

Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



FORAMSULFURON

Volume 3 – B.4 (AS)

Rapporteur Member State: Finland
Co-Rapporteur Member State: Slovakia

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Volume 1

Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application

Level 2: Summary of active substance hazard and of product risk assessment

Level 3: Proposed decision with respect to the application

Appendix 1: Guidance documents used in this assessment

Appendix 2: Reference list

Volume 2

Annex A: List of the tests, studies and information submitted

Volume 3

Annex B (Active Substance): Summary, evaluation and assessment of the data and information

Annex B.1 (AS): Identity

Annex B.2 (AS): Physical and chemical properties of the active substance

Annex B.3 (AS): Data on application

Annex B.4 (AS): Further information

Annex B.5 (AS): Methods of analysis

Annex B.6 (AS): Toxicology and metabolism data

Annex B.7 (AS): Residue data

Annex B.8 (AS): Environmental fate and behaviour

Annex B.9 (AS): Ecotoxicology data

Volume 3

Annex B (Plant Protection Product): Summary, evaluation and assessment of the data and information

Annex B.1 (PPP): Identity

Annex B.2 (PPP): Physical and chemical properties of the plant protection product

Annex B.3 (PPP): Data on application and efficacy

Annex B.4 (PPP): Further information

Annex B.5 (PPP): Methods of analysis

Annex B.6 (PPP): Toxicology and metabolism data and assessment of risks to humans

Annex B.7 (PPP): Residue data

Annex B.8 (PPP): Environmental fate and behaviour and environmental exposure assessment

Annex B.9 (PPP): Ecotoxicology data and assessment of risks for non-target species

Volume 4

Annex C: Confidential information and, where relevant, details of any task force formed for the purpose of generating tests and studies submitted

List of Endpoints

Version History

When	What
2015/March	First draft RAR

Table of contents

B.4. FURTHER INFORMATION.....	5
B.4.1. METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE	5
B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION	6
B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT.....	6
B.4.4. REFERENCES RELIED ON	7

B.4. FURTHER INFORMATION

This dossier contains old study reports, already submitted by Bayer for the first Annex I inclusion of foramsulfuron, as well as new data that have not been evaluated yet at EU level and that are considered by BCS to be necessary for the Annex I renewal of this active substance. General information has been given under each point. Where studies were previously submitted at EU level no study summary has been provided and the study box is in grey text. In this section the only new data that are provided are an updated MSDS according to new classification requirements.

B.4.1. METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE

Report:	KCA 3.8 /02;Anon.;2013;M-470109-01
Title:	Foramsulfuron TC FP
Report No.:	M-470109-01
Document No.:	M-470109-01
Guidelines:	according to Regulation (EC) No. 1907/2006 EC Directive 2001/58/EC;not specified
GLP/GEP:	N

The MSDS submitted for the first approval was done according to the old EU requirements. A new MSDS (KCA 3.8/02) has been prepared according to Regulation 1907/2006. Please refer to the MSDS for full details relating to the handling, storage, transport and actions in case of a fire.

Handling:

Advice on safe handling	Use only in area provided with appropriate exhaust ventilation.
Advice on protection	Dust may form explosive mixture in air. Keep away from heat and sources of ignition
Personal protective equipment	Avoid contact with skin, eyes and clothing. Keep working clothes separately. Wash hands before breaks and immediately after handling the product. Remove soiled clothing immediately and clean thoroughly before using again. Garments that cannot be cleaned must be destroyed (burnt).

Storage:

Requirements for storage areas and containers	Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a place accessible by authorized persons only. Keep away from direct sunlight.
Advice on common storage	Keep away from food, drink and animal feeding stuffs.

Transport:

Further information	According to ADN/ADR/RID/IMDG/IATA not classified as dangerous goods.
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Fire:

Suitable extinguishing media	Water spray, Carbon dioxide (CO ₂), Foam, Sand
Extinguishing media which must not be used for safety reasons	High volume water jet.
Specific hazards during fire fighting	In the event of fire the following may be released: Hydrogen cyanide (hydrocyanic acid), Carbon monoxide (CO), Sulphur oxides, Nitrogen oxides (NOx)

Special protective equipment for fire-fighters	In the event of fire and/or explosion do not breathe fumes. In the event of fire, wear self-contained breathing apparatus.
Further information	Contain the spread of the fire-fighting media. Do not allow run-off from firefighting to enter drains or water courses.

B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION

Pyrolytic behaviour under controlled conditions at 800°C

Foramsulfuron contains no halogen atom, i.e. the halogen content is 0% (w/w).

Possible co-formulated active substances as well as the formulation additives have halogen contents considerably below 60 % (w/w) or contain no halogen at all. The total halogen content in formulated products is therefore below the trigger value of 60 % (w/w).

Consequently, additional studies on the pyrolytic behaviour, combustion products and contents of polyhalogenated dibenzo-p-dioxins and dibenzo-furanes in the products of pyrolysis are not required for foramsulfuron or for plant protection products (preparations, formulations) containing foramsulfuron.

No methods other than controlled incineration are recommended.

Detailed instructions of safe disposal

Leftover quantities must be burned in a commercial incinerator

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

First aid measures:

Inhalation	Move to fresh air. Keep patient warm and at rest. Call a physician or poison control center immediately.
Skin contact	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Do NOT induce vomiting. Call a physician or poison control center immediately.
General advice	Move out of dangerous area. Place and transport victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Notes to physician:	
Symptoms	No symptoms known or expected.
Treatment	Treat symptomatically. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. There is no specific antidote.

B.4.4. REFERENCES RELIED ON**Literature search:**

The literature search carried out by the applicant was summarised in Document MCA section 9. The RMS considers the literature search provided as acceptable.

Databases: STN, a scientific information platform hosted by CAS, itself a division of the American Chemical Society, was selected as the preferred provider. Following data bases were used for the literature search: Agricola, Biosis, CABA, Chemical Abstracts, Derwent Drug File (DRUGU), EMBASE, Esbiobase, IPA, Medline, Pascal, PQSciTech, Registry, Scisearch, Toxcenter, Ulidat and FSTA.

Time window: January 1st 2004 – August 2nd 2013 for the parent compound and metabolites.

Input parameters: IUPAC name, CAS number, common name, code and abbreviation, molecular structure, molecular formula, molar mass and/or other names/codes, as far as available.

Results: A total of 430 identified and evaluated for potential relevance for foramsulfuron and its metabolites. Of these, 384 summary records were excluded after a rapid assessment of relevance, and 46 full-text documents were assessed in detail.

As a summary 45 studies were excluded from the risk assessment because the publications did not meet the relevance criteria for the detailed assessment. Moreover, one study was unclear of relevance and only one study from the whole literature search was revealed for further examination (KCA 8.6.2).

A reference list containing these 46 documents were included in Doc MCA section 9.

There were no articles with relevance for this section.

Study KCA 3.8/01 have been replaced by study done with new purity and specification of active substance. All relevant information are in the new study. The study is acceptable.

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
B.4.1 B.4.3 KCA 3.8/02	Anon.	2013	Foramsulfuron TC FP Bayer CropScience, Report No.: M-470109-01-1, Edition Number:M-470109-01-1 GLP/GEP: n.a., unpublished	N	N	Not relevant	Bayer CropScience	Submitted for the purpose of renewal