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

CLOPYRALID

Volume 3 – B.6 (PPP) – GF-1374

RMS: Finland
Co-RMS: Poland

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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
2017/ May	DRAR- First version submitted to EFSA

Table of contents

B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS 5

B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT 5

B.6.1.1. Oral 5
B.6.1.2. Dermal 6
B.6.1.3. Inhalation 7
B.6.1.4. Skin irritation 8
B.6.1.5. Eye irritation 9
B.6.1.6. Skin sensitization 11
B.6.1.7. Supplementary studies on the plant protection product 13
B.6.1.8. Supplementary studies for combinations of plant protection products 14

B.6.2. DERMAL ABSORPTION 14

B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS 14

B.6.4. EXPOSURE DATA 14

B.6.4.1. Operator exposure 15
B.6.4.2. Bystander and resident exposure 17
B.6.4.3. Worker exposure 20

B.6.5. EXPOSURE AND RISK ASSESSMENT 21

B.6.6. REFERENCES RELIED ON 23

B.6.7. ANNEX 1 DETAILED CALCULATION ON EXPOSURE ASSESSMENT 26

B.6. TOXICOLOGY AND METABOLISM DATA AND ASSESSMENT OF RISKS FOR HUMANS

B.6.1. ACUTE TOXICITY OF PLANT PROTECTION PRODUCT

The acute toxicity of GF-1374, an emulsifiable concentrate formulation, containing 80 g/L clopyralid, 2.5 g/L florasulam and 144 g/L fluroxypyr-meptyl (100 g a.e./L fluroxypyr), as the active ingredients, has been investigated in a package of acute studies. The product GF-1374 was not the representative formulation considered for Annex I inclusion and was not evaluated in the EU Review process earlier.

Results of the studies performed with GF-1374 are summarised in Table 6.1-1. GF-1374 is of low toxicity in respect to acute oral and dermal toxicity. However, GF-1374 is harmful by inhalation and irritating to the skin and to the eyes. All these studies were evaluated as acceptable. The skin sensitization potential could not be determined from the study evaluated as supportive, but the product is not classified as sensitizing to skin according to Regulation (EC) No. 1272/2008.

The kinematic viscosity of the product is < 20.5 mm^2/s and a co-formulant present in the product in a concentration of >10% has a harmonized classification Asp. Tox. 1; H304. Therefore the product is classified as Asp. Tox. 1; H304 according to Regulation (EC) No. 1272/2008.

Table 6.1-1 Summary of acute toxicity studies of GF-1374

Route/method	Species	Result/ Comment	Classification according to Regulation (EC) No. 1272/2008	Reference
Acute oral	Rat (Female)	LD_{50} = 3378 mg/kg	Not Classified	[redacted] (2005) Acceptable
Acute dermal	Rat	LD_{50} > 5000 mg/kg	Not Classified	[redacted] (2005) Acceptable
Acute inhalation	Rat	LC_{50} (males) = 4.58 mg/L LC_{50} (females) = 3.35 mg/L	Acute Tox. 4; H332	[redacted] *et al.* (2005) Acceptable
Skin irritation	Rabbit	Irritating to skin	Skin Irrit. 2; H315	[redacted] (2005) Acceptable
Eye irritation	Rabbit	Irritating to eyes	Eye Irrit. 2; H319	[redacted] (2005) Acceptable
Skin sensitisation (M&K)	Guinea pig	No result	Not classified, based on concentration limits.	[redacted] (2005) Supportive

B.6.1.1. Oral

Study:	GF-1374: Acute Oral Toxicity Up and Down Procedure in Rats ([redacted] 2005)
Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guidelines for the Testing of Chemicals, Procedure 425 (2001). The study is acceptable.

Guideline and GLP
Good Laboratory Practice Compliance Statement was provided. The study was performed in compliance with OECD guideline 425 (2008).

Materials and methods
GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) was administered by gavage to female Fischer 344 rats. A limit dose of 5000 mg/kg bw was administered to single female rat. Due to mortality of this animal, the study proceeded to the main test where

additional 13 animals were dosed at levels of 175, 550, 1750, or 5000 mg/kg bw, by up and down procedure. Dose progressions and stopping criteria were determined by a statistical program (The Acute Oral Toxicity Guideline 425, Statistical Program, Weststat, version 1.0, May 2001). Rats were fasted prior to dosing. Body weights were recorded prior to administration and again on days 7 and 14 after dosing. The animals were observed for mortality, signs of gross toxicity and behavioural changes at least once daily for up to 14 days after dosing. Necropsies were performed on all animals. The statistical program was also used for data analyses of LD_{50} and confidence limit calculations.

Results
At the dose levels 175 mg/kg bw (1 animal) and 550 mg/kg bw (1 animal) both animals survived. The animals gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse clinical signs or abnormal behaviour. No gross abnormalities were noted for either animal during necropsy at the end of the 14-day observation period.

At the dose level of 1750 mg/kg bw (5 animals), all animals survived exposure to the test material. Animals gained body weight during the study. Following administration, most animals exhibited clinical signs including reduced faecal volume, piloerection, and hypoactivity. However, the affected animals recovered by day 2 and appeared active and healthy for the remainder of the 14-day observation period. No gross abnormalities were noted for any of the animals during necropsy at the end of the 14-day observation period.

At the dose level of 5000 mg/kg bw (7 animals), 6 animals died within 2 days of test material administration. Adverse clinical signs noted prior to death were hypoactivity and abnormal posture. The surviving animal exhibited similar clinical signs as well as reduced faecal volume. However, this animal recovered by Day 4 and appeared active and healthy for the remainder of the study, gaining body weight over the entire 14-day observation period. Gross necropsy of the decedents revealed discoloration of the lungs and/or intestines, and a fluid-filled stomach. No gross abnormalities were noted for the euthanized animal during necropsy at the end of the 14-day observation period.
Based on the statistical method associated with this test guideline, the LD_{50} was reported as 5000 mg/kg bw, with a 95% PL (Profile-likelihood based confidence interval) confidence interval of 2,367 mg/kg (lower) to 5,300 mg/kg (upper).

According to the notifier, following completion of this study, calculation of the estimated LD_{50} was performed by linear interpolation of the arcsine transformed data as shown in Table 6.1-2. An approximate LD_{50} of 3378.1 mg/kg bw was obtained by linear interpolation of the arcsine transformed data between 1750 and 5000 mg/kg bw.

Table 6.1-2 Mortality in female rats and calculation of estimated LD_{50}

Dose level (mg/kg bw)	Number dead/ Number dosed	Percent Dead (%)	Binomial Probability (%)
175	0/1	0	50.0
550	0/1	0	50.0
1750	0/5	0	3.125
5000	6/7	85.7	6.250

Conclusion
The LD_{50} was reported as 5000 mg/kg bw, with a 95% PL (Profile-likelihood based confidence interval) confidence interval of 2,367 mg/kg (lower) to 5,300 mg/kg (upper). By linear interpolation the acute oral LD_{50} was estimated to be 3378 mg/kg bw in female rats. It is reasonable to conclude that the product is therefore not classified for acute oral toxicity according to Regulation (EC) No. 1272/2008. The study is acceptable.

B.6.1.2. Dermal

Study:	GF-1374: Acute Dermal Toxicity Study in Rats – Limit Test ([redacted] 2005)

Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guidelines for the Testing of Chemicals, Procedure 402 (1987). The study is acceptable.

Guideline and GLP
Good Laboratory Practice Compliance Statement was provided. The study was performed in compliance with OECD guideline 402 (1987).

Materials and methods
GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) was applied at dose level of 5000 mg/kg bw to the clipped skin of ten Fischer 344 rats (5 males, 5 females). The test substance was applied to a gauze pad which was placed to an area of approximately 10 % of the body surface. The test site was further covered by tape wrapping to avoid dislocation of the pad. After 24 hours the pads were removed and the test site was cleansed. Body weights were recorded prior to application and again on days 7 and 14. The animals were observed for mortality, signs of gross toxicity and behavioural changes at least once daily for 14 days. Necropsies were performed on all animals.

Results
All animals survived, gained body weight, and appeared active and healthy. There were no signs of gross toxicity, dermal irritation, adverse clinical signs, or abnormal behaviour. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

Conclusion
Under the experimental conditions, the dermal LD_{50} of GF-1374 was found to be >5000 mg/kg bw in male and female rats. The product is not classified according to Regulation (EC) No. 1272/2008. The study is acceptable.

B.6.1.3. Inhalation

Study:	GF-1374: Acute Liquid Aerosol Inhalation Toxicity Study in Fischer 344 Rats ([redacted] 2005)
Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guideline 403 (1981). The study is acceptable.

Guideline and GLP
A statement of Compliance with Good Laboratory Practice Standards was provided. The study was mainly performed in compliance with OECD guideline 403 (2009). The mean relative chamber humidity was 13.2% at the minimum, however this was considered not to influence adversely to the result of the study. It seems that chamber equilibration time (t_{95}) was not given.

Materials and methods
The acute inhalation toxicity of aerosolized GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) was evaluated in groups of 5 Fischer 344 rats/sex.

A liquid aerosol of GF-1374 was generated by metering the test material with an FMI pump into a stainless steel ¼-J spray nozzle. The test material was mixed with compressed air in the spray nozzle and aerosol was sprayed into the chamber. Since the formulation contained materials of varying vapour pressures, the test material was not recycled.

The animals were exposed for 4 hours, using a nose-only inhalation exposure system, to a time-weighted average (TWA) chamber concentration of 5.11 mg GF-1374/L. The mass median aerodynamic diameter (MMAD) of aerosolised GF-1374 present in the exposure chamber atmosphere was 2.41 µm with an average geometric standard deviation of 2.22 µm. Approximately 87.7 % of the particulate mass was present in size fractions with an aerodynamic diameter less than 6.1 µm.

Due to the mortality observed at 5.11 mg/L, a second group of rats was subsequently exposed to a TWA chamber concentration of 2.19 mg GF-1374/L. The MMAD of GF-1374 present in the exposure chamber

atmosphere averaged 2.28 µm with an average geometric standard deviation of 2.20 µm. Approximately 92.6% of the particulate mass was present in size fractions with an aerodynamic diameter less than 6.1 µm.

Exposure room and chamber temperature, humidity and airflow were recorded approximately every 30 minutes during exposure. The mass concentration of aerosol in the chamber was gravimetrically determined three times during exposure. The time-weighted-average (TWA) exposure concentration was calculated from the combined aerosol and vapor gravimetric measurements after subtraction of the background measurements. The nominal concentration was calculated based on the amount of test rraterial fed into the generation system divided by the total chamber airflow during the exposure period. The aerodynamic particle size was determined twice during the exposure period through a multi-stage cascade impactor.

A cage-side examination was conducted at least once a day and all animals were observed for morbidity and mortality at least twice daily. Animals were weighed and examined prior to exposure and observed at least every 30 minutes during the exposure period. All surviving rats were weighed on test Days 2, 4, 8, 11 and 15 during the 2-week post-exposure period. All surviving rats were submitted for a complete gross necropsy examination on test Day 15. The necropsy included examination of the eyes with a microscope slide using fluorescent illumination. Tissues were not saved and no histopathologic examination was performed. Detailed clinical observations (DCO) were conducted pre-exposure and daily following the start of treatment. The examination included cage-side, hand-held and open-field observations.

Results
At the exposure level of 5.11 mg/l the nominal concentration was 8.44 mg/l and at 2.19 mg/l the nominal concentration was 5.10 mg/l.

Two males and one female died during exposure at 5.11 mg/L. Two additional females died 1 hour after the exposure and the remaining 2 females and 1 male were found dead on test day 2 and 3, respectively. Clinical observations for the surviving male rats included noisy respiration with laboured mouth-breathing, decreased reactivity to stimuli, decreased responsiveness to touch, decreased faeces, and soiling of the perioral, perineal, perinasal and/or the abdominal regions. One of the male rats was normal by test day 11. The other male rat had cloudy eyes and noisy respiration, which persisted until the scheduled necropsy. The mean body weight of males was decreased compared to weight on study day 1, throug the study. All rats exposed to 5.11 mg/L that died prior to the scheduled necropsy had treatment related gross alterations of the upper and lower respiratory tract consisting of various combinations of oedema, mottled or dark pulmonary lesions, tracheal froth, dark anterior nasal turbinates and hydrothorax. Other treatment-related gross findings included body soiling, tissue congestion and ulcers of the stomach. One male exposed to 5.11 mg/L that survived the two-week observation period had cloudy corneas, and the other surviving rat from this exposure level had no gross observations.

All animals survived the four-hour exposure to 2.19 mg/L GF-1374 as well as the 2 week observation period. There were no clinical effects noted during the 4-hour exposure period. Post-exposure clinical effects were noted in all male and female rats and included noisy respiration and perioral, perinasal, perineal and extensive soiling. All female and male rats appeared normal by test day 2 or 3. Pre-exposure mean body weight values were exceeded by test day 8 in both males and females. There were no treatment-related gross pathologic observations in males or females exposed to 2.19 mg/L GF-1374.

Conclusion
Based on linear interpolation of the data, the four-hour LC_{50} of inhaled GF-1374 is 4.58 mg/L for males and 3.35 mg/L for females. The product is classified as Acute Tox. 4; H332 according to Regulation (EC) No 1272/2008. The study is acceptable.

B.6.1.4. Skin irritation

Study:	GF-1374: Primary Skin Irritation Study in Rabbits ([redacted] 2005)
Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guideline 404 (2002). The study is acceptable.

Guideline and GLP

A Good Laboratory Practice Compliance Statement was provided. The study was mainly performed in compliance with OECD guideline 404 (2015). The relative humidity of animal room exceeded the upper range of 70 % given in OECD guideline. It seems that the residual test item was not removed from skin by using e.g. water at the end of exposure perioid. The weight and exact age of the animals was not given.

Materials and methods
The potential of GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) to cause dermal irritation was evaluated in New Zealand albino rabbits (2 males and 1 female). Day before the application of test material the animals were prepared by clipping the dorsal area and the trunk. Initially, one rabbit was tested and three test sites, each approximately 6 cm², were delineated on this animal. An aliquot of 0.5 mL GF-1374 was applied to each dose site and covered with a 1-inch x 1-inch, 4-ply gauze pad. The pad and entire trunk of each animal were then wrapped with semi-occlusive 3-inch Micropore tape to avoid dislocation of the patch. The patches were removed at the appropriate intervals (3 minutes, 1 hour, and 4 hours). All test sites were evaluated for corrosion 1 hour after patch removal. Subsequent evaluations were performed approximately 24, 48, and 72 hours and at 7, 10, and 14 days after removal of the 4-hour patch. Since there was no corrosion observed at any of the test sites for this animal, 2 additional rabbits were selected for testing and had the material applied for 4 hours. Dose sites were scored according to the Draize scoring system. At least once daily the animals were observed for signs of gross toxicity and behavioural changes.

Results
All animals appeared active and healthy. It was reported that apart from the dermal irritation noted below, there were no other signs of gross toxicity, adverse clinical signs, or abnormal behaviour. In the first animal, very slight erythema was noted at the 3-minute site 1 hour after patch removal until 72 hours. Very slight to well-defined erythema and oedema were observed at the 1-hour site 1 hour after patch removal. Very slight irritation persisted at the 1-hour site through day 14. Well-defined to moderate to severe erythema and very slight to slight oedema were observed at the 4-hour sites on all 3 animals over the 72-hour period following patch removal (Table 6.1-3). Although the incidence and severity of irritation decreased thereafter, erythema and/or oedema persisted at all 4-hour exposure sites through day 14 (study termination).

Table 6.1-3 Individual and mean scores for skin irritation (4 hour exposure)

Animal	Time after removal of patch (erythema/edema)							Mean (24h– 72h)
	1 h	24 h	48 h	72 h	7 d	10 d	14 d	
1 (male)	2/1	3/2	2/2	2/2	2/2	2/1	1/0	2.3 / 2
2 (male)	2/1	3/2	3/2	3/2	2/2	1/1	1/0	3 / 2
3 (female)	2/1	3/2	3/2	3/2	3/2	2/1	1/1	3 / 2

Conclusion
Under the conditions of this study, GF-1374 caused well-defined to moderate to severe erythema and very slight to slight oedema following a 4-hour exposure. Signs of irritation persisted through day 14 (study termination). Based on the results of this study, the product is classified as Skin Irrit. 2; H315 according to Regulation (EC) No. 1272/2008. The study is acceptable.

B.6.1.5. Eye irritation

Study:	GF-1374: Primary Eye Irritation Study in Rabbits ([redacted] 2005)
Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guideline 405 (2002). The study is acceptable.

Guideline and GLP
A Good Laboratory Practice Compliance Statement was provided. The study was mainly performed in compliance with OECD guideline 405 (2012). No analgesic was used before or after test substance administration. The exact age and weight of the animals was not given.

Materials and methods
The potential of GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) to cause eye irritation was evaluated in New Zealand albino rabbits (2 males and 2

females). Prior to instillation the eyes of the rabbits were examined with fluorescein dye procedure (2% ophthalmic fluorescein sodium). Animals without pre-existing ocular irritation were selected for the test.

Initially, one rabbit was placed on the test. An aliquot of 0.1 mL of GF-1374 was instilled into the conjunctival sac of the right eye of the first rabbit by pulling the lower lid away from the eyeball. The upper and lower lids were then gently held together for about 1 second before releasing. Since irritation cleared from the eye of the first animal treated by day 10, two additional animals were tested following the same procedure. Since one of these animals died on test day 8, an additional animal was placed on test following the same procedure.

Due to the irritation noted in the first animal dosed, 2 drops of ocular anaesthetic (Proparacaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the treated and control eye of the remaining 2 animals prior to instillation of the test material. Following instillation of the anaesthetic, 0.1 mL of the test material was instilled into the conjunctival sac of the right eye of these rabbits as before. The other eye of each rabbit remained untreated with the test material and served as a control.

Immediately following the 1-hour evaluation on day 0, the first two animals placed on test received 1-2 drops of ocular anaesthetic (Tetracaine Hydrochloride Ophthalmic Solution, 0.5%) into both the treated and control eye. This treatment continued every 2 hours until the end of day 0 when the treatment was terminated.

Ocular irritation was evaluated using a high-intensity white light (MagLite) in accordance with Draize et al. 1, 24, 48, and 72 hours and at 4, 7, and/or 10 days post-instillation. The fluorescein dye evaluation procedure was used at 24 hours and as needed at subsequent scoring intervals to evaluate the extent of corneal damage or to verify reversal of effects. Individual scores were recorded for each animal. In addition to observations of the cornea, iris, and conjunctivae, any other observed lesions were noted. The animals were observed for signs of gross toxicity and behavioural changes at least once daily during the test period. Observations included gross evaluation of skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity and behaviour pattern.

Results

One animal died spontaneously on test Day 8. According to study report, the cause of death did not appear to be related to the application of the test material and the gross necropsy of the animal revealed fluid in the abdominal cavity and mucous in the G.I. tract. The three remaining animals appeared active and healthy. Apart from the eye irritation noted below (table 6.1-4), it was reported in the study report that there were no other signs of gross toxicity, adverse clinical signs, or abnormal behaviour. Within 24 hours of test material instillation, all 3 treated eyes exhibited corneal opacity and conjunctivitis and one animal developed iritis. The overall incidence and severity of irritation decreased gradually after day 4. All animals were free of ocular irritation by day 10 (study termination).

Table 6.1-4 Individual and mean scores for eye irritation

Time after instillation	**Animal**		
	1 (female)	**2 (male)**	**3 (female)**
Conjunctivae redness			
1 h	3	2	2
24 h	2	3	2
48 h	2	2	2
72 h	2	2	2
4 d	1	2	1
7 d	1	2	0
10 d	0	0	-
Mean score (24-72 h)	2	2.3	2
Conjunctivae chemosis			
1 h	2	2	2
24 h	2	2	2
48 h	2	2	1
72 h	2	2	0
4 d	1	1	0
7 d	0	0	0
10 d	0	0	-

Mean score (24-72 h)	2	2	1
Cornea Opacity			
1 h	0	0	0
24 h	1	1	1
48 h	1	1	1
72 h	1	1	1
4 d	1	1	1
7 d	1	1	0
10 d	0	0	-
Mean score (24-72 h)	1	1	1
Iris			
1 h	0	0	0
24 h	0	1	0
48 h	0	1	0
72 h	0	1	0
4 d	0	1	0
7 d	0	1	0
10 d	0	0	-
Mean score (24-72 h)	0	1	0

The results from the animal that was found dead on day 8 were in line with the results shown above, the mean scores (24-72 h) being for corneal opacity 1, iris 1, conjunctivae redness 2.3 and conjunctivae chemosis 2. Irritation was present on day 7.

Conclusion
Under the experimental conditions, GF-1374 caused corneal opacity and conjunctivitis and 1 animal developed iritis. All signs of irritation had cleared by day 10 (study termination). Based on the results, the product is classified as Eye Irrit. 2; H319 according to Regulation (EC) No 1272/2008. The study is acceptable.

B.6.1.6. Skin sensitization

Study:	GF-1374: Dermal Sensitization Study in Guinea Pigs (Magnusson-Kligman Method), ([redacted] 2005)
Previous evaluation:	This study was submitted for the purpose of renewal and was not evaluated in the DAR (2003). It was mentioned to be performed according to the OECD Guideline 406 (1992). The study is for supportive information.

Guideline and GLP
A Good Laboratory Practice Statement was provided. The study was mainly performed in compliance with OECD guideline 406 (1992). The relative humidity of animal room exceeded the upper range of 70 % given in OECD guideline. The exact age of the animals was not given. Irritation data after intradermal injection in the main test was not presented in the study report. The scoring system for erythema differs slightly from that given in the OECD guideline.

Materials and methods
The dermal sensitization potential of GF-1374 (containing 142 g/L fluroxypyr-meptyl, 86 g/L clopyralid and 2.5 g/L florasulam as the active substances) was evaluated in male and female Hartley albino guinea pigs. Individual body weights of the animals were recorded just prior to the intradermal induction and again on the day of the 24-hour post-challenge scoring.

Preliminary Irritation Test:
Two animals (males) were used to determine the concentration of the test material which produced very faint to moderate irritation via intradermal injection. The fur was removed by clipping the suprascapular area of each guinea pig. This area was divided into 6 test sites (3 sites on each side of the midline) on each animal. Each guinea pig received 6 intradermal injections, 0.1 mL each. Three concentrations, 1%, 3%, and 5%, of the test material in distilled water and the same concentrations in an emulsion of Complete Freund's Adjuvant were assessed. Approximately 24 hours after the injections, each site was evaluated for local reactions (erythema).

Four animals (males) were used to determine the concentration to be used during the topical induction. The suprascapular area of each guinea pig was divided into 2 sites (1 site on each side of the midline). The test material was applied neat (100%) and also diluted with distilled water to yield w/w concentrations of 75%, 12%, and 4%. Each concentration was applied, 0.5 mL each, to 1 of the 2 test sites using a 2-cm x 4-cm, 2-ply gauze patch. The patch was covered with plastic wrap and secured in place with non-allergenic Durapore adhesive tape. After the 48-hour exposure period, the patches were removed and the test sites were cleansed of residual test material. One hour after patch removal, readings were made of local reactions (erythema).

A group of 9 animals (2 males, 7 females) was used to determine the highest non-irritating concentration. The fur was removed by clipping the suprascapular area of each guinea pig. This area was divided into 4 test sites (2 sites on each side of the midline) on each animal. The test material was applied neat (100%) and also diluted with distilled water to yield w/w concentrations of 75%, 50%, 25%, 12%, 6%, 4%, 3%, 2%, and 1%. Each concentration was applied, 0.4 mL each, to a test site using an occlusive 25 mm Hill Top Chamber. The sites were wrapped with non-allergenic Durapore adhesive tape. After 24-hours of exposure, the chambers were removed and the test sites were cleansed of residual test material. 24 hours after patch removal, each site was evaluated for local reactions (erythema).

Based on these findings, the concentration selected for the intradermal induction was a 5% w/w mixture in distilled water, for topical induction 12% w/w mixture in distilled water and for the challenge phase 1% w/w mixture in distilled water.

Main test

Within 24 hours prior to each application, the fur was removed by clipping the suprascapular area of each guinea pig assigned to the test and test vehicle control groups. Prior to the intradermal induction, the skin was checked for any abnormalities. The test group consisted 20 animals and the sham control group 10 animals. The doses administered are presented in the table 6.1-5

On the first day of the induction period, the test and the control group animals received six intradermal injections (0.1 mL each) in the shaved/clipped suprascapular area.

Eight days after the intradermal injections the suprascapular area over the injection sites was re-clipped free of fur. A 0.5 mL aliquot of a 12% w/w mixture of the test material in distilled water was applied to the dose site and covered with a 2-cm x 4-cm, 2-ply gauze patch. The patch was covered with plastic wrap and secured in place with non-allergenic Durapore adhesive tape. After the 48-hour exposure period, the patches were removed and the test sites were cleansed of residual test material and the sites were reclipped. Approximately 1 hour after patch removal, readings were made of local reactions (erythema). The sham control group received the same treatment using 0.5 mL of distilled water.

Twenty-one days after test initiation, an untreated site on the right side of each test and sham control animal was clipped free of fur. A 0.4 mL aliquot of a 1% w/w mixture of the test material in distilled water was applied to an untreated site on each test animal using an occlusive 25 mm Hill Top Chamber. The chambers were secured in place and wrapped with non-allergenic Durapore adhesive tape. After the 24-hour exposure period, the chambers were removed and the sites were cleansed of residual test material. Approximately 24 and 48 hours after patch removal, these sites were evaluated for a sensitization response (erythema).

Table 6.1-5 Doses administered to test and control groups.

	Test group	**Control group**
Intradermal injection	- 50% v/v Complete Freund's Adjuvant mixture in distilled water - 5% w/w mixture of the test substance in distilled water - 5% w/w mixture of test substance in Complete Freund's Adjuvant (50% v/v in distilled water)	- 50% v/v Complete Freund's Adjuvant mixture in distilled water - 100% Distilled water - 50% w/w suspension of distilled water in Complete Freund's Adjuvant (50% v/v in distilled water)
Topical induction	12% w/w mixture of the test substance in distilled water	0.5 ml of distilled water

Topical challenge	1% w/w mixture of the test material in distilled water	1% w/w mixture of the test material in distilled water

The procedures used in this study were validated using alpha-Hexylcinnamaldehyde Technical (HCA) as a positive control substance. The most recent validation testing was completed on August, 2004. The test was conducted on Hartley strain albino guinea pigs.

Results

Preliminary irritation test

After intradermal injection both of the animals showed moderate erythema (score 2) at all concentrations. After topical induction concentrations of 75% and 100% caused severe erythema (score 3), concentration 12% moderate erythema (score 2) and concentration 4% faint erythema (score 1). When determining the highest non-irritating concentration, concentrations starting from 25% and above caused severe erythema (score 3) and there was eschar present at dose site. Concentrations of 6% and 12 % caused moderate erythema (score 2) and concentrations 2%, 3% and 4% very faint erythema (score 0.5). The concentration of 1 % caused no reaction (score 0) to very faint erythema (score 0.5).

Main test

All the animals in the test and sham control groups gained weight during the study. Irritation data after intradermal injection was not presented in the study report.

After topical induction test animals showed faint to moderate erythema (score 1-2) at all test sites 1 hour following patch removal. Faint erythema (score 1) was noted at all sham control sites 1 hour following patch removal. In the historical positive control animals (HCA applied as received) faint to moderate erythema (scores 1-2) was noted at all 10 control animals and in the historical vehicle control animals (100% mineral oil) very faint erythema (score 0.5) was noted at 2 of 5 vehicle control animals, following the topical induction phase.

Very faint erythema (score 0.5) was noted at 10/20 test animals 24 hours following the challenge application. Irritation cleared from all sites by 48 hours. Very faint erythema (score 0.5) was noted at 2/10 sham control animals 24 hours following the challenge application. Irritation cleared from all sites by 48 hours. In the historical positive control animals all the 10 animals exhibited signs of a sensitization response (faint to moderate erythema, scores 1-2) 24 and 48 hours after challenge. In the historical vehicle control animals (75% w/w mixture of HCA in mineral oil) very faint erythema (score 0.5) was noted at all 5 animals 24 and 48 hours after challenge.

Conclusion

The scoring system for erythema differed from Magnusson and Kligman grading scale for the evaluation of challenge patch test reactions presented in the OECD guideline. The score of 0.5 was used but it is not present in the guideline and therefore it is not clear whether the score 0.5 should be considered as positive or negative reaction or should it be rounded to score 1. The interpretation affects the evaluation of the results and therefore no conclusion can be drawn. In the test report it was mentioned that very faint erythema (score 0.5) is not considered a positive reaction.

In addition, the results for erythema from the intradermal injection in the main study were not presented in the study report. Therefore it could not be verified that the concentration used was irritating to skin also in the main test. Based on these considerations the study is considered as supportive information.

The classification of the product is based on the classification of the co-formulants and the concentration limits. The classification of clopyralid with regard skin sensitization could not be determined in this new evaluation and the current harmonized classification is used. The product is not classified as a skin sensitiser according to Regulation (EC) No. 1272/2008.

B.6.1.7. Supplementary studies on the plant protection product

No studies submitted.

B.6.1.8. Supplementary studies for combinations of plant protection products

No studies submitted.

According to notifier GF-1374 will not be mixed with other plant protection products in accordance with approved label instructions therefore it is not possible for anyone to be simultaneously exposed to a combination of undiluted products. Separate acute toxicity studies to cover this possibility have not been conducted and are considered unjustified.

B.6.2. DERMAL ABSORPTION

No studies were submitted. The default dermal absorption values are applied in accordance with EFSA Guidance on Dermal Absorption (EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665), 25% for products containing > 50 g/L active substance and 75% for products or in use dilutions containing ≤ 50 g/L active substance.

Dermal absorption % for active substances		
Clopyralid	Concentrate	25%
	Spray dilution	75%
Florasulam	Concentrate	75%
	Spray dilution	75 %
Fluroxypyr-meptyl	Concentrate	25%
	Spray dilution	75%

B.6.3. AVAILABLE TOXICOLOGICAL DATA RELATING TO CO-FORMULANTS

Confidential information which is provided in Volume 4.

B.6.4. EXPOSURE DATA

Formulation GF-1374 (EC), containing the active substances clopyralid 80 g/l, florasulam 2.5 g/l and fluroxypyr- mepthyl 144 g/l, is intended to be used on winter cereal and established permanent pasture as a herbicide. It is to be applied maximum 1.5 L/ha with spray volume 100-400 l/ha. The recommended single application is made by tractor mounted sprayer.

The default dermal absorption values are applied for the active substances as specified in chapter B.6.2. The other toxicological end-points used in the exposure assessment are presented in the table 6.4-1.

Table 6.4-1 Toxicological end-points for the active substances used in the exposure assessment of operator, worker, bystander and resident

Endpoint	**Value used in evaluation**
AOEL	
Clopyralid	0.15 mg/kg bw/d
Florasulam	0.05 mg/kg bw/d
Fluroxypyr-meptyl	0.8 mg/kg bw/d

Oral absorption	100 %
Inhalation absorption	100 %

Exposure assessment by the EFSA model is included in this evaluation even though it was not mandatory by the time when the dossier was submitted. The results and calculations are presented in the respective chapters. The acute risk assessment is not conducted as there is no final conclusion on determining AAOEL in the EU.

B.6.4.1. Operator exposure

Estimations of potential operator exposure from the proposed uses of GF-1374 have been undertaken for, clopyralid, florasulam and fluroxypyr-meptyl using the following models:

- 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. ('German model'), 75th percentile
- Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992, 2007 version (UK POEM)
- EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874, annexed exposure calculation spreadsheet (EFSA model)

The worst case scenario used in the evaluation is presented in the table 6.4-2. This covers also the use on winter cereals (1 L product/ha, tractor mounted sprayer, spray volume 80-400 l/ha, one application). Container size of 1 L any closure has been used in the exposure assessment by UK POEM.

Table 6.4-2 Summary of critical use pattern (i.e. worst case) for use of GF-1374.

Crop	Application equipment	Application rate per treatment		Spray volume (L/ha)	Number of applications
		kg a.s./ha	L product/ ha		
Established permanent pasture	Tractor mounted sprayer, overall broadcast foliar spray	Clopyralid 0.120 Florasulam 0.00375 Fluroxypyr-meptyl 0.216	1.5	100-400	1

A summary of estimated operator exposure to clopyralid, florasulam and fluroxypyr-meptyl, with or without personal protective equipment (PPE), is presented in the table 6.4-3. The detailed calculations are presented in table 6.7-1 to table 6.7-15 in Annex 1.

Table 6.4-3 Estimated operator exposure to clopyralid, florasulam and fluroxypyr-meptyl.

Active substance and model	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of AOEL
Clopyralid			
German model 75th percentile, 20 ha/day, 60 kg operator	No PPE	0.366	244
	Gloves during mixing, loading and application, coverall and sturdy	0.0236	16

	footwear during application		
UK POEM 50 ha/day, 6 h/day, 100 L/ha, 60 kg operator	No PPE	0.874	583
	Gloves during mixing, loading and application	0.123	82
EFSA model 50 ha/day, 60 kg operator, 100 l/ha	No PPE	0.1518	101
	With gloves and work wear (arms, body and legs covered) during mixing, loading and application	0.0043	3
Florasulam			
German model 75th percentile, 20 ha/day, 60 kg operator	No PPE	0.0199976	40
	Gloves during mixing, loading and application	0.00613	12
UK POEM 50 ha/day, 6 h/day, 100 L/ha, 60 kg operator	No PPE	0.04295	86
	Gloves during mixing, loading and application	0.0054	11
EFSA model 50 ha/day, 60 kg operator, 100 l/ha	No PPE	0.0312	62
	With gloves and work wear (arms, body and legs covered) during mixing, loading and application	0.0006	1
Fluroxypyr-meptyl			
German model 75th percentile, 20 ha/day, 60 kg operator	No PPE	0.6588	82
	Gloves during mixing, loading and application	0.34797	43
UK POEM 50 ha/day, 6 h/day, 100 L/ha, 60 kg operator	No PPE	1.57	196
	Gloves during mixing, loading and application	0.22	28
EFSA model 50 ha/day, 60 kg operator, 100 l/ha	No PPE	0.2398	30
	With gloves and work wear (arms, body and legs covered) during mixing, loading and application	0.0068	0.85

Since the product contains more than one active substance the combined exposure is calculated as the sum of the component exposures (as % of the AOELs). The results are presented in the table 6.4-4. Since the results with PPE were below 100%, based on results by German model and EFSA model, no further consideration was considered necessary.

Table 6.4-4 Combined exposure % to clopyralid, florasulam and fluroxypyr-meptyl.

Model	Level of PPE	Combined exposure %
German model	No PPE	366
	Gloves during mixing, loading and application, coverall and sturdy footwear during application	71
UK POEM	No PPE	865
	Gloves during mixing, loading and application	121
EFSA model	No PPE	193
	With gloves and work wear (arms, body and legs covered) during mixing, loading and application	5

Conclusion
The estimated operator exposure to a single active substance is below AOEL even when no PPE is used with all models used for florasulam. For clopyralid the exposure is below AOEL by all models when PPE (gloves during mixing, loading and application, coverall and sturdy footwear during application or gloves and work wear (arms, body and legs covered) during mixing, loading and application) is considered.
For fluroxypyr-meptyl the exposure is below AOEL by German model and EFSA model when no PPE is considered. By UK POEM the estimated exposure is below AOEL only when PPE (gloves during mixing, loading and application) is considered.

Based on the results of the estimated combined exposure, PPE (gloves and work wear during mixing, loading and application/ Gloves during mixing, loading and application, coverall and sturdy footwear during application) is required in order to have the combined exposure below 100%.

B.6.4.2. Bystander and resident exposure

Estimations of potential bystander and resident exposure from the proposed uses of GF-1374 have been undertaken for clopyralid, florasulam and fluroxypyr-meptyl using the following models:

- Bystander:
    - EUROPOEM II Bystander Exposure to pesticides (Bystander exposure to Pesticides – Report of the Bystander working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002)
    - Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application; S. Martin et al.; J. Verbr. Lebensm. 3 (2008): 272 – 281, 1661-5751/08/030272-10 DOI 10.1007/s00003-008-0361-5, ©Birkhäuser Verlag, Basel, 2008. (Martin et al.)

      The applicant provided also bystander exposure assessment according to UK CRD model. This was however not included since the model was not available for RMS and evaluating the provided modelling was not possible. Instead modelling by Europoem was added by RMS.

- Resident:
    - Guidance for Exposure and Risk Evaluation for Bystanders and Residents exposed to Plant Protection Products during and after Application; S. Martin et al.; J. Verbr. Lebensm. 3 (2008): 272 – 281, 1661-5751/08/030272-10 DOI 10.1007/s00003-008-0361-5, ©Birkhäuser Verlag, Basel, 2008. (Martin et al.)
    - EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874, annexed exposure calculation spreadsheet (EFSA model)

      The applicant provided also resident exposure assessment according to UK CRD model. This was however not included since the model was not available for RMS and evaluating the provided modelling was not possible. Instead modelling by the EFSA Model was added by RMS

The worst case scenario used in the evaluation of bystander and resident exposure is presented in the table 6.4-2. The default dermal absorption values are applied for the active substances as specified in chapter B.6.2. The other parameters used in the bystander and resident exposure assessment are presented in the table 6.4-5. The long term risk assessment for residents by the EFSA Model covers also the bystander long term risk assessment.

Table 6.4-5 Parameters used in the bystander and resident exposure assessment

Parameter	Value
Application rate	Clopyralid 0.120 kg/ha Florasulam 0.00375 kg/ha Fluroxypyr-meptyl 0.216 kg/ha
Spray volume	100 l/ha
Exposure duration	1 h (bystander) 2 h (resident, Martin et al) 2 h, 24 h, 0.25 h (resident, EFSA Model)
Exposed body surface	2 m^2 (adult, Europoem, Martin et al.) 0.66 m^2 (child, Martin et al.)
Inhalation absorption	100%
Oral absorption	100%
Body weight	60 kg (adult) 16.15 kg (child, Martin et al.) 10 kg (child, EFSA Model)
Distance between application and bystander/resident	1 m (Martin et al.)
Airborne vapour concentration	0.001 mg/m^3 (Martin et al.)

The vapour pressures of the active susbstances are clopyralid : 1.36 x 10^{-3} Pa at 25°C, florasulam: 1 x 10^{-5} Pa at 25°C and fluroxypyr-meptyl: 2.0 x 10^{-5} Pa at 25°C. Therefore, the active substances are considered to be semi-volatile based on the criteria given in the Martin et al. (substances with a vapour pressure of ≥1 x 10^{-5} to <5 x 10^{-3} Pa at 20°C are categorised as semi-volatile).

Bystander exposure to vapour following the use of GF-1374 is estimated by the approach presented in the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (2014).

Exposure to vapour $SER_I = (VC \times IR \times IA)/BW$.

SER_I = systemic exposure via the inhalation route (mg/kg bw per day)

VC = vapour concentration (mg/m^3)

IR = inhalation rate (m^3/day)

IA = inhalation absorption (%)

BW = body weight (kg)

Since the vapour pressure of all the active substances are < 0.005 Pa, exposure is calculated assuming a default concentration of 0.001 mg/m^3 in the air.

Adult: $SER_I = (0.001\ mg/m^3 \times 0.23\ m^3/day/kg \times 60\ kg \times 100\%)/\ 60\ kg = 0.00023\ mg/day/kg$

Child: $SER_I = (0.001\ mg/m^3 \times 1.07\ m^3/day/kg \times 10\ kg \times 100\%)/\ 10\ kg = 0.00107\ mg/day/kg$

A summary of estimated bystander and resident exposure to clopyralid, florasulam and fluroxypyr-meptyl is presented in the tables 6.4-6 and 6.4-7. The detailed calculations are presented in table 6.7-16 to table 6.7-24 in Annex 1.

Table 6.4-6 Estimated bystander exposure to clopyralid, florasulam and fluroxypyr-meptyl

	Dermal exposure (mg/kg bw/day)	Inhalation exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day)	% of AOEL

Clopyralid					
EUROPOEM II	Adult	0.09 (mg a.s./day)	0.045 (mg a.s./day)	0.135 (mg a.s./day)	2
Martin et al.	Child	0.0101881	0.0000142	0.0102023	7
	Adult	0.00831	0.0000067	0.0083167	6
Exposure to vapours	Child	-	-	0.00107	0.7
	Adult	-	-	0.00023	0.15
Florasulam					
EUROPOEM II	Adult	0.003 (mg a.s./day)	0.0014 (mg a.s./day)	0.004 (mg a.s./day)	0.1
Martin et al.	Child	0.0003184	0.0000004	0.0003188	0.64
	Adult	0.0002597	0.0000002	0.0002599	0.52
Exposure to vapours	Child	-	-	0.00107	2
	Adult	-	-	0.00023	0.46
Fluroxypyr-meptyl					
EUROPOEM II	Adult	0.162 (mg a.s./day)	0.081 (mg a.s./day)	0.243 (mg a.s./day)	1
Martin et al.	Child	0.0183386	0.0000256	0.0183642	2
	Adult	0.0149580	0.0000120	0.01497	2
Exposure to vapours	Child	-	-	0.00107	0.13
	Adult	-	-	0.00023	0.029

Table 6.4-7 Estimated resident exposure to clopyralid, florasulam and fluroxypyr-meptyl

		Total exposure (mg/kg bw/day)	**% of AOEL**
Clopyralid			
Martin et al.	Child	0.0009674	0.64
	Adult	0.0005795	0.39
EFSA Model	Child	0.0183	12
	Adult	0.0048	3
Florasulam			
Martin et al.	Child	0.0005287	1
	Adult	0.0002856	0.57
EFSA Model	Child	0.0016	3
	Adult	0.0004	0.75
Fluroxypyr-meptyl			

Martin et al.	Child	0.0013296	0.17
	Adult	0.0008221	0.1
EFSA Model	Child	0.0321	4
	Adult	0.0084	1

Since the product contains more than one active substance the combined exposure is calculated as the sum of the component exposures (as % of the AOELs). The results are presented in the table 6.4-8. Since the results are below 100%, no further consideration was considered necessary.

Table 6.4-8 Combined exposure % to clopyralid, florasulam and fluroxypyr-meptyl.

Model	**Combined exposure %**
Bystander	
EUROPOEM II	3
Martin et al.	
Child	10
Adult	9
Exposure to vapours	
Child	3
Adult	0.64
Resident	
Martin et al.	
Child	2
Adult	1
EFSA Model	
Child	19
Adult	5

Conclusion
According to the model calculations, the exposure of a bystander and a resident is below the respective AOEL for each active substance. The combined exposure % is clearly below 100%.

B.6.4.3. Worker exposure

Estimations of potential worker exposure from the proposed uses of GF-1374 have been undertaken for clopyralid, florasulam and fluroxypyr-meptyl using the following models:

- EUROPOEM II Worker Re-entry Model (Post-Application Exposure of Workers toPesticides in Agriculture – Report of the Re-entry Working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002)
- EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874, annexed exposure calculation spreadsheet (EFSA model)

The modelling by Europoem II was added by RMS. The applicant provided worker exposure estimation according to CRD Guidance for Post Application (Re-Entry Worker) Exposure Assessment Document. This is not included, however, the results were about the same as by Europoem II.

GF-1374 will be applied to winter cereal and established permanent pasture and therefore crop inspection is considered a relevant re-entry activity. The worst case scenario used in the evaluation of worker exposure is presented in the table 6.4-2. The default dermal absorption values are applied for the active substances as

specified in chapter B.6.2. The other parameters used in the worker exposure assessment are presented in the table 6.4-9.

Table 6.4-9 Parameters used in the estimation of re-entry worker exposure

Parameter	Value
Application rate	Clopyralid 0.120 kg/ha Florasulam 0.00375 kg/ha Fluroxypyr-meptyl 0.216 kg/ha
Working time	2 h
DFR	30 mg a.s./m^2/kg a.s./ha
TC	2500 cm^2/h (Europoem) 1400 cm^2/h (EFSA model)
Body weight	60 kg

A summary of estimated worker exposure to clopyralid, florasulam and fluroxypyr-meptyl is presented in the table 6.4-10. The detailed calculations are presented in table 6.7-25 to table 6.7-30 in Annex 1.

Table 6.4-10 Estimated worker exposure to clopyralid, florasulam and fluroxypyr-meptyl, no PPE

	Total exposure	% of AOEL
Clopyralid		
EUROPOEM II	1.35 mg a.s./day	15
EFSA Model[1]	0.0126 mg/kg bw/day	8
Florasulam		
EUROPOEM II	0.042 mg a.s./day	1
EFSA Model[1]	0.0004 mg/kg bw/day	0.79
Fluroxypyr-meptyl		
EUROPOEM II	2.43 mg a.s./day	5
EFSA Model[1]	0.0227 mg/kg bw/day	3

[1] Work wear – arms, body and legs covered

Since the product contains more than one active substance the combined exposure is calculated as the sum of the component exposures (as % of the AOELs). The results are presented in the table 6.4-11. As the results are below 100%, no further consideration was considered necessary.

Table 6.4-11 Combined exposure % to clopyralid, florasulam and fluroxypyr-meptyl.

Model	Combined exposure %
EUROPOEM II	21
EFSA Model	12

Conclusion
According to the model calculations, the exposure of a worker is below the respective AOEL for each active substance, when workwear, but no PPE, is worn. The combined exposure % is clearly below 100%. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

B.6.5. EXPOSURE AND RISK ASSESSMENT

The estimated exposure of operators was estimated to be under the respective AOEL for florasulam, when no PPE is considered. Regarding fluroxypyr-meptyl, according to UK POEM the estimated exposure is below AOEL only when PPE (gloves during mixing, loading and application) is considered. For clopyralid the exposure is below AOEL only when PPE (gloves during mixing, loading and application, coverall and sturdy footwear during application or gloves and work wear (arms, body and legs covered) during mixing, loading and application) is considered.

Based on the results of the estimated combined exposure (based on results by German model and EFSA model) PPE (gloves or gloves and work wear during mixing, loading and application/ Gloves during mixing, loading and application, coverall and sturdy footwear during application) is required in order to the combined exposure

to be below 100%. Based on calculations by UK POEM the combined exposure is above 100% even when PPE (gloves during mixing, loading and application) is considered.

When taking into account also the classification of the product as Asp. Tox. 1; H304, Acute Tox. 4; H332, Eye Irrit. 2; H319 and Skin Irrit. 2; H315, relevant PPE (respiratory protection equipment, goggles, cap) in addition to gloves, coverall and sturdy footwear is needed.

According to model calculations, the estimated exposure of a bystander, resident and worker is below the respective AOEL for each active substance (without PPE for workers). The combined exposure % is clearly below 100%.

Regarding combined exposure, the three active substances share a target organ kidney, and clopyralid and florasulam share the target organ liver. However, as the combined exposure % is below 100% based on results by German model and EFSA model, no further consideration was considered necessary.

It is concluded that operators (with relevant PPE), bystanders, residents and workers (no PPE) are not anticipated to be exposed for unacceptable high levels of clopyralid, florasulam and fluroxypyr-meptyl, also when combined exposure is considered.

B.6.6. REFERENCES RELIED ON

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.6.1.1.	[redacted]	2005	GF-1374: Acute Oral Toxicity Up and Down Procedure in Rats. DAS Report No. 040251 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	Submitted for the purpose of renewal.
B.6.1.2.	[redacted]	2005	GF-1374: Acute Dermal Toxicity Study in Rats – Limit Test. DAS Report No. 040252 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	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.6.1.3.	[redacted]	2005	GF-1374: Acute Liquid Aerosol Inhalation Toxicity Study in Fischer 344 Rats. DAS Report No. 041120 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	Submitted for the purpose of renewal.
B.6.1.4.	[redacted]	2005	GF-1374: Primary Skin Irritation Study in Rabbits. DAS Report No. 040254 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	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.6.1.5.	[redacted]	2005	GF-1374: Primary Eye Irritation Study in Rabbits. DAS Report No. 040255 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	Submitted for the purpose of renewal.
B.6.1.6.	[redacted]	2005	GF-1374: Dermal Sensitization Study in Guinea Pigs (Magnusson-Kligman Method) DAS Report No. 040253 [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Yes	Yes	Product data submitted with an application for renewal of authorisation under Article 43 of the Regulation – containing at least one active considered under AIR2 onwards.	Dow AgroSciences	Submitted for the purpose of renewal.

B.6.7. ANNEX 1 DETAILED CALCULATION ON EXPOSURE ASSESSMENT

Table 6.7-1 German model – operator exposure estimation to clopyralid, no PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	GF-1374		Active substance		Clopyralid
Formulation type	Liquid		a.s. concentration		80 g/l
Dermal absorption from product	25 %		Dermal absorption from spray		75 %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	1,5 l product/ha		Work rate/day		20 ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	32,868	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	32,868	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,006252	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,006252	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	1,014	3	14,292	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	18,306	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,008694	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,008694	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	32,868	mg/day	18,306	mg/day
Percent absorbed	25	%	75	%
Absorbed dose (dermal route)	8,217	mg/day	13,7295	mg/day
Inhalation exposure to a.s.	0,006252	mg/day	0,008694	mg/day
Total systemic exposure	8,223252	mg/day	13,738194	mg/day

PREDICTED EXPOSURE

Total systemic exposure	21,961446	mg/day
Operator body weight	60	kg
Operator exposure	0,3660241	mg/kg bw/day

Table 6.7-2 German model – operator exposure estimation to clopyralid, with PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	GF-1374		Active substance		Clopyralid	
Formulation type	Liquid		a.s. concentration		80	g/l
Dermal absorption from product	25	%	Dermal absorption from spray		75	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	Coverall and sturdy footwear	
Dose	1,5	l product/ha	Work rate/day		20	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	32,868	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0,32868	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,006252	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,006252	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	1,014	3	14,292	
Protective clothing	none	gloves	coverall and sturdy footwear	
Transmission to skin	100	1	5	%
Total dermal exposure to a.s.	1,7586	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,008694	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,008694	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0,32868	mg/day	1,7586	mg/day
Percent absorbed	25	%	75	%
Absorbed dose (dermal route)	0,08217	mg/day	1,31895	mg/day
Inhalation exposure to a.s.	0,006252	mg/day	0,008694	mg/day
Total systemic exposure	0,088422	mg/day	1,327644	mg/day

PREDICTED EXPOSURE

Total systemic exposure	1,416066	mg/day
Operator body weight	60	kg
Operator exposure	0,0236011	mg/kg bw/day

Table 6.7-3 UK POEM – operator exposure estimation to clopyralid, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Clopyralid	
Formulation type	organic solvent-based	a.s. concentration	80	mg/ml
Dermal absorption from product	25 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	None	PPE during application	None	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0,75	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	0,75	ml/day	41,55	ml/day
Concen. of a s. product or spray	80	mg/ml	1,2	mg/ml
Dermal exposure to a.s.	60	mg/day	49,86	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	15	mg/day	37,395	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1,2	mg/ml
Inhalation exposure to a.s.	0,072	mg/day
Percent absorbed	100	%
Absorbed dose	0,072	mg/day

PREDICTED EXPOSURE

Total absorbed dose	52,467	mg/day
Operator body weight	60	kg
Operator exposure	0,87445	mg/kg bw/day

Table 6.7-4 UK POEM – operator exposure estimation to clopyralid, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Clopyralid	
Formulation type	organic solvent-based	a.s. concentration	80	mg/ml
Dermal absorption from product	25 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	Gloves	PPE during application	Gloves	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
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	Gloves	Permeable	Permeable	
Penetration	10 %	5 %	15 %	
Dermal exposure	0,65	0,05	0,375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	6,45	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0,075	ml/day	6,45	ml/day
Concen. of a s. product or spray	80	mg/ml	1,2	mg/ml
Dermal exposure to a.s.	6	mg/day	7,74	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	1,5	mg/day	5,805	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	1,2	mg/ml
Inhalation exposure to a.s.	0,072	mg/day
Percent absorbed	100	%
Absorbed dose	0,072	mg/day

PREDICTED EXPOSURE

Total absorbed dose	7,377	mg/day
Operator body weight	60	kg
Operator exposure	0,12295	mg/kg bw/day

Table 6.7-5 EFSA model – operator exposure estimation to clopyralid, with and without PPE

Substance	Clopyralid	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,12 kg a.s. /ha	Spray dilution = 1,2 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,15 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,1518	% of RVNAS	101,23 %
	Acute systemic exposure mg/kg bw/day		0,9514	% of RVAAS	
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0043	% of RVNAS	2,84 %
	Acute systemic exposure mg/kg bw/day		0,0690	% of RVAAS	

Table 6.7-6 German model – operator exposure estimation to florasulam, no PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	GF-1374		Active substance		Florasulam	
Formulation type	Liquid		a.s. concentration		2,5	g/l
Dermal absorption from product	75	%	Dermal absorption from spray		75	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	None					
PPE during application: Head	None	Hands	None	Body	None	
Dose	1,5	l product/ha	Work rate/day		20	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	1,027125	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	1,027125	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,000195375	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,000195375	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	0,0316875	0,09375	0,446625	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	0,5720625	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,000271688	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,000271688	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	1,027125	mg/day	0,5720625	mg/day
Percent absorbed	75	%	75	%
Absorbed dose (dermal route)	0,77034375	mg/day	0,429046875	mg/day
Inhalation exposure to a.s.	0,000195375	mg/day	0,000271688	mg/day
Total systemic exposure	0,770539125	mg/day	0,429318563	mg/day

PREDICTED EXPOSURE

Total systemic exposure	1,199857688	mg/day
Operator body weight	60	kg
Operator exposure	0,019997628	mg/kg bw/day

Table 6.7-7 German model – operator exposure estimation to florasulam, with PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	GF-1374		Active substance		Florasulam	
Formulation type	Liquid		a.s. concentration		2,5	g/l
Dermal absorption from product	75	%	Dermal absorption from spray		75	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	None	
Dose	1,5	l product/ha	Work rate/day		20	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	1,027125	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0,01027125	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,000195375	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,000195375	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	0,0316875	0,09375	0,446625	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	0,47925	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,000271688	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,000271688	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0,01027125	mg/day	0,47925	mg/day
Percent absorbed	75	%	75	%
Absorbed dose (dermal route)	0,007703438	mg/day	0,3594375	mg/day
Inhalation exposure to a.s.	0,000195375	mg/day	0,000271688	mg/day
Total systemic exposure	0,007898813	mg/day	0,359709188	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0,367608	mg/day
Operator body weight	60	kg
Operator exposure	0,0061268	mg/kg bw/day

Table 6.7-8 UK POEM – operator exposure estimation to florasulam, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Florasulam	
Formulation type	organic solvent-based	a.s. concentration	2,5	mg/ml
Dermal absorption from product	75 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	None	PPE during application	None	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0,75	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	0,75	ml/day	41,55	ml/day
Concen. of a s. product or spray	2,5	mg/ml	0,0375	mg/ml
Dermal exposure to a.s.	1,875	mg/day	1,558125	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	1,40625	mg/day	1,16859375	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0,0375	mg/ml
Inhalation exposure to a.s.	0,00225	mg/day
Percent absorbed	100	%
Absorbed dose	0,00225	mg/day

PREDICTED EXPOSURE

Total absorbed dose	2,57709375	mg/day
Operator body weight	60	kg
Operator exposure	0,042951563	mg/kg bw/day

Table 6.7-9 UK POEM – operator exposure estimation to florasulam, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Florasulam	
Formulation type	organic solvent-based	a.s. concentration	2,5	mg/ml
Dermal absorption from product	75 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	Gloves	PPE during application	Gloves	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
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	Gloves	Permeable	Permeable	
Penetration	10 %	5 %	15 %	
Dermal exposure	0,65	0,05	0,375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	6,45	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0,075	ml/day	6,45	ml/day
Concen. of a s. product or spray	2,5	mg/ml	0,0375	mg/ml
Dermal exposure to a.s.	0,1875	mg/day	0,241875	mg/day
Percent absorbed	75	%	75	%
Absorbed dose	0,140625	mg/day	0,18140625	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	0,0375	mg/ml
Inhalation exposure to a.s.	0,00225	mg/day
Percent absorbed	100	%
Absorbed dose	0,00225	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0,32428125	mg/day
Operator body weight	60	kg
Operator exposure	0,005404688	mg/kg bw/day

Table 6.7-10 EFSA model – operator exposure estimation to florasulam, with and without PPE

Substance	Florasulam	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate- 0,00375 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 75	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,05 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0312	% of RVNAS	62,40 %
	Acute systemic exposure mg/kg bw/day		0,6246	% of RVAAS	
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0006	% of RVNAS	1,21 %
	Acute systemic exposure mg/kg bw/day		0,0363	% of RVAAS	

Table 6.7-11 German model – operator exposure estimation to fluroxypyr-meptyl, no PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	GF-1374		Active substance		Fluroxypyr-meptyl
Formulation type	Liquid		a.s. concentration	144	g/l
Dermal absorption from product	25	%	Dermal absorption from spray	75	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	1,5	l product/ha	Work rate/day	20	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	59,1624	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	59,1624	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,0112536	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,0112536	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	1,8252	5,4	25,7256	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	32,9508	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,0156492	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,0156492	mg/day

ABSORBED DOSE

	Mix/load		Application		
Dermal exposure to a.s.	59,1624	mg/day	32,9508	mg/day	
Percent absorbed	25	%	75	%	
Absorbed dose (dermal route)	14,7906	mg/day	24,7131	mg/day	
Inhalation exposure to a.s.	0,0112536	mg/day	0,0156492	mg/day	
Total systemic exposure	14,8018536	mg/day	24,7287492	mg/day	

PREDICTED EXPOSURE

Total systemic exposure	39,5306028	mg/day
Operator body weight	60	kg
Operator exposure	0,65884338	mg/kg bw/day

Table 6.7-12 German model – operator exposure estimation to fluroxypyr-meptyl, with PPE

THE GERMAN MODEL (75th PERCENTILE VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Product	GF-1374		Active substance		Fluroxypyr-meptyl	
Formulation type	Liquid		a.s. concentration		144	g/l
Dermal absorption from product	25	%	Dermal absorption from spray		75	%
RPE during mix/loading	None		RPE during application		None	
PPE during mix/loading	Gloves					
PPE during application: Head	None	Hands	Gloves	Body	None	
Dose	1,5	l product/ha	Work rate/day		20	ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	13,695	mg/kg a.s.
Hand contamination/day	59,1624	mg/day
Protective clothing	gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0,591624	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a s.	0,002605	mg/kg a.s.
Inhalation exposure/day	0,0112536	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,0112536	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0,4225	1,25	5,955	
Dermal contamination/day	1,8252	5,4	25,7256	
Protective clothing	none	gloves	none	
Transmission to skin	100	1	100	%
Total dermal exposure to a.s.	27,6048	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a s.	0,0036225	mg/kg a.s.
Inhalation exposure/day	0,0156492	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0,0156492	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0,591624	mg/day	27,6048	mg/day
Percent absorbed	25	%	75	%
Absorbed dose (dermal route)	0,147906	mg/day	20,7036	mg/day
Inhalation exposure to a.s.	0,0112536	mg/day	0,0156492	mg/day
Total systemic exposure	0,1591596	mg/day	20,7192492	mg/day

PREDICTED EXPOSURE

Total systemic exposure	20,8784088	mg/day
Operator body weight	60	kg
Operator exposure	0,34797348	mg/kg bw/day

Table 6.7-13 UK POEM – operator exposure estimation to fluroxypyr-meptyl, no PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Fluroxypyr-meptyl	
Formulation type	organic solvent-based	a.s. concentration	144	mg/ml
Dermal absorption from product	25 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	None	PPE during application	None	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	0,75	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	0,75	ml/day	41,55	ml/day
Concen. of a s. product or spray	144	mg/ml	2,16	mg/ml
Dermal exposure to a.s.	108	mg/day	89,748	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	27	mg/day	67,311	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	2,16	mg/ml
Inhalation exposure to a.s.	0,1296	mg/day
Percent absorbed	100	%
Absorbed dose	0,1296	mg/day

PREDICTED EXPOSURE

Total absorbed dose	94,4406	mg/day
Operator body weight	60	kg
Operator exposure	1,57401	mg/kg bw/day

Table 6.7-14 UK POEM – operator exposure estimation to fluroxypyr-meptyl, with PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	GF-1374	Active substance	Fluroxypyr-meptyl	
Formulation type	organic solvent-based	a.s. concentration	144	mg/ml
Dermal absorption from product	25 %	Dermal absorption from spray	75	%
Container	1 litre any closure			
PPE during mix/loading	Gloves	PPE during application	Gloves	
Dose	1,5 l/ha	Work rate/day	50	ha
Application volume	100 l/ha	Duration of spraying	6	h

EXPOSURE DURING MIXING AND LOADING

Container size	1	litres
Hand contamination/operation	0,01	ml
Application dose	1,5	litres product/ha
Work rate	50	ha/day
Number of operations	75	/day
Hand contamination	0,75	ml/day
Protective clothing	Gloves	
Transmission to skin	10	%
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	Gloves	Permeable	Permeable	
Penetration	10 %	5 %	15 %	
Dermal exposure	0,65	0,05	0,375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	6,45	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	0,075	ml/day	6,45	ml/day
Concen. of a s. product or spray	144	mg/ml	2,16	mg/ml
Dermal exposure to a.s.	10,8	mg/day	13,932	mg/day
Percent absorbed	25	%	75	%
Absorbed dose	2,7	mg/day	10,449	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0,01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	2,16	mg/ml
Inhalation exposure to a.s.	0,1296	mg/day
Percent absorbed	100	%
Absorbed dose	0,1296	mg/day

PREDICTED EXPOSURE

Total absorbed dose	13,2786	mg/day
Operator body weight	60	kg
Operator exposure	0,22131	mg/kg bw/day

Table 6.7-15 EFSA model – operator exposure estimation to fluroxypyr-meptyl, with and without PPE

Substance	Fluroxypyr-meptyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,216 kg a.s. /ha	Spray dilution = 2,16 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,8 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,2398	% of RVNAS	29,98 %
	Acute systemic exposure mg/kg bw/day		1,3085	% of RVAAS	
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No
Exposure (including PPE options above)	Longer term systemic exposure mg/kg bw/day		0,0068	% of RVNAS	0,85 %
	Acute systemic exposure mg/kg bw/day		0,0863	% of RVAAS	

Table 6.7-16 EUROPOEM II – bystander exposure estimation to clopyralid

BYSTANDER EXPOSURE			EUROPOEM II MODEL	
form	GF-1374		**Outdoor application**	
as	Clopyralid			
Parameter		**Value**	**Unit**	**References, comments**
SPRAYING Process outdoor				
AR	Application rate	0,12	kg a.s. / ha	summary of intended uses
SV	Spray volume	100	L / ha	summary of intended uses
Inhalation Exposure				without PPE
	Default value			
SE	Surrogate Exposure Value	0,03	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1,25	m3 / h	default
Inhalation Exposure		**0,0450**	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
	Default value			
SE	Surrogate Exposure Value	0,005		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
Dermal Exposure		**0,12**	mg a.s./ day	DE = SExSA X (AR x 100)
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	75	%	
	AOEL	9	mg a.s./ day	based on 70 kg bw
		Without PPE		
	Internal exposure	[mg a.s./ day]		
	Inhalation	0,0450		IE(int) = IE x (IA/100)
	Dermal	0,090		DE(int) = DE x (DA/100)
	Total	**0,135**		**sum**
	% AOEL			
	Inhalation	0,5		%AOEL = 100 x IE(int) / AOEL
	Dermal	1,0		%AOEL = 100 x DE(int) / AOEL
	Total	**2**		**sum**
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			

Note: The AOEL is based on body weight of 60 kg

Table 6.7-17 Martin et al.– bystander and resident exposure estimation to clopyralid

Estimation of bystander and resident exposure (adults and children)

Active substance (a.s.)	Clopyralid	
Product	GF-1374	
Intended uses	Field Crops, Tractor Mounted (FCTM)	
Treated area per day (A)	20	ha/d
Application rate (AR)	0,12	kg a.s./ha
Number of applications (NA)	1	1)

1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).

Dermal absorption (DA)	75	% (worst case, e.g. during applica ion)
Inhalation absorption (IA)	100	%
Oral absorption (OA)	100	%
Systemic AOEL	0,15	mg/kg bw/d
Body weight (BW)	60	kg/person (adults)
	16,15	kg/person (children)

Distance between application and bystander or resident:

FCTM:	1	m
High crops not selected		
		m
Home & garden not selected		
		m

Drift deposit (D) for 1 appl. based on appl. technique and distance: 2,77 % (FCTM, 1 m)

Airborne vapour concentration (ACv) 0.001 mg/m³ 2)

2) 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ $1x10^{-5}$ - < $5x10^{-3}$ Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ $5x10^{-3}$ Pa

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,12	kg a s /ha	**Exposed Body Surface Area (BSA):**	2	m² (adults)
				0,66	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0,001	mg/kg a s (6 hours, adults)
	16,15	kg/person (children)		0,00057	mg/kg a s (6 hours, children)
Dermal absorption (DA):	75,00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops,
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	60	min
AOEL:	0,15	mg/kg bw/d			

Bystander exposure towards Clopyralid					
Adults			**Children**		
Bystander: Dermal exposure after application in (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(12 x 2,77% x 2 x 75%) / 60			(12 x 2,77% x 0,66 x 75%) / 16,15		
External exposure	0,6648	mg/person	External exposure	0,219384	mg/person
External exposure	0,01108	mg/kg bw/d	External exposure	0,01358415	mg/kg bw/d
Absorbed dose:	**0,0083100**	**mg/kg bw/d**	**Absorbed dose:**	**0,0101881**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,001 / 360 x 0,12 x 20 x 60 x 100%) / 60			(0,001 / 360 x 0,12 x 20 x 60 x 100%) / 16,15		
External exposure	0,0004	mg/person	External exposure	0,00022989	mg/person
External exposure	6,6667E-06	mg/kg bw/d	External exposure	1,4234E-05	mg/kg bw/d
Absorbed dose:	**0,0000067**	**mg/kg bw/d**	**Absorbed dose:**	**0,0000142**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0,499	mg/person	Total systemic exposure (absorbed dose)	0,16476789	mg/person
Total systemic exposure (absorbed dose)	**0,0083167**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0102023**	**mg/kg bw/d**
% of AOEL:	**5,54**	**%**	**% of AOEL:**	**6,80**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,12	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**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):	75,00	% ('worst case')	**Inhalation Rate (IR):**	16,57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8,31	m^3/d (children)
Oral absorption (OA)	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0,15	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Clopyralid					
Adults			**Children**		
Residents: Dermal exposure after application in (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,0012 x 1 x 2,77% x 5% x 7300 x 2 x 75%) / 60			(0,0012 x 1 x 2,77% x 5% x 2600 x 2 x 75%) / 16,15		
External exposure	0,0242652	mg/person	External exposure	0,0086424	mg/person
External exposure	0,00040442	mg/kg bw/d	External exposure	0,00053513	mg/kg bw/d
Absorbed dose:	**0,0003033**	**mg/kg bw/d**	**Absorbed dose:**	**0,0004013**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16,57 x 100%) / 60			(0.001 x 8,31 x 100%) / 16,15		
External exposure	0,01657	mg/person	External exposure	0,00831	mg/person
External exposure	0,00027617	mg/kg bw/d	External exposure	0,00051455	mg/kg bw/d
Absorbed dose:	**0,0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0,0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0,0012 x 1 x 2,77% x 5% x 50% x 20 x 20 x 2 x 100%) / 16,15		
			External exposure	0,0006648	mg/person
			External exposure	4,1164E-05	mg/kg bw/d
			Absorbed dose	**0,0000412**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0,0012 x 1 x 2,77% x 20% x 25 x 100%) / 16,15		
			External exposure	0,0001662	mg/person
			External exposure	1,0291E-05	mg/kg bw/d
			Absorbed dose	**0,0000103**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0,0347689	mg/person	Total systemic exposure (absorbed dose)	0,0156228	mg/person
Total systemic exposure (absorbed dose)	**0,0005795**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0009674**	**mg/kg bw/d**
% of AOEL:	**0,39**	**%**	**% of AOEL:**	**0,64**	**%**

Table 6.7-18 EFSA Model –resident exposure estimation to clopyralid

Substance	Clopyralid	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,12 kg a.s. /ha	Spray dilution = 1,2 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,15 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0242	% of RVNAS	16,11 %
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	0,71 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0014	% of RVNAS	0,94 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0037	% of RVNAS	2,45 %
	All pathways (mean) mg/kg bw/day	0,0183	% of RVNAS	12,22 %
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0058	% of RVNAS	3,86 %
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,15 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0006	% of RVNAS	0,41 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0014	% of RVNAS	0,91 %
	All pathways (mean) mg/kg bw/day	0,0048	% of RVNAS	3,20 %

Table 6.7-19 EUROPOEM II – bystander exposure estimation to florasulam

BYSTANDER EXPOSURE			EUROPOEM II MODEL	
form	GF-1374		**Outdoor application**	
as	Florasulam			
Parameter		**Value**	**Unit**	**References, comments**
SPRAYING Process outdoor				
AR	Application rate	0,00375	kg a.s. / ha	summary of intended uses
SV	Spray volume	100	L / ha	summary of intended uses
Inhalation Exposure				without PPE
	Default value			
SE	Surrogate Exposure Value	0,03	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1,25	m3 / h	default
Inhalation Exposure		**0,0014**	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
	Default value			
SE	Surrogate Exposure Value	0,005		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
Dermal Exposure		**0,00375**	mg a.s./ day	DE = SExSA X (AR x 100)
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	75	%	
	AOEL	3	mg a.s./ day	based on 70 kg bw
		Without PPE		
	Internal exposure	[mg a.s./ day]		
	Inhalation	0,0014		IE(int) = IE x (IA/100)
	Dermal	0,003		DE(int) = DE x (DA/100)
	Total	**0,004**		**sum**
	% AOEL			
	Inhalation	0,0		%AOEL = 100 x IE(int) / AOEL
	Dermal	0,1		%AOEL = 100 x DE(int) / AOEL
	Total	**0**		**sum**
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			

Note: The AOEL is based on body weight of 60 kg

Table 6.7-20 Martin et al. – bystander and resident exposure estimation to florasulam

Estimation of bystander and resident exposure (adults and children)		
Active substance (a.s.)	Florasulam	
Product	GF-1374	
Intended uses	Field Crops, Tractor Mounted (FCTM)	
Treated area per day (A)	20	ha/d
Application rate (AR)	0,00375	kg a.s./ha
Number of applications (NA)	1	1)
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).		
Dermal absorption (DA)	75	% (worst case, e.g. during application)
Inhalation absorption (IA)	100	%
Oral absorption (OA)	100	%
Systemic AOEL	0,05	mg/kg bw/d
Body weight (BW)	60	kg/person (adults)
	16,15	kg/person (children)
Distance between application and bystander or resident:		
FCTM:	1	m
High crops not selected		
		m
Home & garden not selected		
		m
Drift deposit (D) for 1 appl. based on appl. technique and distance:	2,77 % (FCTM, 1 m)	
Airborne vapour concentration (ACv)	0.001	mg/m³ 2)
2) 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ 1x10^{-5} - < 5x10^{-3} Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ 5x10^{-3} Pa		

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,00375	kg a s /ha	**Exposed Body Surface Area (BSA):**	2	m² (adults)
				0,66	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*$_A$):**	0,001	mg/kg a s (6 hours, adults)
	16,15	kg/person (children)		0,00057	mg/kg a s (6 hours, children)
Dermal absorption (DA):	75,00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops,
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	60	min
AOEL:	0,05	mg/kg bw/d			

Bystander exposure towards Florasulam					
Adults			**Children**		
Bystander: Dermal exposure after application in (via spray drift)					
$SDE_B = (AR \times D \times BSA \times DA) / BW$			$SDE_B = (AR \times D \times BSA \times DA) / BW$		
(0,375 x 2,77% x 2 x 75%) / 60			(0,375 x 2,77% x 0,66 x 75%) / 16,15		
External exposure	0,020775	mg/person	External exposure	0,00685575	mg/person
External exposure	0,00034625	mg/kg bw/d	External exposure	0,0004245	mg/kg bw/d
Absorbed dose:	**0,0002597**	**mg/kg bw/d**	**Absorbed dose:**	**0,0003184**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in					
$SIE_B = (I^*_A \times AR \times A \times T \times IA) / BW$			$SIE_B = (I^*_A \times AR \times A \times T \times IA) / BW$		
(0,001 / 360 x 0,00375 x 20 x 60 x 100%) / 60			(0,001 / 360 x 0,00375 x 20 x 60 x 100%) / 16,15		
External exposure	0,0000125	mg/person	External exposure	7,1839E-06	mg/person
External exposure	2,0833E-07	mg/kg bw/d	External exposure	4,4482E-07	mg/kg bw/d
Absorbed dose:	**0,0000002**	**mg/kg bw/d**	**Absorbed dose:**	**0,0000004**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure (absorbed dose)	0,01559375	mg/person	Total systemic exposure (absorbed dose)	0,005149	mg/person
Total systemic exposure (absorbed dose)	**0,0002599**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0003188**	**mg/kg bw/d**
% of AOEL:	**0,52**	**%**	**% of AOEL:**	**0,64**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,00375	kg a s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**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):	75,00	% ('worst case')	**Inhalation Rate (IR):**	16,57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8,31	m^3/d (children)
Oral absorption (OA)	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0,05	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Florasulam					
Adults			**Children**		
Residents: Dermal exposure after application in (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,0000375 x 1 x 2,77% x 5% x 7300 x 2 x 75%) / 60			(0,0000375 x 1 x 2,77% x 5% x 2600 x 2 x 75%) / 16,15		
External exposure	0,00075829	mg/person	External exposure	0,00027008	mg/person
External exposure	1,2638E-05	mg/kg bw/d	External exposure	1,6723E-05	mg/kg bw/d
Absorbed dose:	**0,0000095**	**mg/kg bw/d**	**Absorbed dose:**	**0,0000125**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16,57 x 100%) / 60			(0.001 x 8,31 x 100%) / 16,15		
External exposure	0,01657	mg/person	External exposure	0,00831	mg/person
External exposure	0,00027617	mg/kg bw/d	External exposure	0,00051455	mg/kg bw/d
Absorbed dose:	**0,0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0,0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0,0000375 x 1 x 2,77% x 5% x 50% x 20 x 20 x 2 x 100%) /		
			External exposure	2,0775E-05	mg/person
			External exposure	1,2864E-06	mg/kg bw/d
			Absorbed dose	**0,0000013**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0,0000375 x 1 x 2,77% x 20% x 25 x 100%) / 16,15		
			External exposure	5,1938E-06	mg/person
			External exposure	3,2159E-07	mg/kg bw/d
			Absorbed dose	**0,0000003**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0,01713872	mg/person	Total systemic exposure (absorbed dose)	0,00853853	mg/person
Total systemic exposure (absorbed dose)	**0,0002856**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0005287**	**mg/kg bw/d**
% of AOEL:	**0,57**	**%**	**% of AOEL:**	**1,06**	**%**

Table 6.7-21 EFSA Model –resident exposure estimation to florasulam

Substance	Florasulam	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate- 0,00375 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 75	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,05 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0008	% of RVNAS	1,51 %
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	2,14 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,09 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0001	% of RVNAS	0,23 %
	All pathways (mean) mg/kg bw/day	0,0016	% of RVNAS	3,22 %
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,36 %
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,46 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,04 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0000	% of RVNAS	0,09 %
	All pathways (mean) mg/kg bw/day	0,0004	% of RVNAS	0,75 %

Table 6.7-22 EUROPOEM II – bystander exposure estimation to fluroxypyr-meptyl

BYSTANDER EXPOSURE			**EUROPOEM II MODEL**	
form	GF-1374		**Outdoor application**	
as	Fluroxypyr-meptyl			
Parameter		**Value**	**Unit**	**References, comments**
SPRAYING Process outdoor				
AR	Application rate	0,216	kg a.s. / ha	summary of intended uses
SV	Spray volume	100	L / ha	summary of intended uses
Inhalation Exposure				without PPE
	Default value			
SE	Surrogate Exposure Value	0,03	mL / m3	downwards: 0.03; upwards: 0.06 (EUROPOEM II)
T	Time of exposure	1	h	most probable estimation*
RR	Respiratory rate	1,25	m3 / h	default
Inhalation Exposure		**0,0810**	mg a.s. / day	IE = (ARx1000/SV)xSExTxRR
Dermal Exposure				
	Default value			
SE	Surrogate Exposure Value	0,005		downwards: 0.005; upwards with leaves: 0.05; upward without leaves: 0.15 (EUROPOEM II)
SA	Surface area bystander	2	m2	EUROPOEM II
Dermal Exposure		**0,216**	mg a.s./ day	DE = SExSA X (AR x 100)
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	75	%	
	AOEL	48	mg a.s./ day	based on 70 kg bw
		Without PPE		
	Internal exposure	[mg a.s./ day]		
	Inhalation	0,0810		IE(int) = IE x (IA/100)
	Dermal	0,162		DE(int) = DE x (DA/100)
	Total	**0,243**		**sum**
	% AOEL			
	Inhalation	0,2		%AOEL = 100 x IE(int) / AOEL
	Dermal	0,3		%AOEL = 100 x DE(int) / AOEL
	Total	**1**		**sum**
*	One hour exposure is the default. It is referring to a potential 1 hour exposure, rather than the actual. It is based on the study design, and should not be lowered.			

Note: The AOEL is based on body weight of 60 kg

Table 6.7-23 Martin et al. – bystander and resident exposure estimation to fluroxypyr-meptyl

Estimation of bystander and resident exposure (adults and children)		
Active substance (a.s.)	Fluroxypyr-meptyl	
Product	GF-1374	
Intended uses	Field Crops, Tractor Mounted (FCTM)	
Treated area per day (A)	20	ha/d
Application rate (AR)	0,216	kg a.s./ha
Number of applications (NA)	1	1)
1) Consideration of more than two applications are not necessary if degradation of the active substance on foliage of at least 50 % can be assumed between two applications (otherwise use multiple application factor).		
Dermal absorption (DA)	75	% (worst case, e.g. during application)
Inhalation absorption (IA)	100	%
Oral absorption (OA)	100	%
Systemic AOEL	0,8	mg/kg bw/d
Body weight (BW)	60	kg/person (adults)
	16,15	kg/person (children)
Distance between application and bystander or resident:		
FCTM:	1	m
High crops not selected		
		m
Home & garden not selected		
		m
Drift deposit (D) for 1 appl. based on appl. technique and distance:	2,77 % (FCTM, 1 m)	
Airborne vapour concentration (ACv)	0.001	mg/m³ 2)
2) 1 µg/m³ for semivolatile substances, i.e. vapour pressure (20 °C): ≥ 1x10^{-5} - < 5x10^{-3} Pa; 15 µg/m³ for volatile substances, i.e. vapour pressure (20 °C): ≥ 5x10^{-3} Pa		

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,216	kg a.s./ha	**Exposed Body Surface Area (BSA):**	2	m² (adults)
				0,66	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0,001	mg/kg a.s. (6 hours, adults)
	16,15	kg/person (children)		0,00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75,00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops,
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	60	min
AOEL:	0,8	mg/kg bw/d			

Bystander exposure towards Fluroxypyr-meptyl					
Adults			**Children**		
Bystander: Dermal exposure after application in (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(21,6 x 2,77% x 2 x 75%) / 60			(21,6 x 2,77% x 0,66 x 75%) / 16,15		
External exposure	1,19664	mg/person	External exposure	0,3948912	mg/person
External exposure	0,019944	mg/kg bw/d	External exposure	0,02445147	mg/kg bw/d
Absorbed dose:	**0,0149580**	**mg/kg bw/d**	**Absorbed dose:**	**0,0183386**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,001 / 360 x 0,216 x 20 x 60 x 100%) / 60			(0,001 / 360 x 0,216 x 20 x 60 x 100%) / 16,15		
External exposure	0,00072	mg/person	External exposure	0,00041379	mg/person
External exposure	0,000012	mg/kg bw/d	External exposure	2,5622E-05	mg/kg bw/d
Absorbed dose:	**0,0000120**	**mg/kg bw/d**	**Absorbed dose:**	**0,0000256**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0,8982	mg/person	Total systemic exposure (absorbed dose)	0,29658219	mg/person
Total systemic exposure (absorbed dose)	**0,0149700**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0183642**	**mg/kg bw/d**
% of AOEL:	**1,87**	**%**	**% of AOEL:**	**2,30**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):			**Drift (D):**	2,77	% (FCTM, 1 m)
Application rate (AR):	0,216	kg a s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**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):	75,00	% ('worst case')	**Inhalation Rate (IR):**	16,57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8,31	m^3/d (children)
Oral absorption (OA)	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0,8	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Fluroxypyr-meptyl					
Adults			**Children**		
Residents: Dermal exposure after application in (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0,00216 x 1 x 2,77% x 5% x 7300 x 2 x 75%) / 60			(0,00216 x 1 x 2,77% x 5% x 2600 x 2 x 75%) / 16,15		
External exposure	0,04367736	mg/person	External exposure	0,01555632	mg/person
External exposure	0,00072796	mg/kg bw/d	External exposure	0,00096324	mg/kg bw/d
Absorbed dose:	**0,0005460**	**mg/kg bw/d**	**Absorbed dose:**	**0,0007224**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16,57 x 100%) / 60			(0.001 x 8,31 x 100%) / 16,15		
External exposure	0,01657	mg/person	External exposure	0,00831	mg/person
External exposure	0,00027617	mg/kg bw/d	External exposure	0,00051455	mg/kg bw/d
Absorbed dose:	**0,0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0,0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0,00216 x 1 x 2,77% x 5% x 50% x 20 x 20 x 2 x 100%) / 16,15		
			External exposure	0,00119664	mg/person
			External exposure	7,4095E-05	mg/kg bw/d
			Absorbed dose	**0,0000741**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0,00216 x 1 x 2,77% x 20% x 25 x 100%) / 16,15		
			External exposure	0,00029916	mg/person
			External exposure	1,8524E-05	mg/kg bw/d
			Absorbed dose	**0,0000185**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0,04932802	mg/person	Total systemic exposure (absorbed dose)	0,02147304	mg/person
Total systemic exposure (absorbed dose)	**0,0008221**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0,0013296**	**mg/kg bw/d**
% of AOEL:	**0,10**	**%**	**% of AOEL:**	**0,17**	**%**

Table 6.7-24 EFSA Model –resident exposure estimation to fluroxypyr-meptyl

Substance	Fluroxypyr-meptyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,216 kg a.s. /ha	Spray dilution = 2,16 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,8 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Resident - child	Spray drift (75th percentile) mg/kg bw/day	0,0435	% of RVNAS	5,44 %
	Vapour (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	0,13 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0025	% of RVNAS	0,32 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0066	% of RVNAS	0,83 %
	All pathways (mean) mg/kg bw/day	0,0321	% of RVNAS	4,02 %
Resident - adult	Spray drift (75th percentile) mg/kg bw/day	0,0104	% of RVNAS	1,30 %
	Vapour (75th percentile) mg/kg bw/day	0,0002	% of RVNAS	0,03 %
	Surface deposits (75th percentile) mg/kg bw/day	0,0011	% of RVNAS	0,14 %
	Entry into treated crops (75th percentile) mg/kg bw/day	0,0025	% of RVNAS	0,31 %
	All pathways (mean) mg/kg bw/day	0,0084	% of RVNAS	1,06 %

Table 6.7-25 EUROPOEM II – worker exposure estimation to clopyralid

WORKER EXPOSURE			**EUROPOEM II MODEL**	
form	GF-1374		**Re-entry in the field**	
a.s.	Clopyralid			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,12	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**1,8**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	75	%	
	PPE-factor dermal	5		gloves*
	AOEL	9	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	1,350	0,270	DE(int) = DE x (DA/100)
	Total	**1,350**	**0,270**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	15	3	%AOEL = 100 x DE(int) / AOEL
	Total	**15**	**3**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Note: The AOEL is based on body weight of 60 kg

Table 6.7-26 EFSA model – worker exposure estimation to clopyralid

Substance	Clopyralid	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,12 kg a.s. /ha	Spray dilution = 1,2 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,15 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0,1125	% of RVNAS	75,00 %
	Working clothing mg/kg bw/day	0,0126	% of RVNAS	8,40 %
	Working clothing and gloves mg/kg bw/day		% of RVNAS	

Table 6.7-27 EUROPOEM II – worker exposure estimation to florasulam

WORKER EXPOSURE			EUROPOEM II MODEL	
form	GF-1374		Re-entry in the field	
a.s.	Florasulam			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,00375	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				without PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**0,05625**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	75	%	
	PPE-factor dermal	5		gloves*
	AOEL	3	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	0,042	0,008	DE(int) = DE x (DA/100)
	Total	**0,042**	**0,008**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	1	0	%AOEL = 100 x DE(int) / AOEL
	Total	**1**	**0**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Note: The AOEL is based on body weight of 60 kg

Table 6.7-28 EFSA model – worker exposure estimation to florasulam

Substance	Florasulam	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate- 0,00375 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 75	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,05 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0,0035	% of RVNAS	7,03 %
	Working clothing mg/kg bw/day	0,0004	% of RVNAS	0,79 %
	Working clothing and gloves mg/kg bw/day		% of RVNAS	

Table 6.7-29 EUROPOEM II – worker exposure estimation to fluroxypyr-meptyl

WORKER EXPOSURE			**EUROPOEM II MODEL**	
form	GF-1374		**Re-entry in the field**	
a.s.	Fluroxypyr-meptyl			
Parameter		**Value**	**Unit**	**References, comments**
Re-entry activities in the field				
AR	Application rate	0,216	kg a.s./ha	summary of intended uses
Worker				
Duration				
T		2	hours / day	default: 6 h (Europoem II)
Inhalation Exposure				w ithout PPE
	no model available	-		
Dermal Exposure				
DFR	Dislodgeable foliar residue	30	mg a.s./m2/kg a.s./ha	default (Europoem II)
TC	Transfer coefficient	0,25	m2/ hour	vegetable (field): 0.25; ornamentals: 0.5; small fruit: 0.3; large fruit: 0.45 (Europoem II)
Dermal Exposure		**3,24**	mg a.s./ day	DE = DFR x AR x TC x T
Internal exposure				
DA	Dermal Absorption	75	%	
	PPE-factor dermal	5		gloves*
	AOEL	48	mg a.s./ day	based on 70 kg bw
		Without PPE	**With PPE**	
	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	
	Inhalation	-	-	no model available
	Dermal	2,430	0,486	DE(int) = DE x (DA/100)
	Total	**2,430**	**0,486**	**sum**
	% AOEL			
	Inhalation	-	-	no model available
	Dermal	5	1	%AOEL = 100 x DE(int) / AOEL
	Total	**5**	**1**	**sum**

* It is assumed in the used TC values, that body exposure is already reduced by (protective) clothing. The use of gloves will result in an extra reduction factor of 5.

Note: The AOEL is based on body weight of 60 kg

Table 6.7-30 EFSA model – worker exposure estimation to fluroxypyr-meptyl

Substance	Fluroxypyr-meptyl	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,216 kg a.s. /ha	Spray dilution = 2,16 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of
Scenario	Grassland and lawns / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absoprtion	Dermal for product = 25	Dermal for in use diluation = 75	Oral = 100	Inhalation = 100	
RVNAS	0,8 mg/kg bw/day		RVAAS	mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	30 days	

Worker - Inspection, irrigation	Potential exposure mg/kg bw/day	0,2025	% of RVNAS	25,31 %
	Working clothing mg/kg bw/day	0,0227	% of RVNAS	2,84 %
	Working clothing and gloves mg/kg bw/day		% of RVNAS	