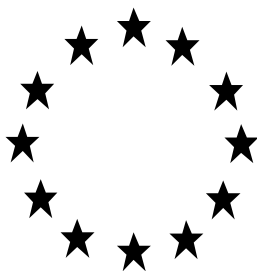


Draft Renewal Assessment Report
under Regulation (EC) 1107/2009



FORAMSULFURON
Volume 3 – B.4 (PPP) –
foramsulfuron+isoxadifen-ethyl OD 45
(22.5+22.5 g/L)

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

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Version History

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B.4. FURTHER INFORMATION

This dossier contains study reports already submitted by Bayer CropScience for the Annex I inclusion of foramsulfuron, as well as new data, not yet evaluated at EU level and that was considered by the applicant to be necessary for the renewal of approval of foramsulfuron. In order to distinguish these reference to studies in the original dossier are depicted in grey.

For summaries of studies submitted during the frame of the first Annex I inclusion, please refer to the corresponding section in the Monograph.

Copies of the study reports are provided in the baseline dossier provided by Bayer CropScience.

Additional studies which were not submitted during the Annex I inclusion process are provided in the dossier and summarized in this document.

B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

Pre-harvest interval (in days) for each relevant crop:

It is not necessary to define a pre-harvest interval. Instead, the pre-harvest interval is given by the growing period between the growth stage at treatment and harvest.

Re-entry period (in days) for livestock, to areas to be grazed:

Foramsulfuron is not intended for use in areas where livestock animals may be grazed. Therefore no re-entry period needs to be proposed.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated:

Foramsulfuron is intended for use in maize. Re-entry in treated fields is generally not necessary. Therefore no re-entry period needs to be proposed for European product labels.

Withholding period (in days) for animal feeding stuffs:

Due to the time between last treatment and harvest, as defined by the GAPs, it is not necessary to set a withholding period for use of treated plants as animal feeding-stuff. Residues of foramsulfuron in corn grain were found to be below the limit of quantification (< 0.01 mg/kg) at harvest. Residues were also found to be below the limit of quantification (< 0.05 mg/kg) in green plants which might be used for silage. Due to the recommended application of products containing foramsulfuron, the withholding period is covered by the vegetation period of the crop.

Waiting period (in days) between application and handling of treated products:

Handling of treated crops is generally not required before harvest, which is always done mechanically. Thus, there is no need to define a waiting period between application and handling the treated corn commodities. It is covered by the vegetation period of the crop.

Waiting period (in days) between last application and sowing or planting succeeding crops:

No measurable residues are expected in succeeding crops. Therefore there is no need to define a waiting period before sowing or planting succeeding crops.

Information on specific conditions under which the preparation may or may not be used:

There are no specific conditions under which the preparation may not be used.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Recommended methods and precautions for the washing and cleaning of machinery and protective clothing. In the original dossier two reports were submitted concerning the cleaning of machinery and the quantification of foramsulfuron remaining in the tank rinses (KCP 4.2/01) and the impact of the rinse solutions on plants (KCP 4.2/02). It was concluded that the levels of foramsulfuron in the tank rinses were low and no impact was observed on plants.

Report:	KCP 4.2 /01;Jacob, T.; Rexer, K.;2000;M-194569-01-1
Title:	Determination of residual quantities of sulfonyl urea in fieldsprayers after rinsing AEF130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304

Report No.:	C006754
Document No.:	M-194569-01-1
Guidelines:	Deviation not specified
GLP/GEP	N

Report:	KCP 4.2 /02;Friessleben, R.;1999;M-193546-01-1
Title:	Bioassay results to characterise spray tank cleaning behaviour - tank wash recommendations Code: AE F130360 01 1K05 A3
Report No.:	C006246
Document No.:	M-193546-01-1
Guidelines:	Deviation not specified
GLP/GEP	N

The text below summarises the current recommendations for the washing and cleaning of machinery and protective clothing.

General statement

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:

Product left over in field spraying equipment which has not been sufficiently cleaned may cause damage during sequential treatment of sensitive crops. As a consequence, cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.

Procedure:

Empty the spraying equipment completely on the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Protective clothing:

All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.
- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

Effectiveness of the cleaning procedures

Since the first approval of foramsulfuron at European level Bayer CropScience has performed many tank cleaning studies for herbicides to avoid phytotoxicity in non-target crops. All these studies have been reviewed and summarised in the following document.

Report:	KCP 4.2/04;Friessleben, R.;2008;M-357166-01-1
Title:	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000-2008
Report No.:	M-357166-01-1
Document No.:	M-357166-01-1
Guidelines:	not specified
GLP/GEP	n.a.

The report summarizes the results of trials on tank cleaning realized in the years 2000-2008. These trials were carried out because registration of crop protection products requires specific information on the cleaning of sprayer tanks to avoid damages during subsequent treatments.

During this period, 72 studies were conducted, in which a total of 60 active substances (16 fungicides, 33 herbicides, 3 safeners, 7 insecticides and 1 growth regulator) were tested. All tests were done with the same spraying equipment and under the same test protocol, thus the differences found in the results reflect the different behaviour of active substances and formulation systems.

Within this report it has been shown that cleaning efficacy does not depend on chemical or formulation related parameters and therefore a global statement on tank cleaning efficacy is justified.

The results can be summarized as follows:

1. The established cleaning procedure, including two rinsing processes and the careful cleaning of all filters, is able to remove or reduce active substances leftover down to negligible quantities.
2. By following the tank cleaning recommendation product groups (herbicides, fungicides, insecticides, and growth regulators), formulations and concentrations differ only quantitatively. The cleaning success follows an exponential function of the general formula $y = a e^{-b \cdot x}$. From one cleaning step to the next one, the initial concentration is reduced by at least one order of magnitude.
3. After filling the tank with fresh water, the active substance concentrations in all trials are either below the Limit of Quantification or are not relevant as far as biological effects during follow-up treatments are concerned.
4. According to the extensive number of results available, the recommendations on the product label regarding tank cleaning can apply equally to all products.

Guidelines in the case of fire.

In the original dossier a report was submitted regarding guidelines in case of fire. The recommendations have not significantly changed over the years and the current MSDS (KCP 4.2/05) lists the current recommendations.

Report:	KCP 4.2 /05;Anon.;2013;M-443049-02-1; Amended: 2013-05-16
Title:	FSN+IDF OD 22,5+22,5A G-U-EU
Report No.:	M-443049-02-1
Document No.:	M-443049-02-1
Guidelines:	Regulation (EC) No. 1907/2006;not specified
GLP/GEP	N

Suitable extinguishing media:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Unsuitable extinguishing media:	High volume water jet
Specific hazards during fire fighting :	hydrogen cyanide (hydrocyanic acid), carbon monoxide (CO), 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 fire fighting to enter drains or water courses

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

In the original dossier a report was submitted regarding emergency measures in case of an accident. The recommendations have not significantly changed over the years and the current MSDS (KCP 4.2/05) lists the current recommendations.

Personal precautions:	Avoid contact with spilled product or contaminated surfaces.
Environmental precautions:	Do not allow to get into surface water, drains and ground water
First aid measures:	
General advice:	Move out of dangerous area. Place and transport

	victim in stable position (lying sideways). Remove contaminated clothing immediately and dispose of safely.
Inhalation:	Move to fresh air. Keep patient warm and at rest. If symptoms persist, call a physician.
Skin contact:	Wash off thoroughly with plenty of soap and water, if available with polyethyleneglycol 400, subsequently rinse with water. If symptoms persist, call a physician.
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
Notes to physician: symptoms	Aspiration may cause pulmonary oedema and pneumonitis., Symptoms and hazards refer to the solvent.
Notes to physician: 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. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

Report:	KCP 4.4 /01;Sixl, F.; Rexer, K.;1999;M-192367-01-1
Title:	Information on packaging AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A300
Report No.:	C005620
Document No.:	M-192367-01-1
Guidelines:	Deviation not specified
GLP/GEP	N

Description of packaging submitted for the first approval of foramsulfuron at European level.

Primary packaging (HDPE/PA):

Type: Coextruded blow-moulded container
 Materials: Polyamide (PA) / adhesive / high density polyethylene (HDPE) (from inside to the outside)
 Capacity: 0.25 to 10 litres
 Opening: Bottles 0.25 to 1 litre: KS 50 (DIN 6063, 50 mm)
 Container size: 3 to 10 litres: ECPA 63 (ECPA 63 mm Standard)
 Closure: Injection moulded with induction sealing disc
 KS 50: polyethylene or polypropylene
 ECPA 63: polyethylene

Primary packaging is in compliance with FAO Guidelines

Outer packaging:

Type: Corrugated case

Suitability of complete packaging:

Packages have been tested and comply with Annex A.5 of ADR respectively Annex V of RID respectively Annex I of IMDG-Code.

Resistance of packaging material to its contents

Resistance of the packaging material to its contents has been tested in accordance with GIFAP Technical Monograph No 17 (May 1993). The stability of primary packaging material is considered to be acceptable. No detrimental effects were noted after completion of the storage test of 24 months at ambient temperature. Appearance and weight change were acceptable, active content and suspensibility were within the specification, the packaging showed no sign of deformation and the closure seal was intact.

For the first approval only one type of packaging was presented. Today Bayer CropScience markets the formulation in HDPE/PA and HDPE/EVOH packaging. Please see below for details of the HDPE/EVOH packaging. Please note that in the storage stability studies reported in section 2 of this dossier (physical and chemical properties of the plant protection product) the storage stability studies were performed with both types of packaging.

Primary packaging (HDPE/EVOH):

The only difference between the original packaging (HDPE/PA) and the additional packaging (HDPE/EVOH) is the internal barrier layer. The additional packaging has an internal barrier layer made of ethylene vinyl alcohol copolymer (EVOH).

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

In the original dossier a report was submitted regarding destruction or decontamination of the plant protection product and its packaging. The recommendations have not significantly changed over the years and the current MSDS (KCP 4.2/05) lists the current recommendations.

Waste treatment methods :	
Product :	In accordance with current regulations and, if necessary, after consultation with the site operator and/or with the responsible authority, the product may be taken to a waste disposal site or incineration plant.
Contaminated packaging :	Not completely emptied packagings should be disposed of as hazardous waste
Waste key for the unused product :	020108 agrochemical waste containing dangerous substances
Accidental spillage :	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Clean contaminated floors and objects thoroughly, observing environmental regulations. Keep in suitable, closed containers for disposal.

B.4.5.1. Neutralisation procedure

Neutralisation procedures are not recommended for foramsulfuron containing products

B.4.5.2. Controlled incineration

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.

B.4.6. REFERENCES RELIED ON

Studies KCP 4.2/03, KCP 4.3/01 and KCP 4.5/01 are no longer important for the re-evaluation, all information needed are sufficiently covered in study KCP 4.2/05
All the remaining studies satisfy the conditions for re-approval of the ppp, they are 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.4.2 KCP 4.2/01	Jacob, T.; Rexer, K.	2000	Determination of residual quantities of sulfonyl urea in fieldsprayers after rinsing AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A304 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006754, Edition Number: M-194569-01-1 Date: 2000-01-10 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.4.2 KCP 4.2/02	Friessleben, R.	1999	Bioassay results to characterise spraytank cleaning behaviour-tank wash recommendations Code: AE F130360 01 1K05 A3 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006246, Edition Number:M-193546-01-1 Date: 1999-11-03 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001
B.4.2 KCP 4.2/04	Friessleben, R.	2008	Summary and conclusive report of studies on spray tank cleaning realized in the years 2000-2008 Bayer CropScience, Report No.:M-357166-01-1, Edition Number:M-357166-01-1 GLP/GEP: n.a., unpublished	N	N	Not relevant	Bayer CropScience	Submitted for the purpose of renewal

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.4.2 KCP 4.2/05	Anon.	2013	FSN+IDF OD 22,5+22,5A G-U-EU -public data-, Report No.:M-443049-02-1, Edition Number:M-443049-02-1 GLP/GEP: n.a., unpublished also filed KCP 4.2/03 also filed KCP 4.3/01 also filed KCP 4.5/01	N	N	Not relevant	Bayer CropScience	Submitted for the purpose of renewal
B.4.4 KCP 4.4/01	Sixl, F.; Rexer, K.	1999	Information on packaging AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Code: AE F130360 01 1K05 A300 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C005620, Edition Number:M-192367-01-1 Date: 1999-10-07 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	In DAR 2001