

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 Bleeker, 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

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).