter size or perinatal mortality as in the first study would have occurred, they might have been noted.

Roundup® herbicide
In a one-generation study, pregnant Wistar rats (15 per group) were administered a Roundup® herbicide that is commercially available in Brazil (containing 36% glyphosate and 18% of the POE-surfactant) at dose levels of 50, 150, or 450 mg/kg bw/day by oral gavage from day 1 of presumed gestation through the end of lactation (postnatal day 21). The calculated daily intake of the surfactant was 9, 27, or 81 mg/kg bw. A control group received only the vehicle, i.e., distilled water (2007, ASB2012-2721).
Evaluation of toxicity in the parental generation was based on observations for mortality and clinical signs, body weight measurements and determination of selected organ weights at termination. Reproductive toxicity was assessed by determining litter size, number of living and dead pups, viability and sex ratio. Possible effects on offspring development, in particular with regard to sexual maturation, were studied in one male pup and one female pup per litter which were killed at an age of 65 days and in one more pup per sex and litter which were sacrificed on postnatal day 140. Organ weights were also determined in these animals.
Up to the highest dose level, there was no evidence of maternal toxicity. Likewise, litter size, mean number of live and dead pups and sex ratio among the pups were not affected at any dose level. Thus, the NOAEL for parental and reproductive toxicity was 450 mg Roundup/kg bw/day, corresponding to a dose of 81 mg/kg bw/day for the surfactant.
However, sexual development in offspring was affected. In female pups, delayed vaginal opening suggested a slower sexual development in all treated groups. Since this finding was associated with a markedly lower body weight in the low dose group, a possible treatment- related effect was assumed only for the two upper dose levels. In male pups, functional disturbances were confined to the highest dose level of 450 mg Roundup/kg bw/day and were partly contradictory. On one hand, preputial separation was noted to occur a bit earlier than in the control group. On the other hand, at an age of 65 days, testosterone serum concentration was significantly lower (but not at 140 days) and, when measured at 140 days, daily sperm production and total number of sperm in the epididymis tail were diminished suggesting rather a delay in sexual development. Interpretation of this data is difficult since a similar decrease in both parameters was observed at the low dose level, too, whereas the mean values in the mid dose group were similar to the controls. At all three dose levels, histopathological examination revealed degenerative changes in the testes with the absence of tubular lumen being the most outstanding finding. However, all these observations were flawed by a low number of animals on which the findings are based, e.g., histopathology of the testes was confined to only five male pups per dose level.
Thus, a NOAEL for offspring effects cannot be established.
A direct comparison of the results by (2007, ASB2012-2721) with the two studies of (2007, ASB2010-365 and 2008, ASB2010-364) is not possible because the test material was different and the same holds true for the study design and the range of parameters under investigation. Unfortunately, it is also not feasible to compare these studies and their results with the Guideline-compliant reproduction studies with glyphosate. Thus, no definite conclusion can be drawn if the effects of treatment with Roundup can be allocated to the surfactant. Nonetheless, the published findings suggest that offspring development was in fact a particularly sensitive target of Roundup and the POE- The findings in young male rats might indicate impairment of spermatogenesis.
Developmental toxicity
The surfactant formulation MON 0818 and a Roundup® herbicide that is commercially available in Brazil were tested for developmental toxicity and teratogenicity in rats. A study in a second species was not submitted. However, it is unclear whether the data requirements for pesticides or drugs can

be applied to co-formulants. Furthermore, the rabbit as the usual second species is known to be very sensitive to gut irritation. Thus, severe maternal toxicity at low doses due to the well known irritation potential of the surfactant must be expected in a rabbit study that might prevent meaningful evaluation of fetal effects at sufficiently high dose levels.

MON 0818

A preliminary (range-finding) and a main study were performed under GLP conditions in which MON 0818 was administered to pregnant rats (Charles River Crl:CD Br). Although the studies themselves can be considered acceptable, it is not clear how much POE-
was contained because its amount even in different batches of MON 0818 can vary. However, based on the information given in the study report of (1990, ASB2009-9027) and in line with the EPA evaluation (EPA, 2009, ASB2009-9022), it is assumed that the amount of this surfactant in the tested formulation had accounted for 71.9 %, too. The NOAELs/LOAELs will be corrected accordingly.

Preliminary study

MON 0818 was administered by oral gavage to groups of 8 pregnant rats from day 6 through day 15 post mating at dose levels of 0, 25, 50, 100, 200, or 400 mg/kg bw/day. On pregnancy day 20, the dams were killed and fetuses developed by caesarian section. The uteri were dissected and examined. Foetuses were counted and inspected for external anomalies.

Mortality, clinical signs and body weight losses were clear indications of severe maternal toxicity at a dose of 100 mg/kg bw/day and above. The NOAEL for maternal toxicity was 50 mg MON 0818/kg bw/day, corresponding to 36 mg/kg bw/day for the POE-

Obvious developmental toxicity, in contrast, was confined to the highest dose level of 400 mg/kg bw/day at which post implantation losses were increased. However, due to mortality among the dams, only 3 litters were available at this dose for evaluation preventing meaningful evaluation of teratogenicity (1989, ASB2009-9028). Based on these results, the dose selection for the subsequent main study appears acceptable.

Main study

25 pregnant rats per groups received MON 0818 from days 6 through 15 post mating by oral gavage at dose levels of 0, 15, 100 and 300 mg/kg bw/day. Following sacrifice of the dams and caesarean section, uteri were inspected and fetuses examined for external, visceral and skeletal anomalies by appropriate methods (1990, ASB2009-9029).

Severe maternal toxicity became apparent at the top dose level by the death of 6 dams between treatment days 8 and 13, clinical signs, initial body weight losses and a diminished body weight gain thereafter. Furthermore, food consumption was decreased. After cessation of treatment, body weight gain and food consumption showed a trend towards normalisation from study day 16 onwards. Soft and mucous faeces might suggest mucosal damage. A lower mean liver weight was probably a reflection of the lower body weight.

At the mid dose level of 100 mg/kg bw/day, mean food consumption was significantly reduced during the first three days of treatment and five out of 25 dams lost weight although the mean body weight and body weight gain were not different from the control group. Clinical signs were only rarely seen. Based on these minor findings, and in accordance to the study author, this dose is considered the LOAEL. For this assessment, it was also taken into
account that clear maternal toxicity occurred at the same dose level in the range-finding study. After adjustment for a content of 71.9 %, the LOAEL for the surfactant was calculated to be 72 mg/kg bw/day. The low dose of 15 mg MON 0818/kg bw/day was the NOAEL in this study corresponding to 10.8 mg /kg bw/day.

(In the 2009 EPA evaluation (ASB2009-9022), the findings at 100 mg MON 0818/kg bw/day were

disregarded and, accordingly, 72 mg/kg bw/day was considered the NOAEL for the
This dose was also used as starting point to derive the ARfD.)
In the study report (1990, ASB2009-9029) as well as in the EPA evaluation (EPA, 2009, ASB2009-9022), it is stated that no developmental toxicity was observed up to the highest dose level of 300 mg/kg bw/day. However, the total number of visceral and skeletal anomalies at this dose was increased. Due to maternal mortality, only 15 litters were available for evaluation but the incidence of exencephalia and stenosis of the right carotid were already above the historical control range. It may be expected that, with a higher number of litters, the frequency of these anomalies would be even higher. Furthermore, malformations such as Situs inversus and absent bladder were noted only in this high dose group for which no historical control data was provided. Therefore, the NOAEL for developmental toxicity of MON 0818 was the mid dose level of 100 mg/kg bw/day corresponding to 72 mg/kg bw/day for the The highest dose of 300 mg/kg bw/day (216 mg/kg bw/day) was considered the
LOAEL for this endpoint.
Roundup® herbicide
Pregnant Wistar rats (14 - 16 per group) were administered a Roundup® formulation that is commercially distributed in Brazil and was reported to contain 36% glyphosate and 18% of the POE-surfactant (2003, ASB2012-11600). The test material was applied in distilled water once a day by oral gavage from day 6 through 15 of gestation at dose levels of 500, 750, or 1000 mg/kg bw whereas the control group received only the vehicle. The respective doses of the accounted for approximately 91, 135, and 180 mg/kg bw/day. On gestation day 21, dams were anaesthetised and the uteri with contents were removed by caesarean section and weighed. Afterwards, the dams were sacrificed, necropsied and organ weights of heart, lung, liver, kidneys, and spleen determined. Uteri were inspected for live and dead fetuses and number of implantation sites. The fetuses were weighed, sexed and examined for external and skeletal but not for visceral anomalies.
Maternal toxicity was severe with 50% of the dams (7 out of 14 in that group) dying between gestation days 7 and 14 but was confined to the highest dose level of 1000 mg Roundup/kg bw/day. In the surviving dams, no remarkable findings were reported and relative organ weights did not show statistically significant differences although relative liver weight at the top dose level tended to be increased.
Developmental toxicity was observed in all dose groups and was characterised by a developmental delay of the skeleton and an increase in certain skeletal anomalies. Whereas only 15.4% of the fetuses in the control group exhibited skeletal findings of any kind, the total frequency was higher in a dose-related manner in the treated groups (33.1%, 42.0%, and 57.3%). Incomplete ossification of the skull was noted in all three dose groups and was dose- related as well as a reduced number of caudal vertebrae at the two upper dose levels. In contrast, for other findings, a clear relation to dose was absent. Thus, the incidence of the malformation ”fused zygomatic bone” was higher only at the lowest dose level and, accordingly, cannot be attributed to treatment.
The NOAEL for maternal toxicity of the POE- in a Roundup formulation in this study was 135 mg/kg bw/day. In contrast, a NOAEL for fetotoxicity/teratogenicity could not be established.
Similar maternal or developmental effects in rats were not reported for the active ingredient glyphosate (see Volume 3, B.6.6 and Volume, 2.6.6 of this RAR). It may be concluded that the higher maternal and developmental toxicity of Roundup® was due to co-formulants in the herbicidal formulation. It is quite likely that they result from the rather high amount of the POE- surfactant in the product but a definitive proof is lacking. It must be emphasised that the selected dose levels in the more recent Brazilian study were clearly above the LOAELs in the 90-day study (1990, ASB2009-

9027) and the developmental studies (1989, ASB2009-9028; 1990, ASB2009-9029) with the surfactant in the formulation MON 0818. However, these previous studies were apparently not known to the authors because the reports were unpublished. When the different studies are compared, it is surprising that maternal toxicity in the study by (2003, ASB2012-11600) occurred only at the highest dose level. It may be doubted if the investigations in the dams were sufficiently extensive to reveal adverse findings at the lower dose levels. In contrast, developmental (skeletal) effects were obviously more pronounced as in the more comprehensive study by (1990, ASB2009-9029).

Neurotoxicity

No data available. Based on chemical structure, a specific neurotoxic potential is not expected. The available studies do not suggest neurotoxicity of the surfactant.

Mechanistic studies

A systemic effect of a surfactant was demonstrated by . (1990, TOX9552419) who studied the haemodynamic effects of continuous i.v. application of either glyphosate IPA salt, the formulation Roundup or the surfactant in dogs. The impact on cardiovascular functions was studied in groups of five anesthetised and artificially ventilated female Beagle dogs. Duration of i.v. exposure was 60 minutes. A total of 8.2 g glyphosate (IPA salt administration) or 2.8 g glyphosate (Roundup) was injected. These amounts would correspond to doses of about 550 - 820 mg/kg bw or 180 - 280 mg/kg bw, respectively, since the body weight of the dogs was 10 to 15 kg.

The surfactant alone and Roundup significantly reduced the blood pressure, cardiac output and left ventricular stroke work index suggesting a marked effect on circulation. It could be shown that the cardiac depression observed with Roundup was likely due to the surfactant since, in contrast, arterial blood pressure was even increased when glyphosate isopropylamine salt had been injected. Similarly, the IPA salt did not cause changes in heart rate or cardiac output. A decrease in blood pH observed in this group could be either due to a direct effect of administration or to metabolic acidosis. In any case, it was not strong enough to affect the circulatory system.

(1990, Z44833) reported a high toxicity of a following intratracheal application to dogs, due to severe lung irritation. A similar effect after oral administration was assumed to result from aspiration because vomiting occurred.

Human data (poisoning incidents)

Despite the low acute toxicity of glyphosate technical, a number of poisoning incidents in humans sometimes even resulting in death were reported in particular from Asian countries (DAR, 1998, ASB2010-10302). Severe intoxication was mainly characterized by a decrease in blood pressure and further cardiovascular symptoms followed by pulmonary dysfunction and renal failure and by signs of irritation in the gastointestinal tract. Pathophysiology of poisoning by the oral route is assumed to include irritation or corrosion of the intestinal mucosa as a first step resulting in electrolyte imbalances, shock and disturbances in the cardiovascular system. The respiratory signs, as well as renal symptoms, are considered secondary to this mechanism being caused either by pulmonary edema related to disturbed circulation or by aspiration pneumonia following emesis. It is generally assumed that all these effects were mainly due to the (surfactants (2004, ASB2012-11576; n, 2004, ASB2012-12038), as well as disturbances of lung function and circulation and histopathological lung lesions after acute inhalation (, 2007, ASB2013-4034). (1987, Z35531) reported two cases of human poisonings with surfactants causing clinical signs resembling very much those observed after ingestion of large amounts of Roundup.

Reference doses

Table B.6.13-1 provides an overview on the toxicological studies with the surfactant formulations

MON 0818 or G-3780 that might be used for setting reference values for the POE- with the CAS no. 61791-26-2. For correction of the NOAELs/LOAELs, a content of 72% is assumed. Although acute studies might point to, e.g., a need
for setting an ARfD, they are usually not considered an appropriate basis to derive any of the reference doses. Likewise, mechanistic studies are often performed under very artificial conditions and unrealistic high doses are employed. Long-term studies that are mostly used to derive the ADI are not available. Therefore, only short-term toxicity, reproduction and developmental toxicity studies can be taken into consideration for this purpose.

Table B.6.13-1: NOAELs and effect doses for the POE- with CAS no.
61791-26-2 in relevant toxicological studies

Study type / Formulation	NOAEL	LOAEL	Effects at LOAEL	Reference
90-days (feeding), rat / MON 0818	20 mg/kg bw/d	60 mg/kg bw/d	Histopathological lesions of intestinal mucosa, bw gain and food consumption ↓	1990 ASB2009-9027
14-weeks (capsules), dog / G- 3780	21 mg/kg bw/d	42 mg/kg bw/d	Clinical signs (vomiting, diarrhea); bw (gain) ↓	1973 ASB2009-9026
4-weeks (inhalation), rat / MON 2139 (Roundup)	1.6 mg/kg bw/d (calculated from NOAEC)	5 mg/kg bw/d (calculated from LOAEC)	Clinical chemistry findings, histopathological lesions (lung, trachea, nasal turbinates) at higher concentration	1983 TOX2002-694
2-generation (feeding), rat / MON 0818	12 mg/kg bw/d	38 mg/kg bw/d	Implantation rate, litter size, pup survival ↓	2007 ASB2010-365

One-generation
(feeding), rat / MON 0818
Not established
74 mg/kg bw/d
Equivocal evidence of maternal toxicity
2008
ASB2010-364
One-generation (feeding), rat / Roundup
81 mg/kg bw/d (reproductive and parental toxicity), not established for
offspring effects
> 81 mg/kg bw/d (reproduction and parental toxicity); 9 mg/kg bw/d
(offspring effects)
Sexual development mainly of male pups affected
2007
ASB2012-2721
Developmental toxicity (gavage), rat (range-finding
study) / MON 0818
36 mg/kg bw/d
72 mg/kg bw/d
Clinical signs and bw losses in pregnant dams
1989
ASB2009-9028
Developmental toxicity (gavage), rat (main study) / MON 0818
10.8 mg/kg bw/d (maternal toxicity); 72 mg/kg bw/d (developmental
effects)
72 mg/kg bw/d (maternal toxicity); 216 mg/kg bw/d (developmental
effects)
Food consumption ↓ and bw losses in dams; visceral and skeletal anomalies in
fetuses ↑
1990
ASB2009-9029
Developmental toxicity (gavage), rat / Roundup
135 mg/kg bw/d (maternal toxicity); not established for
developmental effects
180 mg/kg bw/d (maternal toxicity); 91 mg/kg bw/d
(developmental effects)
Mortality in pregnant dams; skeletal anomalies in
fetuses ↑, delay in ossification
2003
ASB2012-11600
Studies with MON 0818 are of greater value for deriving the reference values because it cannot be excluded that the active ingredient or co-formulants other than the
to a certain degree may have contributed to the toxicity of Roundup. In the studies with oral administration of MON 0818, the lowest NOAELs were obtained in the Two-generation study by (2007, ASB2010-365) and, with regard to maternal toxicity, in the developmental toxicity study by (1990, ASB2009-9029). Numerically, both NOAELs were in the same magnitude of 10 – 12 mg/kg

bw/day. The LOAEL of 9 mg/kg bw/day as calculated from the reproduction study with Roundup is in the same range. It is proposed to derive both the ADI and the AOEL on this basis. Since postnatal effects on pup survival in the reproduction study could be an acute effect and because a lower food consumption and body weight losses in pregnant dams in the developmental study at the LOAEL were observed during the first days of treatment, a NOAEL of 10 – 12 mg/kg bw/day is also considered suitable for deriving the ARfD.

The toxic effects of the POE- can be partly attributed to its irritating potential. However, systemic effects were also noted and, therefore, reduction of the usual safety factor is not feasible. When a safety factor of 100 is applied, a numeric value of 0.1 mg/kg bw(/day) for all three reference values (ADI, systemic AOEL, ARfD) will result.

In its recent evaluation, U.S. EPA has set a “chronic RfD” (ADI) and a reference value for ”incidental oral (short-term and intermediate-term) exposure” (corresponding to the AOEL) of 0.15 mg/kg bw/day each (EPA, 2009, ASB2009-9022). However, these values are intended to be applied for the whole group of ethoxylated alkyl amines and are based on the NOAEL of 15 mg/kg bw/day as obtained in a 90-day rat study with ATMER®163. In this study, mortality occurred at the next higher dose level of 30 mg/kg bw/day (1991, ASB2009- 10488). ATMER®163 is an alkylamine formulation (CAS no. 70955-14-5) that is not contained as a co-formulant in plant protection products which are authorised in Germany. Therefore, this study is of no relevance for this evaluation.

The POE- with CAS no. 61791-26-2 proved more toxic by the inhalation route than by oral intake. Therefore, setting of an inhalative AOEL as an additional reference value is needed. In the absence of an appropriate inhalative study with the surfactant itself, a calculation must be performed on the basis of a 4-week study with Roundup (1983, TOX2002-694) under the (conservative) assumption that the effects were entirely due to the Based on the calculated NOAEL of 1.66 mg/kg bw/day for the in this study (see section on short-term toxicity), an inhalative AOEL for this surfactant of 0.0166 mg/kg bw/day can be set when the safety factor of 100 is applied.

Dermal absorption

The POE- with CAS no. 61791-26-2 is a surfactant that is used to enhance the uptake of the herbicidal compound glyphosate (or other herbicides) into the leaves or other part of the weeds which are intended to be controlled. Accordingly, it is a surface-active substance and a certain ability to penetrate through biological membranes can be assumed. However, estimation of dermal absorption for substances with strong irritating properties is difficult because dermal penetration can be either inhibited or facilitated.

Experimental data on dermal absorption is not available. Furthermore, there is no reliable data available that would allow “read-across”. Thus, the default values as proposed in the EFSA guidance document (EFSA, 2012, ASB2012-6959) should be used, depending on the concentration of the surfactant in the plan protection product.

Also if physico-chemical properties are taken into consideration, a high molecular weight of 928.31 D (EPA, 2009, ASB2009-9022) suggests poor dermal penetration. However, according to the EU guidance document on dermal absorption, the logPOW of 3 15 does not allow reduction of the default values to 10 %.

Impact of POE- on the toxicity of Roundup formulations

With regard to nearly all endpoints investigated, the POE- (CAS no. 61791-26-2) was clearly more toxic than glyphosate. A direct comparison is shown in Table B.6.13-2. Data for the active substance have been taken from a recent evaluation (EU, 2001, ASB2009- 4191).

Table B.6.13-2: Comparison of toxicity data for glyphosate and the POE- surfactant with CAS no. 61791-26-2

End point	Glyphosate	POE-surfactant
Acute oral (rat)	LD50 >5000 mg/kg bw	LD50: 864 mg/kg bw
Acute dermal (rabbit)	LD50 >2000 mg/kg bw	LD50 >907 mg/kg bw
Skin irritation	Not irritant	Irritant
Eye irritation	Moderately to severely irritant	Severely irritant
Skin sensitization	Negative	Sensitising
Mutagenicity (gene mutations)	Negative	Negative
Mutagenicity (chromosome aberrations)	Negative	Negative
DNA damage	Negative	Equivocal (some evidence at high and clearly toxic doses)
NOAEL (mg/kg bw/day)		
LOAEL (mg/kg bw/day)		
NOAEL (mg/kg bw/day)		
LOAEL (mg/kg bw/day)		
Short-term toxicity (rat, oral, 90 d)	150	300

20
60
Short-term toxicity
(dog, oral, ca 3 mo)
300
1000
21
42
Reproduction toxicity (rat)
700 (parental)
2000 (repro)
700 (offspring)
2000 (parental)
>2000 (repro)
2000 (offspring)
38 (parental)
12 (repro)
12 (offspring)
74 (parental)
38 (repro)
38 (offspring)
Developmental studies (rat),
maternal toxicity
300
1000
10.8
72
Developmental studies (rat), fetal
effects
300
1000
72
216
The higher toxicity of the surfactant might explain that also Roundup formulations when tested for different endpoints were more toxic than glyphosate (1982, TOX2002- 693 and 1983, TOX2002-694; 2003, ASB2012-11600 and
., 2007, ASB2012-2721). This is also the most likely explanation for poisoning incidents in humans by the oral or the inhalation route. A possible potentiation of toxicity of glyphosate IPA salt and the in animals was suspected by
(1991, Z80636) who tested the acute oral toxicity of Roundup formulations in rats. However, taking into consideration the toxicological profile of glyphosate, synergism is not very likely. Most effects of both substances are different by nature. Even if the surfactant would enhance the oral absorption of glyhosate (usually about 2030 % only), adverse effects are not expected because they occur only at exaggerated doses. The only effect for which dose additivity could be theoretically assumed is eye (and perhaps mucosal) irritation. However, the low acute oral toxicity and the high NOAELs of glyphosate in short-term oral studies (see Table B.6.13-2) suggest that the irritating potential of this

active ingredient is not relevant after oral intake. Therefore, it is not very likely that glyphosate itself contributed that much to the toxicity of Roundup products in poisoning incidents in humans.
In sum, the available data is sufficient to support the assumption that critical effects of glyhosate-based PPP that were not seen with the active ingredient were due to toxicity of the POE- surfactant alone.

B.6.14 Exposure data (Annex IIIA 7.3 to 7.5)

The review report for glyphosate 6511/VI/99-final – 21 January 2002 (ASB2009-4191) is considered to provide relevant basic information on risk assessment for glyphosate. But, new studies on the active substance glyphosate have been performed since then (see IIA 5 of the dossier for the active substance and chapter IIIA 7.6). Based on all available data, more appropriate values for the AOEL and dermal absorption have been derived (see Table B.6.14-1). The assessment presented below is based on these data.

Table B.6.14-1: Product information and toxicological reference values used for exposure assessment

Product	
MON 52276	
Formulation type	
SL	
Category	
Herbicide	
Container sizes, short description	
1 L, 5 L, 10 L HDPE-containers with 63 mm openings, 20 L HDPE-containers with 61 mm openings and 60 – 1000 L drums	
Active substances (incl. content)	Glyphosate (as its isopropylamine salt) 360 g/L (salt techn.: 486 g/L)
AOEL systemic	0.1 mg/kg bw/d
Inhalative absorption	100 %
Oral absorption	20 %
Dermal absorption	Concentrate: 0.1 % Dilution: 0.3 1 % (Dilution rate: ~ 1:150, i.e. concentration of glyphosate: 2.5 g/L)* (SL-formulation containing 360 g/L glyphosate, MON 52276)

* Although the lowest concentration of glyphosate in the ready-to-use spray dilution of intended uses, i.e. 0.9 g a.s./L (360 g a.s./400 L, cf Table B.6.14-2) is not fully covered by the concentration of the dermal absorption study (see above) no correction of the value is considered necessary since there is no significant dose dependance of dermal absorption based on the available in vitro study using human skin.

MON 52276 is used as a herbicide against annual, perennial and biennial weeds. It is applied pre- and post-planting, pre-emergence of crops or pre-harvest as well as post-emergence of weeds. Spray treatments are performed using tractor-mounted ground-boom sprayers and knapsack sprayers. A summary of the representative uses for MON 52276 is presented in Table B.6.14-2 below.

Table B.6.14-2: Summary of supported uses of MON 52276
Crops
F
Application rate per treatment
Spray volume
Maximum in-use
concentration
Number of treatments
Application technique
Acceptability of exposure assessment
[L product
/ha]
[kg a.s./ha]
[L/ha]
[kg a.s./hL]
min - max
Operator GM
Operator UK POEM
Worker
Bystander
Residents
All crops
F
1 – 6*
0.36 – 2.16
100 - 400
2.16
1 – 2*
Tractor- mounted ground boom sprayer with hydraulic nozzles
(pre-planting) 1), 6)
All crops
F
1 – 6*
0.36 – 2.16
100 - 400
2.16
1 – 2*
(pre-planting) 1), 7)
All crops
(post-planting/pre-
F
1 - 3
0.36 – 1.08
100 - 400
1.08
1

emergence of crops)
Cereals, oil seeds 1)
F
2 - 6
0.72 – 2.16
100 - 400
2.16
1
(both pre-harvest)
Orchard crops, vines,
Knapsack
incl. citrus & tree nuts
2), 3), 4), 5), 6)
F
2 – 8*
0.72 – 2.88
100 - 400
2.88
1 – 3*
sprayer
(post emergence of
weeds)
Orchard crops, vines,
incl. citrus & tree nuts
2), 3), 4), 5), 6)
F
2 – 8*
0.72 – 2.88
100 - 400
2.88
1 – 3*
(post emergence of
weeds; spot treatment)
F = field use
GM = German model
* Maximum dose per season not to exceed 4.32 kg a.s./ha
1) critical use for operators in low crops
2) critical use for operators during applications under high crops
3) critical use for bystanders
4) critical use for residents
5) critical use for workers
Since it could not be figured out unequivocally what is meant by ‘all crops’ by the applicant two different ‘worst case’scenarios for residents are presented:
6) Applications on lawn, pasture or meadow not included in ‘all crops’
7) Applications on lawn, pasture or meadow included in ‘all crops’
Exposure acceptable without PPE / risk mitigation measures

Exposure acceptable with PPE or risk mitigation measures required
Exposure not acceptable/ Evaluation not possible
No critical use
The results of exposure estimations for operators, bystanders, residents and workers are summarised in Table B.6.14-4, Table B.6.14-6, Table B.6.14-8 and Table B.6.14-10 below. Detailed estimations are provided in A.1.1, 1.2 and 1.3.
B.6.14.1 Operator exposure (IIIA 7.3.1 and 7.3.2)
B.6.14.1.1 Estimation of operator exposure
A summary of the exposure models used for estimation of operator exposure towards the active substances during application of MON 52276 according to intended uses is presented in Table B.6.14-3. Outcome of the estimation is presented in Table B.6.14-4. Detailed calculations are given in 0.
Table B.6.14-3: Exposure models used for operator exposure estimations
Critical use
Cereals, oil seed rape, etc. (max. 6 L product/ha);
Orchard crops, vines, incl. citrus & tree nuts (max. 8 L product/ha)
Model
German model
[Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
Critical use
Cereals, oil seed rape, etc. (max. 6 L product/ha);
Orchard crops, vines, incl. citrus & tree nuts (max. 8 L product/ha)
Model
Revised UK-POEM
[Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]
Table B.6.14-4: Estimated operator exposure towards glyphosate from the use of MON 52276
Model data
Level of PPE
Total absorbed dose (mg/kg/day)
% of systemic AOEL
Tractor mounted boom spray applications outdoors to low crops
Application rate: 2.16 kg a.s./ha
German Model
no PPE 1)
0.0062450.028389
6.228.4
Body weight: 70 kg
+ Gloves
mixing/loading
0.0047790.013725
4.813.7
UK POEM
no PPE 2)

0.0750.2612
75.5261.2
Application volume: 100 L/ha Container: 10 litres 63 mm closure Body weight: 60 kg
+ Gloves mixing/loading and
application
0.0670.0493
66.949.3
Hand-held spray applications outdoors to high crops 3)
Application rate: 2.88 kg a.s./ha
German Model
no PPE 1)
0.02780.115365
27.8115.4
Body weight: 70 kg
+ Gloves
mixing/loading
0.01950.031865
19.531.9
Hand-held spray applications (15 L tank) outdoors to low crops
Application rate: 2.88 kg a.s./ha
UK POEM
no PPE 2)
0.2070.5682
206.6568.2
Application volume: 100 L/ha Container: 10 litres 63 mm closure Body weight: 60 kg
+ Gloves mixing/
loading and application and impermeable
coverall during application
0.0850.1487
84.7148.7
1) no PPE: Operator wearing T-shirt and shorts
2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves
3) Since there are no data for outdoor applications of herbicides under high crops in the German model, this represents 'worst case'.
In conclusion, MON 52276 can be applied safely by operators using tractor-mounted and hand-held application techniques based on exposure calculations. Only in the case of hand- held spray applications using the UK POEM allocation of PPE to operators is necessary.
B.6.14.1.2 Measurement of operator exposure (mixer/loader/applicator) (IIIA 7.3.3)
Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses according to the German model (without PPE for hand-held applications), a study to provide measurements of operator exposure was not necessary and was therefore not performed.
or if PPE is worn aAccording to the UK POEM the acceptable operator exposure level (AOEL) will not be exceeded (with PPE) in the case of applications using tractor mounted boom spray equipment, but will be exceeded for hand-held applications even if PPE is worn.
Nevertheless, Additionally, the applicants submitted respective biomonitoring data from the Farm

Family Exposure Study for farmers and their families published in the open literature (2004; ASB2012-11528). This study was conducted in a southern (South Carolina) and northern (Minnesota) agricultural production area of the U.S.. The purpose of the study was to quantify actual internal pesticide exposure immediately before, during and after pesticide application.

For forty-eight farmer families, including 79 children, urine samples were collected for a 24- hour period prior to application, on the day of application and for three consecutive 24-hour periods thereafter. Urine specimens from 24-hour periods were mixed in such a way that the proportion of the individual volumes of the specimens remained unchanged in the composite mixture. Subsequently glyphosate concentrations were determined in the samples.

Farmers were not instructed or coached by the study investigators on how to apply the products. All farmers used tractor-mounted boom-sprayers and applied Roundup® Ultra (Monsanto Company) over glyphosate tolerant crops early in the growing season. About one- third of the farmers made applications on between 4 and 18 hectares, another third on 18–50 ha, and another third on 50–178 ha. Application rates were according to label recommendations. Sixty percent of applications were carried out using closed-cabs. 71 % of the farmers wore rubber gloves during application. 27 % of the farmers repaired their equipment during the application.

Glyphosate concentrations in the farmers' urine ranged from less than the limit of detection (LOD = 1 ppb) to a maximum of 233 ppb. Overall, only 60 % of the farmers showed detectable levels on the day of application, which further declined afterwards. Figure B.6.14-1 shows the cumulative frequency distribution of systemic doses obtained by the farmers.

Figure B.6.14-1: Systemic dose distribution for farmers applying glyphosate (Acquavella et al., 2004; ASB2012-11528)

The maximum estimated systemic dose for operators was 0.004 mg/kg/day, whereas the geometric mean was 0.0001 mg/kg bw/day.

B.6.14.2 Bystander and resident exposure (IIIA 7.4)

B.6.14.2.1 Estimation of bystander and resident exposure

Table B.6.14-5 shows the exposure model used for estimation of bystander and resident exposure towards glyphosate. Estimations are presented for adults as well as for children. In the case applications on lawn, on meadows and on pasture can be excluded, outcome of the 'worst case' estimations for applications in orchards etc. is presented in Table B.6.14-6. Detailed calculations are given in A.1.2.

If applications on lawn etc. have to be considered this scenario will represent 'worst case' conditions for residents. In this case it is referred to Table B.6.14-7 and Table B.6.14-8 and calculations in 0, too.

Table B.6.14-5: Exposure model used for bystander and resident exposure estimations

Critical use

Orchard crops, vines, incl. citrus & tree nuts (max. 3 x 8 L product/ha *)

Model

Martin, S. et al. (2008, ASB2009-450) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

* Maximum dose per season not to exceed 4.32 kg as/ha

Table B.6.14-6: Estimated bystander and resident exposure towards glyphosate from the use of MON 52276

t

exceed 4.32 kg a.s./ha

12) drift rate for ornamentals > 50 cm used as a default for herbicidal applications under high crops
23) 82th percentile for two applications
In the case applications on lawn are included in the term 'all crops' given by the applicant an alternative calculation for resident exposure is presented below.
Table B.6.14-7: Exposure model used for resident exposure estimations for applications on lawn
Critical use
Lawn, meadows, pasture (max. 2 x 6 L product/ha)
Model
Martin, S. et al. (2008, ASB2009-450) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76
Table B.6.14-8: Estimated resident exposure towards glyphosate from the use of MON 52276 on lawn
Glyphosate
Model data
Total absorbed dose (mg/kg/day)
% of systemic AOEL
Tractor mounted spray application on lawn, pasture, meadow Application rate: 2 x 2.16 kg a.s./ha
Bystanders (adult) Deposit: 100 % Body weight: 60 kg
0.001850.00553
1.855.53
Bystanders (children) Deposit: 100 %
Body weight: 16.15 kg
0.015980.02084
16.020.84
B.6.14.2.2 Measurement of bystander or resident exposure
Since the bystander and resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of bystander or resident exposure was not necessary and was therefore not performed.
B.6.14.3 Worker exposure
For the intended uses of MON 52276 there are no foreseen re-entry activities. The only reasonable re-entry scenario is inspection of the crops. Furthermore, for spray treatments pre- and post-planting, and pre-emergence of the crops, as well as post-emergence of weeds in orchards, crop inspection activities normally require no dermal contact to the foliage, but rather consist of a visual inspection. Nevertheless, dermal contact with residues after application is considered as a 'worst case' scenario.
B.6.14.3.1 Estimation of worker exposure
Due to the low vapour pressure of glyphosate (1.31 × 10-5 Pa (25 °C)) respiratory exposure is considered irrelevant for re-entry tasks, so that exposure during these tasks occurs via skin contact with treated surfaces predominantly.
Table B.6.14-9 shows the exposure model used for estimation of dermal worker exposure after entry into a previously treated area or handling a crop treated with MON 52276 according to the critical use. Outcome of the estimation is presented in Table B.6.14-10. Detailed calculations are in A.1.3.
Table B.6.14-9: Exposure model for intended uses

Critical use
Orchard crops, vines, incl. citrus & tree nuts (max. 3 x 8 L product/ha *)
Model
German re-entry model, Krebs et al. (2000, TOX2004-1971)
[Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]
* Maximum dose per season not to exceed 4.32 kg as/ha
Table B.6.14-10: Estimated worker exposure
Glyphosate
Model data
Level of PPE
Total absorbed dose (mg/kg/day)
% of systemic AOEL
Number of applications and application rate:
4.32 kg a.s./ha 1)
8 hours/day 2),
TC: 5000 cm2/person/h 3)
DFR 1 µg/cm²/kg a.s. 4)
Body weight: 60 kg
no PPE 5)
0.008640.0288
8.628.8
+ Gloves and protective suit
0.000430.0014
0.41.4
1) Maximum dose per season; 'worst case' (no degradation between splitted dose applications taken into account)
2) 8 h/day for professional applications; 'worst case', since normally there is no classical re-entry scenario for herbicidal applications under high crops
3) Ornamentals, EUROPOEM II, 2002, Post-Application Exposure of Workers to Pesticides in Agriculture;
default used for herbicidal applications under high crops
4) no harmonised default is available, therefore default value acc. to the above mentioned model (even if a more conservative default value of 3 µg/cm²/kg a.s. is used, worker exposure is < 100 % of AOEL (86.426 % of AOEL))
5) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
B.6.14.3.2 Measurement of worker exposure
Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed.
Appendix 1 Exposure calculations
Operator exposure calculations (IIIA 7.3)
Table A 1: Input parameters considered for the estimation of operator exposure according to the German model (FCTM)
Formulation type:
SL

Application technique:
Field Crop Tractor Mounted (FCTM)
Application rate (AR):
2.16
kg a.s./ha
Area treated per day (A):
20
ha
Dermal hands m/l (DM(H)):
2.4
mg/person/kg
a.s.
Dermal absorption (DA):
0.1.0
% (concentr.)
Dermal hands appl. (DA(H)):
0.38
mg/person/kg a.s.
0.31.0
% (dilution)
Dermal body appl. (DA(B)):
1.6
mg/person/kg
a.s.
Inhalation absorption
(IA):
100
%
Dermal head appl. (DA(C)):
0.06
mg/person/kg
a.s.
Body weight (BW):
70
kg/person
Inhalation m/l (IM):
0.0006
mg/person/kg
a.s.
AOEL
0.1
mg/kg bw/d
Inhalation appl. (IA):
0.001
mg/person/kg
a.s.

Table A 2: Estimation of operator exposure towards glyphosate using the German model
Without PPE
With PPE
Operators: Systemic dermal exposure after application in cereals, oil seeds, pre-harvest; all crops, pre-planting
Dermal exposure during mixing/loading
Hands
Hands
SDEOM(H) = (DM(H) x AR x A x DA) / BW
SDEOM(H) = (DM(H) x AR x A x PPE 1) x DA) / BW
(2.4 x 2.16 x 20 x 0.1.0 %) / 70
(2.4 x 2.16 x 20 x 0.01 x 0.1.0 %) / 70
External dermal exposure
103.68
mg/person
External dermal exposure
1.0368
mg/person
External dermal
exposure
1.481143
mg/kg bw/d
External dermal
exposure
0.014811
mg/kg bw/d
Systemic dermal
exposure
0.001481
mg/kg bw/d
Systemic dermal
exposure
0.0000150.000148
mg/kg bw/d
Dermal exposure during application
Hands
Hands
SDEOA(H) = (DA(H) x AR x A x DA) / BW
SDEOA(H) = (DA(H) x AR x A x PPE x DA) / BW
(0.38 x 2.16 x 20 x 0.31.0 %) / 70
(0.38 x 2.16 x 20 x 1 x 0.31.0%) / 70
External dermal
exposure
16.416
mg/person
External dermal

exposure
16.416
mg/person
External dermal
exposure
0.234514
mg/kg bw/d
External dermal
exposure
0.234514
mg/kg bw/d
Systemic dermal
exposure
0.0007040.002345
mg/kg bw/d
Systemic dermal
exposure
0.0007040.002345
mg/kg bw/d
Body
Body
SDEOA(B) = (DA(B) x AR x A x DA) / BW
SDEOA(B) = (DA(B) x AR x A x PPE x DA) / BW
(1.6 x 2.16 x 20 x 0.31.0 %) / 70
(1.6 x 2.16 x 20 x 1 x 0.31.0 %) / 70
External dermal
exposure
69.12
mg/person
External dermal
exposure
69.12
mg/person
External dermal
exposure
0.987429
mg/kg bw/d
External dermal
exposure
0.987429
mg/kg bw/d
Systemic dermal
0.0029620.009874
mg/kg bw/d
Systemic dermal
0.0029620.009874

mg/kg bw/d
Without PPE
With PPE
exposure
exposure
Head
Head
SDEOA(C) = (DA(C) x AR x A x DA) / BW
SDEOA(C) = (DA(C) x AR x A x PPE x DA) / BW
(0.06 x 2.16 x 20 x 0.31.0 %) / 70
(0.06 x 2.16 x 20 x 1 x 0.31.0 %) / 70
External dermal
exposure
2.592
mg/person
External dermal
exposure
2.592
mg/person
External dermal exposure
0.037029
mg/kg bw/d
External dermal exposure
0.037029
mg/kg bw/d
Systemic dermal
exposure
0.0001110.000370
mg/kg bw/d
Systemic dermal
exposure
0.0001110.000370
mg/kg bw/d
Total systemic dermal exposure: SDEO = SDEOM(H) +
SDEOA(H) + SDEOA(B) + SDEOA(C)
Total systemic dermal exposure: SDEO = SDEOM(H) +
SDEOA(H) + SDEOA(B) + SDEOA(C)
Total external
dermal exposure
191.808
mg/person
Total external
dermal exposure
89.1648
mg/person
Total external

dermal exposure
2.740114
mg/kg bw/d
Total external
dermal exposure
1.273783
mg/kg bw/d
Total systemic dermal exposure
0.0052580.027401
mg/kg bw/d
Total systemic dermal exposure
0.0037920.012748
mg/kg bw/d
Operators: Systemic inhalation exposure after application in Cereals, oil seeds, pre-harvest; all crops, pre-
planting
Inhalation exposure during mixing/loading
SIEOM = (IM x AR x A x IA) / BW
SIEOM = (IM x AR x A x PPE x IA) / BW
(0.0006 x 2.16 x 20 x 100 %) / 70
(0.0006 x 2.16 x 20 x 1 x 100 %) / 70
External inhalation exposure
0.02592
mg/person
External
inhalation exposure
0.02592
mg/person
External inhalation exposure
0.00037
mg/kg bw/d
External
inhalation exposure
0.00037
mg/kg bw/d
Systemic inhalation exposure
0.00037
mg/kg bw/d
Systemic
inhalation exposure
0.00037
mg/kg bw/d
Inhalation exposure during application
SIEOA = (IA x AR x A x IA) / BW
SIEOA = (IA x AR x A x PPE x IA) / BW
(0.001 x 2.16 x 20 x 100 %) / 70

(0.001 x 2.16 x 20 x 1 x 100 %) / 70
External inhalation exposure
0.0432
mg/person
External inhalation
exposure
0.0432
mg/person
External inhalation exposure
0.000617
mg/kg bw/d
External
inhalation exposure
0.000617
mg/kg bw/d
Systemic inhalation exposure
0.000617
mg/kg bw/d
Systemic inhalation
exposure
0.000617
mg/kg bw/d
Total systemic inhalation exposure: SIEO = SIEOM +
SIEOA
Total systemic inhalation exposure: SIEO = SIEOM +
SIEOA
Total external inhalation exposure
0.06912
mg/person
Total external
inhalation exposure
0.06912
mg/person
Total external inhalation exposure
0.000987
mg/kg bw/d
Total external
inhalation exposure
0.000987
mg/kg bw/d
Total systemic inhalation exposure
0.000987
mg/kg bw/d
Total systemic
inhalation exposure
0.000987

mg/kg bw/d
Total systemic exposure: SEO = SDEO + SIEO
Total systemic exposure: SEO = SDEO + SIEO
Total systemic
exposure
0.4371841.987200
mg/person
Total systemic
exposure
0.3345410.960768
mg/person
Without PPE
With PPE
Total systemic
exposure
0.0062450.028389
mg/kg bw/d
Total systemic
exposure
0.0047790.013725
mg/kg bw/d
% of AOEL
6.228.4
%
% of AOEL
4.813.7
%
1) reduction factor for gloves is 0.01 (professional appl.)
Table A 3: Input parameters considered for the estimation of operator exposure according to the German model (HCHH)
Formulation type:
SL
Application technique:
High Crop Hand Held (HCHH)
Application rate (AR):
2.88
kg a.s./ha
Area treated per day (A):
1
ha
Dermal hands m/l (DM(H)):
205
mg/person/kg
a.s.
Dermal absorption (DA):
0.1.0

% (concentr.)
Dermal hands appl.
(DA(H)):
10.6
mg/person/kg
a.s.
0.31.0
% (dilution)
Dermal body appl. (DA(B)):
25
mg/person/kg
a.s.
Inhalation absorption
(IA):
100
%
Dermal head appl. (DA(C)):
4.8
mg/person/kg
a.s.
Body weight (BW):
70
kg/person
Inhalation m/l (IM):
0.05
mg/person/kg a.s.
AOEL
0.1
mg/kg bw/d
Inhalation appl. (IA):
0.3
mg/person/kg
a.s.
Table A 4: Estimation of operator exposure towards glyphosate using the German model (HCHH)
Without PPE
With PPE
Operators: Systemic dermal exposure after application in grapevine, orchard crops, tree nuts
Dermal exposure during mixing/loading
Hands
Hands
SDEOM(H) = (DM(H) x AR x A x DA) / BW
SDEOM(H) = (DM(H) x AR x A x PPE 1) x DA) / BW
(205 x 2.88 x 1 x 0.1.0 %) / 70
(205 x 2.88 x 1 x 0.01 x 0.1.0 %) / 70
External dermal
exposure

590.4
mg/person
External dermal exposure
5.904
mg/person
External dermal
exposure
8.434286
mg/kg bw/d
External dermal exposure
0.084343
mg/kg bw/d
Systemic dermal exposure
0.008434
mg/kg bw/d
Systemic dermal exposure
0.000084
0.000843
mg/kg bw/d
Dermal exposure during application
Hands
Hands
SDEOA(H) = (DA(H) x AR x A x DA) / BW
SDEOA(H) = (DA(H) x AR x A x PPE x DA) / BW
(10.6 x 2.88 x 1 x 0.31.0 %) / 70
(10.6 x 2.88 x 1 x 1 x 0.31.0 %) / 70
External dermal
exposure
30.528
mg/person
External dermal exposure
30.528
mg/person
External dermal
exposure
0.436114
mg/kg bw/d
External dermal exposure
0.436114
mg/kg bw/d
Systemic dermal
exposure
0.001308
0.004361
mg/kg bw/d
Systemic dermal exposure

0.001308
0.004361
mg/kg bw/d
Body
Body
SDEOA(B) = (DA(B) x AR x A x DA) / BW
SDEOA(B) = (DA(B) x AR x A x PPE x DA) / BW
(25 x 2.88 x 1 x 0.31.0 %) / 70
(25 x 2.88 x 1 x 1 x 0.31.0 %) / 70
External dermal
exposure
72
mg/person
External dermal exposure
72
mg/person
External dermal
1.028571
mg/kg bw/d
External dermal exposure
1.028571
mg/kg bw/d
Without PPE
With PPE
exposure
Systemic dermal
exposure
0.003086
0.010286
mg/kg bw/d
Systemic dermal exposure
0.003086
0.010286
mg/kg bw/d
Head
Head
SDEOA(C) = (DA(C) x AR x A x DA) / BW
SDEOA(C) = (DA(C) x AR x A x PPE x DA) / BW
(4.8 x 2.88 x 1 x 0.31.0 %) / 70
(4.8 x 2.88 x 1 x 1 x 0.31.0 %) / 70
External dermal exposure
13.824
mg/person
External dermal exposure
13.824
mg/person

External dermal
exposure
0.197486
mg/kg bw/d
External dermal exposure
0.197486
mg/kg bw/d
Systemic dermal
exposure
0.000592
0.001975
mg/kg bw/d
Systemic dermal exposure
0.000592
0.001975
mg/kg bw/d
Total systemic dermal exposure: SDEO = SDEOM(H)
+ SDEOA(H) + SDEOA(B) + SDEOA(C)
Total systemic dermal exposure: SDEO = SDEOM(H) +
SDEOA(H) + SDEOA(B) + SDEOA(C)
Total external dermal
exposure
706.752
mg/person
Total external dermal
exposure
122.256
mg/person
Total external dermal exposure
10.096457
mg/kg bw/d
Total external dermal exposure
1.746514
mg/kg bw/d
Total systemic dermal
exposure
0.013421
0.100965
mg/kg bw/d
Total systemic dermal
exposure
0.005071
0.017465
mg/kg bw/d
Operators: Systemic inhalation exposure after application in Grapevine, orchard crops, tree nuts
Inhalation exposure during mixing/loading

SIEOM = (IM x AR x A x IA) / BW
SIEOM = (IM x AR x A x PPE x IA) / BW
(0.05 x 2.88 x 1 x 100 %) / 70
(0.05 x 2.88 x 1 x 1 x 100 %) / 70
External inhalation
exposure
0.144
mg/person
External inhalation
exposure
0.144
mg/person
External inhalation
exposure
0.002057
mg/kg bw/d
External inhalation
exposure
0.002057
mg/kg bw/d
Systemic inhalation
exposure
0.002057
mg/kg bw/d
Systemic inhalation
exposure
0.002057
mg/kg bw/d
Inhalation exposure during application

SIEOA = (IA x AR x A x IA) / BW
SIEOA = (IA x AR x A x PPE x IA) / BW
(0.3 x 2.88 x 1 x 100 %) / 70
(0.3 x 2.88 x 1 x 1 x 100 %) / 70
External inhalation
exposure
0.864
mg/person
External inhalation
exposure
0.864
mg/person
External inhalation
exposure
0.012343
mg/kg bw/d

External inhalation
exposure
0.012343
mg/kg bw/d
Systemic inhalation
exposure
0.012343
mg/kg bw/d
Systemic inhalation
exposure
0.012343
mg/kg bw/d
Total systemic inhalation exposure: SIEO = SIEOM +
SIEOA
Total systemic inhalation exposure: SIEO = SIEOM +
SIEOA
Total external inhalation
exposure
1.008
mg/person
Total external inhalation
exposure
1.008
mg/person
Total external inhalation
exposure
0.0144
mg/kg bw/d
Total external inhalation
exposure
0.0144
mg/kg bw/d
Total systemic inhalation
exposure
0.0144
mg/kg bw/d
Total systemic inhalation
exposure
0.0144
mg/kg bw/d
Total systemic exposure: SEO = SDEO + SIEO
Total systemic exposure: SEO = SDEO + SIEO
Total systemic exposure
1.947456
8.075520
mg/person

Total systemic exposure
1.36296
2.230560
mg/person
Total systemic exposure
0.027821
0.115365
mg/kg bw/d
Total systemic exposure
0.019471
0.031865
mg/kg bw/d
% of AOEL
27.8115.4
%
% of AOEL
19.531.9
%
1) reduction factor for gloves is 0.01 (professional appl.)
Table A 5: Estimation of operator exposure towards glyphosate using the UK- POEM (FCTM)
Without PPE
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Active substance
Glyphosate
Product
MON 52276
Formulation type
water-based
Concentration of a.s.
360
mg/mL
Dose
6
L preparation/ha
(2.16 kg a.s./ha)
Application volume
100
L/ha
Application method
Tractor-mounted/trailed boom sprayer: hydraulic nozzles
Container
10 litres 63 mm closure
Work rate/day
50
ha
Duration of spraying

6
h
PPE during mix./loading
None
PPE during application
None
Dermal absorption from product
0.1.0
%
Dermal absorption from spray
0.31.0
%
EXPOSURE DURING MIXING AND LOADING
Container size
10
Litres
Hand contamination/operation
0,05
mL
Application dose
6
Litres product/ha
Work rate
50
ha/day
Number of operations
30
/day
Hand contamination
1.5
mL/day
Protective clothing
None
Transmission to skin
100
%
Dermal exposure to formulation
1.5
mL/day
DERMAL EXPOSURE DURING SPRAY APPLICATION
Application technique
Tractor-mounted/trailed boom sprayer: hydraulic nozzles
Application volume
100
spray/ha
Volume of surface contamination

10
mL/h
Distribution
Hands
Trunk
Legs
65 %
10 %
25 %
Clothing
None
Permeable
Permeable
Penetration
100 %
5 %
15 %
Dermal exposure
6.5
0.05
0.375
mL/h
Duration of exposure
6
h
Total dermal exposure to spray
41.55
mL/day
ABSORBED DERMAL DOSE
Mix/load
Application
Dermal exposure
1.5
mL/day
41.55
mL/day
Concen. of a.s. product or spray
360
mg/mL
21.6
mg/mL
Dermal exposure to a.s.
540
mg/day
897.48
mg/day

Percent absorbed
0.1.0
%
0.31.0
%
Absorbed dose
0.5.40
mg/day
2.6928.97
mg/day
INHALATION EXPOSURE DURING SPRAYING
Inhalation exposure
0.01
mL/h
Duration of exposure
6
h
Concentration of a.s. in spray
21.6
mg/mL
Inhalation exposure to a.s.
1.296
mg/day
Percent absorbed
100
%
Absorbed dose
1.296
mg/day
PREDICTED EXPOSURE
Total absorbed dose
4.52815.671
mg/day
Operator body weight
60
kg
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Operator exposure
0.0750.2612
mg/kg bw/day
Amount of AOEL
75.5261.2
%
With PPE
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Active substance

Glyphosate
Product
MON 52276
Formulation type
water-based
Concentration of a.s.
360
mg/mL
Dose
6
L preparation/ha
(2.16 kg a.s./ha)
Application volume
100
L/ha
Application method
Tractor-mounted/trailed boom sprayer: hydraulic nozzles
Container
10 litres 63 mm closure
Work rate/day
50
ha
Duration of spraying
6
h
PPE during mix./loading
Gloves
PPE during application
NoneGloves
Dermal absorption from product
0.1.0
%
Dermal absorption from spray
0.31.0
%
EXPOSURE DURING MIXING AND LOADING
Container size
10
Litres
Hand contamination/operation
0,05
mL
Application dose
6
Litres product/ha
Work rate

50
ha/day
Number of operations
30
/day
Hand contamination
1.5
mL/day
Protective clothing
Gloves
Transmission to skin
5
%
Dermal exposure to formulation
0.075
mL/day
DERMAL EXPOSURE DURING SPRAY APPLICATION
Application technique
Tractor-mounted/trailed boom sprayer: hydraulic nozzles
Application volume
100
spray/ha
Volume of surface contamination
10
mL/h
Distribution
Hands
Trunk
Legs
65 %
10 %
25 %
Clothing
NoneGloves
Permeable
Permeable
Penetration
100 %
5 %
15 %
Dermal exposure
0.65
0.05
0.375
mL/h
Duration of exposure

6
h
Total dermal exposure to spray
41.556.45
mL/day
ABSORBED DERMAL DOSE
Mix/load
Application
Dermal exposure
0.075
mL/day
41.556.45
mL/day
Concen. of a.s. product or spray
360
mg/mL
21.6
mg/mL
Dermal exposure to a.s.
27
mg/day
897.48139.32
mg/day
Percent absorbed
0.1.0
%
0.31.0
%
Absorbed dose
0.02700
mg/day
2.6921.3932
mg/day
INHALATION EXPOSURE DURING SPRAYING
Inhalation exposure
0.01
mL/h
Duration of exposure
6
h
Concentration of a.s. in spray
21.6
mg/mL
Inhalation exposure to a.s.
1.296
mg/day

Percent absorbed
100
%
Absorbed dose
1.296
mg/day
PREDICTED EXPOSURE
Total absorbed dose
4.0152.9592
mg/day
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Operator body weight
60
kg
Operator exposure
0.0670.0493
mg/kg bw/day
Amount of AOEL
66.949.3
%
Table A 6: Estimation of operator exposure towards glyphosate using the UK- POEM (Hand-held, 15 L tank, downwards)
Without PPE
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Active substance
Glyphosate
Product
MON 52276
Formulation type
water-based
Concentration of a.s.
360
mg/mL
Dose
8
L preparation/ha
(2.88 kg a.s./ha)
Application volume
100
L/ha
Application method
Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level
target
Container
10 litres 63 mm closure
Work rate/day

1
ha
Duration of spraying
6
h
PPE during mix./loading
None
PPE during application
None
Dermal absorption from product
0.1.0
%
Dermal absorption from spray
0.31.0
%
EXPOSURE DURING MIXING AND LOADING
Container size
10
Litres
Hand contamination/operation
0,05
mL
Application dose
8
Litres product/ha
Work rate
1
ha/day
Number of operations
7
/day
Hand contamination
0.35
mL/day
Protective clothing
None
Transmission to skin
100
%
Dermal exposure to formulation
0.35
mL/day
DERMAL EXPOSURE DURING SPRAY APPLICATION
Application technique
Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level
target

Application volume
100
spray/ha
Volume of surface contamination
50
mL/h
Distribution
Hands
Trunk
Legs
25 %
25 %
50 %
Clothing
None
Permeable
Permeable
Penetration
100 %
20 %
18 %
Dermal exposure
10
2.5
4.5
mL/h
Duration of exposure
6
h
Total dermal exposure to spray
102
mL/day
ABSORBED DERMAL DOSE
Mix/load
Application
Dermal exposure
0.35
mL/day
102
mL/day
Concen. of a.s. product or spray
360
mg/mL
28.8
mg/mL
Dermal exposure to a.s.

126
mg/day
2937.6
mg/day
Percent absorbed
0.1.0
%
0.31.0
%
Absorbed dose
0.1.260
mg/day
8.81329.376
mg/day
INHALATION EXPOSURE DURING SPRAYING
Inhalation exposure
0.02
mL/h
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Duration of exposure
6
h
Concentration of a.s. in spray
28.8
mg/mL
Inhalation exposure to a.s.
3.456
mg/day
Percent absorbed
100
%
Absorbed dose
3.456
mg/day
PREDICTED EXPOSURE
Total absorbed dose
12.39534.0920
mg/day
Operator body weight
60
kg
Operator exposure
0.2070.5682
mg/kg bw/day
Amount of AOEL
206.6568.2

%
With PPE
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Active substance
Glyphosate
Product
MON 52276
Formulation type
water-based
Concentration of a.s.
360
mg/mL
Dose
8
L preparation/ha
(2.88 kg a.s./ha)
Application volume
100
L/ha
Application method
Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level
target
Container
10 litres 63 mm closure
Work rate/day
1
ha
Duration of spraying
6
h
PPE during mix./loading
Gloves
PPE during application
Gloves and impermeable coveralls
Dermal absorption from product
0.1.0
%
Dermal absorption from spray
0.31.0
%
EXPOSURE DURING MIXING AND LOADING
Container size
10
Litres
Hand contamination/operation
0,05

mL
Application dose
8
Litres product/ha
Work rate
1
ha/day
Number of operations
7
/day
Hand contamination
0.35
mL/day
Protective clothing
Gloves
Transmission to skin
5
%
Dermal exposure to formulation
0.01875
mL/day
DERMAL EXPOSURE DURING SPRAY APPLICATION
Application technique
Hand-held sprayer (15 L tank): hydraulic nozzles. Outdoor, low level target
Application volume
100
spray/ha
Volume of surface contamination
50
mL/h
Distribution
Hands
Trunk
Legs
25 %
25 %
50 %
Clothing
Gloves
Impermeable
Impermeable
Penetration
10 %
5 %
5 %

Dermal exposure
1.25
0.625
1.25
mL/h
Duration of exposure
6
h
Total dermal exposure to spray
18.75
mL/day
ABSORBED DERMAL DOSE
Mix/load
Application
Dermal exposure
0.01875
mL/day
18.75
mL/day
Concen. of a.s. product or spray
360
mg/mL
28.8
mg/mL
Dermal exposure to a.s.
6.3
mg/day
540
mg/day
Percent absorbed
0.1.0
%
0.31.0
%
THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)
Absorbed dose
0.0063
mg/day
1.625.4
mg/day
INHALATION EXPOSURE DURING SPRAYING
Inhalation exposure
0.02
mL/h
Duration of exposure
6

h
Concentration of a.s. in spray
28.8
mg/mL
Inhalation exposure to a.s.
3.456
mg/day
Percent absorbed
100
%
Absorbed dose
3.456
mg/day
PREDICTED EXPOSURE
Total absorbed dose
5.0828.9190
mg/day
Operator body weight
60
kg
Operator exposure
0.0850.1487
mg/kg bw/day
Amount of AOEL
84.7148.7
%
Bystander and resident exposure calculations (IIIA 7.4)
Table A 7: Input parameters considered for the estimation of bystander exposure
Intended use::
All high crops intended
Drift (D) 1):
8.02
% (HC, 3 m)
Application rate (AR):
2.88
kg a.s./ha
Exposed body surface area (BSA):
1
m^2 (adults)
288
mg/m2
0.21
m^2 (children)
Body weight (BW):
60
kg/person (adults)

Specific Inhalation Exposure (I*A):
0.3
mg/kg a.s. (6 hours, adults)
16.15
kg/person (children)
0.172414
mg/kg a.s. (6 hours, children)
Dermal absorption (DA):
0.31.0
% ('worst case')
Area Treated (A):
1
ha/d (based on HCHH)
Inhalation absorption (IA):
100
%
AOEL:
0.1
mg/kg bw/d
Exposure duration (T):
5
min
1) drift rate for ornamentals > 50 cm used as a default for herbicidal applications under high crops
Table A 8: Estimation of bystander exposure towards glyphosate
Adults
Children
Bystander: Systemic dermal exposure during/after application under high crops (via spray drift)
SDEB = (AR x D x BSA x DA) / BW
SDEB = (AR x D x BSA x DA) / BW
(288 x 8.02 % x 1 x 0.31.0 %) / 60
(288 x 8.02 % x 0.21 x 0.31.0 %) / 16.15
External dermal
exposure
23.0976
mg/person
External dermal
exposure
4.850496
mg/person
External dermal
exposure
0.38496
mg/kg bw/d
External dermal
exposure
0.30034

mg/kg bw/d
Systemic dermal
exposure
0.0011550.00385
mg/kg bw/d
Systemic dermal
exposure
0.0009010.00300
mg/kg bw/d
Bystander: Systemic inhalation exposure during/after application under high crops (via spray drift)
SIEB = (I*A x AR x A x T x IA) / BW
SIEB = (I*A x AR x A x T x IA) / BW
(0.3 / 360 x 2.88 x 1 x 5 x 100 %) / 60
(0.172414 / 360 x 2.88 x 1 x 5 x 100 %) / 16.15
External inhalation
exposure
0.012
mg/person
External inhalation
exposure
0.006897
mg/person
External inhalation
exposure
0.0002
mg/kg bw/d
External inhalation
exposure
0.000427
mg/kg bw/d
Systemic inhalation
exposure
0.0002
mg/kg bw/d
Systemic inhalation
exposure
0.000427
mg/kg bw/d
Total systemic exposure: SEB = SDEB + SIEB
Total systemic exposure: SEB = SDEB + SIEB
Total systemic
exposure
0.0812930.242976
mg/person
Total systemic
exposure

0.0214480.055401
mg/person
Total systemic
exposure
0.0013550.004050
mg/kg bw/d
Total systemic
exposure
0.0013280.0034304
mg/kg bw/d
% of AOEL
1.354.05
%
% of AOEL
1.333.43
%
Table A 9: Input parameters considered for the estimation of resident exposure ('worst case' if no applications on lawn, pasture and meadow are intended)
Intended uses:
All high crops intended
Drift (D) 2):
7.23
% (HC, 3 m)
Application rate (AR): 1)
4.32
kg a.s./ha
Transfer coefficient (TC):
7300
cm2/h (adults)
0.0432
mg/cm2
2600
cm2/h (children)
Number of applications
(NA):
2
Turf Transferable
Residues (TTR):
5
%
Body weight (BW):
60
kg/person
(adults)
Exposure Duration (H):
2

h
16.15
kg/person
(children)
Airborne Concentration of
Vapour (ACV):
0.001
mg/m3
Dermal absorption (DA):
0.31.0
% ('worst
case')
Inhalation Rate (IR):
16.57
m3/d (adults)
Inhalation absorption
(IA):
100
%
8.31
m3/d (children)
Oral absorption (OA):
20
%
Saliva Extraction Factor
(SE):
50
%
AOEL:
0.1
mg/kg bw/d
Surface Area of Hands
(SA):
20
cm2
Frequency of Hand to
Mouth (Freq):
20
events/h
Dislodgeable foliar
residues (DFR):

20
%
Ingestion Rate for Mouthing of Grass/Day
(IgR):

25
cm2/d
1) maximum dose per season
2) drift rate for ornamentals > 50 cm used as a default for herbicidal applications under high crops, 82 th percentile for 2 applications
Table A 10: Estimation of resident exposure towards glyphosate (‘worst case’ if no applications on lawn, pasture and meadow are intended)
Adults
Children
Residents: Systemic dermal exposure after application under high crops (via deposits caused by spray drift)
SDER = (AR x NA x D x TTR x TC x H x DA) / BW
SDER = (AR x NA x D x TTR x TC x H x DA) / BW
(0.0432 x 7.23 % x 5 % x 7300 x 2 x 0.31.0 %) / 60
(0.0432 x 1 x 7.23 % x 5 % x 2600 x 2 x 0.31.0 %) /
16.15
External dermal
exposure
2.280053
mg/person
External dermal exposure
0.812074
mg/person
External dermal
exposure
0.038001
mg/kg bw/d
External dermal exposure
0.050283
mg/kg bw/d
Systemic dermal
exposure
0.000114
0.000380
mg/kg bw/d
Systemic dermal exposure
0.000151
0.000503
mg/kg bw/d
Residents: Systemic inhalation exposure after application under high crops (via vapour)
SIER = (ACV x IR x IA) / BW
SIER = (ACV x IR x IA) / BW
(0.001 x 16.57 x 100 %) / 60
(0.001 x 8.31 x 100 %) / 16.15
External inhalation
exposure

0.01657
mg/person
External inhalation
exposure
0.00831
mg/person
External inhalation
exposure
0.000276
mg/kg bw/d
External inhalation
exposure
0.000515
mg/kg bw/d
Systemic inhalation exposure
0.000276
mg/kg bw/d
Systemic inhalation exposure
0.000515
mg/kg bw/d
Residents: Systemic oral exposure (hand-to-mouth
transfer)
SOER(H) = (AR x NA x D x TTR x SE x SA x Freq x H x
OA) / BW
(0.0432 x 1 x % x 5 % x 50 % x 20 x 20 x 2 x 20 %) /
16.15
External oral exposure
0.062467
mg/person
External oral exposure
0.003868
mg/kg bw/d
Systemic oral exposure
0.000774
mg/kg bw/d
Residents: Systemic oral exposure (object-to-mouth
transfer)
SOER(O) = (AR x NA x D x DFR x IgR x OA) / BW
(0.0432 x 1 x % x 20 % x 25 x 20 %) / 16.15
External oral exposure
0.015617
mg/person
External oral exposure
0.000967
mg/kg bw/d
Systemic oral exposure

0.000193
mg/kg bw/d
Total systemic exposure: SER = SDER + SIER
Total systemic exposure: SER = SDER + SIER + SOER(H)
+ SOER(O)
Total systemic exposure
0.02341
0.039372
mg/person
Total systemic exposure
0.026363
0.032048
mg/person
Total systemic exposure
0.00039
0.000656
mg/kg bw/d
Total systemic exposure
0.001632
0.001984
mg/kg bw/d
% of AOEL
0.390.66
%
% of AOEL
1.631.98
%
Table A 11: Input parameters considered for the estimation of resident exposure ('worst case' if applications on lawn, pasture and meadow are intended)
Intended uses:
Pastures, lawn, meadow
Deposit (D):
100
Application rate (AR):
2.16
kg a.s./ha
Transfer coefficient (TC):
7300
cm2/h (adults)
0.0216
mg/cm2
2600
cm2/h (children)
Number of applications
(NA):
2

Turf Transferable
Residues (TTR):
5
%
Body weight (BW):
60
kg/person
(adults)
Exposure Duration (H):
2
h
16.15
kg/person
(children)
Airborne Concentration of
Vapour (ACV):
0.001
mg/m3
Dermal absorption (DA):
0.31.0
% ('worst case')
Inhalation Rate (IR):
16.57
m3/d (adults)
Inhalation absorption
(IA):
100
%
8.31
m3/d (children)
Oral absorption (OA):
20
%
Saliva Extraction Factor
(SE):
50
%
AOEL:
0.1
mg/kg bw/d
Surface Area of Hands
(SA):
20
cm2
Frequency of Hand to
Mouth (Freq):

20
events/h
Dislodgeable foliar
residues (DFR):
20
%
Ingestion Rate for
Mouthing of Grass/Day (IgR):
25
cm2/d
Table A 12: Estimation of resident exposure towards glyphosate (‘worst case’ if applications on lawn, pasture and meadow are intended)
Adults
Children
Residents: Systemic dermal exposure after application on pastures, lawn, meadow (via deposits caused by
spray drift)
SDER = (AR x NA x D x TTR x TC x H x DA) / BW
SDER = (AR x NA x D x TTR x TC x H x DA) / BW
(0.0216 x 2 x 100% x 5% x 7300 x 2 x 0.31.0%) / 60
(0.0216 x 2 x 100% x 5% x 2600 x 2 x 0.31.0%) /
16.15
External dermal
exposure
31.536
mg/person
External dermal
exposure
11.232
mg/person
External dermal
exposure
0.52560
mg/kg bw/d
External dermal
exposure
0.69548
mg/kg bw/d
Systemic dermal
exposure
0.001577
0.0052560
mg/kg bw/d
Systemic dermal
exposure
0.002086

0.0069548
mg/kg bw/d
Residents: Systemic inhalation exposure after application on pastures, lawn, meadow (via vapour)
SIER = (ACV x IR x IA) / BW
SIER = (ACV x IR x IA) / BW
(0.001 x 16.57 x 100%) / 60
(0.001 x 8.31 x 100%) / 16.15
External inhalation
exposure
0.01657
mg/person
External inhalation
exposure
0.00831
mg/person
External inhalation exposure
0.000276
mg/kg bw/d
External inhalation exposure
0.000515
mg/kg bw/d
Systemic inhalation
exposure
0.000276
mg/kg bw/d
Systemic inhalation
exposure
0.000515
mg/kg bw/d
Residents: Systemic oral exposure (hand-to-mouth
transfer)
SOER(H) = (AR x NA x D x TTR x SE x SA x Freq x H
x OA) / BW
(0.0216 x 2 x % x 5% x 50% x 20 x 20 x 2 x 20%) /
16.15
External oral exposure
0.864
mg/person
External oral exposure
0.053498
mg/kg bw/d
Systemic oral exposure
0.0107
mg/kg bw/d
Residents: Systemic oral exposure (object-to-mouth
transfer)

SOER(O) = (AR x NA x D x DFR x IgR x OA) / BW
(0.0216 x 2 x % x 20% x 25 x 20%) / 16.15
External oral exposure
0.216
mg/person
External oral exposure
0.013375
mg/kg bw/d
Systemic oral exposure
0.002675
mg/kg bw/d
Total systemic exposure: SER = SDER + SIER
Total systemic exposure: SER = SDER + SIER +
SOER(H) + SOER(O)
Total systemic exposure
0.111178
0.331932
mg/person
Total systemic
exposure
0.258006
0.336631
mg/person
Total systemic exposure
0.001853
0.005532
mg/kg bw/d
Total systemic
exposure
0.015976
0.020844
mg/kg bw/d
% of AOEL
1.855.53
%
% of AOEL
15.98
20.84
%
Worker exposure calculations (IIIA 7.5)
Table A 13: Input parameters considered for the estimation of worker exposure
Intended use(s):
All high crops intended
Dislodgeable foliar residues (DFR):
1
µg/cm2/kg a.s.

Application rate (AR):
4.32 1)
kg a.s./ha
Transfer coefficient (TC):
5000
cm2/person/h
Number of applications (NA):
Work rate per day (WR):
8
h/d
Body weight (BW):
60
kg/person
PPE
5
%
Dermal absorption (DA):
0.31.0
% ('worst case')
AOEL
0.1
mg/kg bw/d
1) Maximum dose per season, therefore no number of applications considered; no degradation between splitted dose applications taken into account
Table A 14: Estimation of worker exposure towards glyphosate using the German re-entry model
Without PPE 1)
With PPE 2)
Worker (re-entry): Systemic dermal exposure after application under high crops
SDEW = (DFR x TC x WR x AR x DA) / BW
SDEW = (DFR x TC x WR x AR x PPE x DA) / BW
(1 x 5000 x 8 x 4.32 x x 0.31.0 %) / 60
(1 x 5000 x 8 x 4.32 x x 5 % x 0.31.0 %) / 60
External dermal
exposure
172.8
mg/person
External dermal exposure
8.64
mg/person
External dermal
exposure
2.88
mg/kg bw/d
External dermal exposure
0.144
mg/kg bw/d

Total systemic exposure
0.5184
1.7280
mg/person
Total systemic exposure
0.02592
0.0864
mg/person
Total systemic exposure
0.00864
0.02880
mg/kg bw/d
Total systemic exposure
0.000432
0.00144
mg/kg bw/d
% of AOEL
8.628.8
%
% of AOEL
0.41.4
%
1) acceptable without PPE: Treated areas/crops may not be entered until the spray coating has dried
2) acceptable only with PPE: see ‘instructions for use’