

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



CLOPYRALID

Volume 3 – B.3 (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

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

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

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

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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

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B.3. DATA ON APPLICATION AND EFFICACY

The representative formulation includes a different product (GF-1374) compared to the product evaluated for the first approval (Lontrel 100 Herbicide). GF-1374 is an emulsifiable concentrate containing the active substance clopyralid at 80 g ae/l and 2 mixing partners namely Fluroxypyr mepthyl 144 g/l (100 g ae/L) and Florasulam 2.5 g/l. Lontrel 100 Herbicide was a soluble concentrate (SL) formulation containing 100 g/L clopyralid.

The representative uses include two uses evaluated during the first approval (cereals and pasture) which also reflect changes in dosage of clopyralid containing products as doses have been reduced.

B.3.1. FIELD OF USE ENVISAGED

GF-1374 is used as an herbicide in cereals and grassland for the control of a range of broad leaf weeds.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

Clopyralid belongs to the chemical group of the pyridine carboxylic acid herbicide family (HRAC group O). Clopyralid will mainly be absorbed through green leaves, uptake through roots is of much less importance. Acropetal translocation of clopyralid in xylem into young meristem and youngest leaves as well as basipetal transport in phloem into roots is possible. The MoA is similar to fluroxypyr and not yet completely understood. But it has been shown that clopyralid is being accumulated in meristematic tissue and influencing cell division, cell elongation and cell extension as well as RNA synthesis. Consequently, meristematic tissue dies off. Typical symptoms of susceptible plants are deformation and curling of young leaves and stem followed by growth stop and necrosis.

Fluroxypyr belongs to the chemical group of the pyridine carboxylic acid herbicide family (HRAC group O). Fluroxypyr is formulated, and therefore applied as, the 1-methylheptyl ester. Fluroxypyr will hydrolyse during penetration to form fluroxypyr-acid which acts as an auxin like herbicide causing rapid cell growth within the plant. Once absorbed fluroxypyr acid moves readily through the plant via both the xylem and phloem and is distributed throughout the entire plant to the meristems and other developing parts. In susceptible plant species fluroxypyr induces an epinastic response (ie stimulation of cell elongation and premature senescence, particularly in meristematic tissue) leading to cessation of normal growth and rapid necrosis followed by plant death.

Florasulam (HRAC group B) is a member of the triazolopyrimidine sulfonanilides, a class of herbicides known to inhibit the plant enzyme acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS), a key enzyme in the biosynthesis of the branched chained amino acids isoleucine, leucine and valine.

B.3.3. DETAILS OF INTENDED USE

GF-1374 is used as a post emergence herbicide to control a range of broadleaf weeds in Cereals and Established grassland.

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	Lk a.i./ha min max (*) (g/ha)		
Winter cereal (wheat, barley oat, rye, triticale, spelt)	CZ/SZ	GF-1374	F	Broadleaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144 g/L fluroxypyr-methyl (equivalent to 100 g ae/ha fluroxypyr)	Overall broadcast foliar spray	BBCH 13-39 (1 st Feb to 30 th of June)	1	n/a	Clopyralid: 0.02 to 0.1 kg as/hL + Florasulam 0.0000625 to 0.0003125 kg as/hL + Fluroxypyr meptyl: 0.036 to 0.18 kg as/hL (0.025 to 0.125 kg ae/hL)	80-400	Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-meptyl 0.144 kg as/ha (0.100 kg ae/ha)	n/a	Dose: 1L GF-1374/ha Due to clopyralid content, straw treated with GF-1374 must not be used for compost production (for cultivating susceptible vegetables).

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.i./hl min max (g/hl)	Water l/ha min max	Lk a.i./ha min max (*) (g/ha)		
Established permanent pasture	CZ/SZ	GF-1374	F	Broadleaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144 g/L fluroxypyr-methyl (equivalent to 100 g ae/ha fluroxypyr)	Overall broadcast foliar spray	1 st Feb to 30 th September	1	n/a	Clopyralid: 0.03 to 0.15 kg as/hL + Florasulam 0.00009375 to 0.00046875 kg as/hL + Fluroxypyr meptyl: 0.054 to 0.27 kg as/hL (0.0375 to 0.1875 kg ae/hL)	100-400	Clopyralid 0.12 kg as/ha + Florasulam 0.00375 kg as/ha + Fluroxypyr-meptyl 0.216 kg as/ha (0.15kg ae/ha)	7 to 14 days (see note 1)	Dose: 1.5L GF-1374/ha. Note 1: PHI: 7 days for CZ and 14 days for SZ is the interval before any crop cutting or grazing. Fluroxypyr is the limiting factor. Clopyralid residues in plant tissue (including manure) which has not completely decayed may affect succeeding susceptible crops. Do not use any plant material treated with GF-1374 for composting. Do not use manure from animals fed on crops treated with GF-1374 for composting or mulching.

- Remarks:
- (a) For crops the EU and Codex classifications (both) should be used.
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GIFAP Codes - GIFAP Technical Monograph No. 2, 1989
 - (f) All abbreviations must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment, including where relevant information on season at time of application
 - (k) The minimum and maximum number of applications possible under practical conditions must be given
 - (l) PHI - Pre-harvest interval
 - (m) Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications. Indicate uses not yet authorised.

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Crop	Timing	Mode of application	Rate g as/ha
Winter cereal (wheat, barley oat, rye, triticale, spelt)	BBCH 13-39 (1st Feb to 30th of June)	Broadcast Tractor mounted boom sprayer	Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-meptyl 0.144 kg as/ha (0.100 kg ae/ha)
Established permanent pasture	1st Feb to 30th September	Broadcast Tractor mounted boom sprayer	Clopyralid 0.12 kg as/ha + Florasulam 0.00375Kg as/ha + Fluroxypyr-meptyl 0.216KG as/ha (0.150kgas/ha)

B.3.5. METHOD OF APPLICATION

The method of application used is a broadcast application with a tractor mounted, self-propelled or trailed hydraulic boom sprayer delivering a water volume of 80 l to 400 l/ha in cereals or 100-400l/ha in permanent pasture.

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION**Maximum number of applications and their timings**

In cereals a maximum of one application per crop may be made between BBCH 13-39 (1st Feb to 30th of June).

In permanent pasture a maximum of one application per year may be made between 1st Feb and 30th September.

Growth stages of crops or plants to be protected

Cereals, BBCH 13-39

Permanent pasture. As a perennial crop growth stage is not relevant.

Development stages of the harmful organism concerned

In cereals target weed species are generally annual weeds and are treated post emergence in the spring at an early growth stage of BBCH12 – 16. In permanent pasture where target weeds are perennial weeds they are treated when actively growing.

Duration of protection afforded by each application

A single well timed application will protect a cereal crop to harvest. In permanent pasture a single well timed application will suppress weed competition for one growing season.

Duration of protection afforded by the maximum number of applications

Only one application may be made per year, a single well timed application will protect a cereal crop to harvest. In permanent pasture a single well timed application will suppress weed competition for one growing season.

B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

When GF-1374 is applied at its normal application timing the following crops can be grown in the year of application:

Cereals, oilseed rape, vegetable brassicas as transplants, grass.

Any crop may be sown in the calendar year following treatment with GF-1374

Limitations on choice of succeeding crops

Having regard to the precautions outlined in CP3.7 there are no further restrictions on succeeding crops.

B.3.8. PROPOSED INSTRUCTIONS FOR USE

The representative formulation is registered in the EU. Please refer to national labels for detailed information.

B.3.9. EFFECTIVENESS

Clopyralid and the representative formulation GF1374 are intended for agricultural use. Clopyralid is a contact acting, selective, auxin type herbicide, for post emergence control of annual, biennial and perennial dicotyledonous weeds.

Summary of representative crops and target weeds controlled by GF-1374.

Crop	Pest
Winter cereals (wheat, barley oat, rye, triticale, spelt)	<i>Galium aparine</i> <i>Sinapis arvensis</i> <i>Matricaria spp</i> <i>Brassica napus</i> (Vol oilseed rape) <i>Centaurea cyanus</i> <i>Stellaria media</i>
Established permanent pasture	<i>G. aparine</i> <i>S. media</i> <i>Taraxacum officinalis</i> <i>Bellis perennis</i> <i>Ranunculus repens</i> <i>Plantago major</i> <i>Plantago lanceolata</i> <i>Rumex obtusifolius</i> <i>Rumex acetosa</i>

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

An assessment of the likelihood of the development of resistance has been carried out. Herbicides representing this mode of action have been used commercially for more than 35 years. Only two species that are sensitive clopyralid have been shown to have developed resistance to two herbicides with a synthetic auxin mode of action. In Europe, these were creeping thistle (*Cirsium arvensis*) and scentless mayweed (*Matricaria perforata*). Both of these species have shown increased tolerance to MCPA and 2,4-D (International Survey of Herbicide Resistant Weeds). The level of resistance is generally low and restricted to a small area. Furthermore these

weeds were detected between 1975 and 1985 and no increase in range has been reported. No cases of clopyralid resistance have been reported in Europe.

The risk of practical resistance in unrestricted use is very low and the unmodified risk is acceptable. In view of the acceptable risk of unrestricted use no resistance management strategy is deemed necessary.

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

When used according to the dose rates and application timings detailed in the directions for use no adverse effects on treated crops are expected.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

When used according to the dose rates and application timings detailed in the directions for use no undesirable or unintended side effects are expected adverse effects on treated crops are expected.

B.3.13. REFERENCES RELIED ON

No references

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