REGISTRATION REPORT
Part A
Risk Management

Product code: GF-3678
Product name(s): ELIPRIS

Chemical active substance(s):

Halauxifen-methyl, 11.7 g a.s./L (11.2 g ae/L)

Flufenacet, 240 g a.s./L

Diflufenican, 180 g a.s./L

Safener Cloquintocet acid 7.8 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(new application)

Applicant: CORTEVA
Date:12/04/2024

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PART A
RISK MANAGEMENT

1 Details of the application

The company CORTEVA Agriscience has requested a marketing authorisation in France for the product ELIPRIS (formulation code: GF-3678), containing 11,7 g/L Halauxifen-methyl[1], 240 g/L Flufenacet[2] and 180 g/L diflufenican[3] as an herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of CORTEVA Agriscience's application submitted on 30/08/2021 to market ELIPRIS (GF-3678) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-0230) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[4], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[5]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ELIPRIS (GF-3678) has been made using endpoints agreed in the EU peer reviews of Halauxifen-methyl, Flufenacet and diflufenican. It also includes assessment of data and information related to ELIPRIS (GF-3678) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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1 Commission implementing regulation (EU) 2015/1165 of 15 July 2015 approving the active substance halauxifen-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

2 Commission implementing regulation (EU) No 540/2011of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

3 Commission implementing regulation (EU) No 540/2011of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

4 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

5 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

6 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

This document also describes the specific conditions of use and labelling required for France for the registration of ELIPRIS (GF-3678).

1.2 Letters of Access

The applicant has provided letters of access for active substance and PPP data. These letters of access is/are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « The studies submitted are necessary for first authorisation in Southern Zone and are in accordance with Reg. (EU) No. 284/2013. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ELIPRIS (GF-3678), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	GF-3678
Product name in MS	ELIPRIS
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	CORTEVA Agriscience
Active substance(s) (incl. content)	Halauxifen-methyl, 11.2 g/L (acid form) Flufenacet, 240.0 g/L Diflufenican, 180.0 g/L Cloquintocet acid, 7.8 g/L
Formulation type	Suspension Concentrate [SC]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

The evaluation of the application for (GF-3678) resulted in the decision **to refuse** the authorisation ELIPRIS.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : no marketing authorisation granted.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[7] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 Avril 2021[8] provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision

[7] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[9] is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021[10] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop[11]when in flower and on foraging area is forbidden.

Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted.

[9] SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

[10] Arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques - Légifrance (legifrance.gouv.fr)

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" , the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 12/04/2024

PPP (product name/code):	ELIPRIS / GF-3678	Formulation type:	SC [a, b]
Active substance 1:	Halauxifen-methyl	Conc. of a.s. 1:	11,7 g/L [c]
Active substance 2:	Flufenacet	Conc. of a.s. 2:	240 g/L [c]
Active substance 3:	Diflufenican	Conc. of a.s. 3:	180 g/L [c]
Safener:	Cloquintocet acid>	Conc. of safener:	7,8 g/L [c]
Synergist:	<synergist>	Conc. of synergist:	conc. g/L or g/kg [c]
Applicant:	CORTEVA Agriscience	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1.1	FR	**Winter cereals:** Soft wheat (TRZAW) *MRL code: 0500090* Spelt (TRZSP) *MRL code: 0500090* Barley (HORVW) *MRL code: 0500010* Rye (SECCE) *MRL code: 0500070* Triticale (TTLWI) *MRL code: 0500090*	F	**Grasses:** Apera spica-venti (APESV) Poa annua (POAAN) **+ Broadleaf weeds:** Viola arvensis (VIOAR) Veronica spp (VERSS) Centaurea cyanus (CENCY) Matricaria spp (MATSS) Papaver rhoeas (PAPRH)	Overall, Broadcast foliar spray	BBCH 00-09	a) 1 b) 1	N/a	a, b) 0.5	a, b) 5.85 (5.6ae) + 120 + 90	100-400	N/a	**Not acceptable** (no national evaluation of cloquintocet acid, aquatic organisms, birds, mammals, earthworms and other soil organisms)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1.2	FR	**Winter cereals:** Soft wheat (TRZAW) *MRL code: 0500090* Spelt (TRZSP) *MRL code: 0500090* Barley (HORVW) *MRL code: 0500010* Rye (SECCE) *MRL code: 0500070* Triticale (TTLWI) *MRL code: 0500090*	F	**Grasses:** Apera spica-venti (APESV) Poa annua (POAAN) **+ Broadleaf weeds:** Viola arvensis (VIOAR) Veronica spp (VERSS) Centaurea cyanus (CENCY) Matricaria spp (MATSS) Papaver rhoeas (PAPRH)	Overall, Broadcast foliar spray	BBCH 09-13	a) 1 b) 1	N/a	a, b) 0.5	a, b) 5.85 (5.6ae) + 120 + 90	100-400	N/a	**Not acceptable** (no national evaluation of cloquintocet acid, aquatic organisms, birds, mammals, earthworms and other soil organisms)

GF-3678/ ELIPRIS
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1.3	FR	**Winter cereals:** Soft wheat (TRZAW) *MRL code: 0500090* Spelt (TRZSP) *MRL code: 0500090* Barley (HORVW) *MRL code: 0500010* Rye (SECCE) *MRL code: 0500070* Triticale (TTLWI) *MRL code: 0500090*	F	**Grasses:** Apera spica-venti (APESV) Poa annua (POAAN) **+ Broadleaf weeds:** Viola arvensis (VIOAR) Veronica spp (VERSS) Centaurea cyanus (CENCY) Matricaria spp (MATSS) Papaver rhoeas (PAPRH)	Overall, Broadcast foliar spray	BBCH 13-21	a) 1 b) 1	N/a	a, b) 0.5	a, b) 5.85 (5.6ae) + 120 + 90	100-400	N/a	**Not acceptable** (no national evaluation of cloquintocet acid, aquatic organisms, birds, mammals, earthworms and other soil organisms)
2	FR	**Winter cereals:** Durum wheat (TRZDU) *MRL code: 0500090*	F	**Grasses:** Apera spica-venti (APESV) Poa annua (POAAN) **+ Broadleaf weeds:** Viola arvensis (VIOAR) Veronica spp (VERSS) Centaurea cyanus (CENCY) Matricaria spp (MATSS) Papaver rhoeas (PAPRH)	Overall, Broadcast foliar spray	BBCH 09-21	a) 1 b) 1	N/a	a, b) 0.5	a, b) 5.85 (5.6ae) + 120 + 90	100-400	N/a	**Not acceptable** (no national evaluation of cloquintocet acid, aquatic organisms, birds, mammals, earthworms and other soil organisms)

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

ELIPRIS (GF-3678) is an suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of tan liquid. It is not explosive, has no oxidising properties. The product has a flash point of >100 °C. It has a self-ignition temperature of >400 °C. In aqueous solution, it has a pH value around 6.45 at 20.7 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least a 2 years at ambient temperature when stored in PET and HDPE containers. Its technical characteristics are acceptable for a SC formulation.

In the absence of the data required to establish specifications for cloquintocet acid, it was not possible to assess the specifications for this safener.

3.2 Efficacy (Part B, Section 3)

Considering the submitted, data it can be concluded that:

- The interest of the association has been demonstrated only for early post emergence application in autumn (BBCH 09-13 of winte cereals). **However, no data has been submitted in order to justify the association neither for pre emergence application nor late post emergence application. This is considered as a data gap**.

- The level of efficacy of the product ELIPRIS (GF-3678) applied in early post emergence of winter cereals is considered acceptable.

- The level of selectivity on winter soft wheat, winter barley and winter rye is considered acceptable for these crops whatever the intended timing of application. Moreover, the risk of negative effect on yield, quality transformation processes and germination on these crops is also considered acceptable.

- On triticale, the level of selectivity is considered acceptable for pre-emergence, early post-emergence and late post-emergence applications in the fall and early winter. Nevertheless, strong symptoms of phytotoxicity are recorded for applications on sandy soils and in the event of heavy rains after application. Job recommendations were issued by the petitioner. Risks of negative impact on yield, quality and multiplication are considered acceptable on triticale.

- On durum winter wheat, the number of trials provided is insufficient to assess the selectivity of the product ELIPRIS (GF-3678) in early post-emergence and no data has been provided to assess the selectivity of the product in late post-emergence in autumn/early of winter. In addition, to deal with risks of phytotoxicity, the firm does not claim the use of the product in pre-emergence on this crop.

Consequently, the assessment of the selectivity of the product on hard winter wheat could not be finalized and a risk of phytotoxicity cannot be excluded. Similarly, the assessment of the risk of negative impact on yield could not be assessed. Consequently, the use of the product ELIPRIS (GF-3678) on hard winter wheat is deemed non-compliant.

The risk of negative effect on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.

The risk of negative effect on adjacent crops is considered acceptable. No management measures are required.

There is a risk of resistance development or appearance to flufenacet for *Lolium sp.* and *Alopecurus myosuroides* requiring a survey of resistance.

There is a risk of resistance development or appearance to halauxyfen methyl for *Papaver rhoaes* requiring a survey of resistance.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier, and are validated for the determination of flufenacet, diflufenican, halauxifen-methyl and cloquintocet-acid residues of in plants (high water, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids. The pre-registration methods for the determination of flufenacet in matrices of claimed crops were assessed at EU level before the guidance document SANTE/2017/16032 rev.4 entered into force. With these methods, an uncertainty exists on the quantification of residue level in matrices of the claimed crops due to the absence of demonstration of extraction efficiency.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints				
Active substance	**Halauxifen-methyl** 11.7 g as/L; 11.2 g ae/L	**Flufenacet** 240 g as/L;	**Diflufenican** 180 g as/L	**Cloquintocet-acid*** 7.8 g/L
AOEL systemic	0.058 mg/kg bw/d	0.017 mg/kg bw/d	0.11 mg/kg bw/d	Not established
Oral absorption	100%	100%	100%	
Vapour pressure	100%	100%	58%	
Dermal absorption	Concentrate: 50% Dilution: 50%	Concentrate: 0,48% Dilution: 13%	Concentrate: 10% Dilution: 50%	Concentrate: Dilution:

***The risk assessment of the safener cloquintocet acid for operators, workers, residents and bystanders could not be conducted since this safener has not been evaluated at a national level and no specific request has been submitted.**

3.4.1 Acute toxicity

GF-3678/ ELIPRIS containing 11.7 g a.s./L (11.2 g ae/L) of Halauxifen-methyl 240 g a.s./L of Flufenacet, 180 g a.s./L of Diflufenican, and 7.8 g/L of Cloquintocet acid (Safener) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

However, the classification of the safener cloquintocet acid for human health hazard cannot be established since this safener has not been evaluated at a national level and no specific request has been submitted.

Therefore, the classification of the product GF-3678/ ELIPRIS cannot be established.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[12]:

Spray application: Tractor mounted boom spray application outdoors to winter cereals Area Treated: 50 ha/day (AOEM**;** 75th percentile) Body weight: 60 kg						
Model Information	**Halauxifen-methyl**		**Flufenacet**		**Diflufenican**	
Number of applications and application rate	1 × 0.0056 kg ae/ha		1 × 0.120 kg/ha		1 × 0.090 kg/ha	
Level of PPE	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Work wear (arms, body and legs covered) M/L & A	0.016	27%	0.0029	17%	0.032	29%
Work wear (arms, body and legs covered) M/L & A + PPE	0.0006	1%	0.0005	3%	0.0019	2%

Based on the exposure assessment using the EFSA model, operator exposure to ELIPRIS (GF-3678) is below the AOEL value of active substances Halauxifen-methyl, Flufenacet, Diflufenican for all intended uses, with or without a working coverall and gloves during mixing and loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

[12] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to EFSA model.

Inspection and irrigation Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha							
Model Information		**Halauxifen-methyl**		**Flufenacet**		**Diflufenican**	
Number of applications and application rate		1 × 0.0056 kg ae/ha		1 × 0.120 kg/ha		1 × 0.090 kg/ha	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Work wear (arms, body and legs covered) TC: 1,400 cm²/person/h		0.0004	0.7%	0.002	13%	0.0063	6%

Based on the exposure assessment using the EFSA model, worker exposure to ELIPRIS (GF-3678) is below the AOEL value of active substances Halauxifen-methyl, Flufenacet, Diflufenican for all intended uses, considering the use of workwear.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[13].
Only resident exposure is provided since, according to EFSA 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): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.4.5 Resident exposure

Resident exposure was assessed according to EFSA model with mitigation measures, a distance of 3 metres from the spray boom and no drift reduction technology was considered.

[13] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Model data		Halauxifen-methyl		Flufenacet		Diflufenican	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray Buffer zone: 2-3(m) Drift reduction technology: No DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha							
Number of applications and application rate		1 × 0.0056 kg ae/ha		1 × 0.120 kg/ha		1 × 0.090 kg/ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0008	1%	0.004	25%	0.01	11%
	Vapour (75th perc.)	0.001	2%	0.001	6%	0.001	1%
	Deposits (75th perc.)	0.0000	0.1%	0.0003	2%	0.0007	1%
	Re-entry (75th perc.)	0.0005	1%	0.003	15%	0.008	7%
	Sum (mean)	**0.002**	**3%**	**0.006**	**34%**	**0.014**	**13%**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.3%	0.001	6%	0.003	3%
	Vapour (75th perc.)	0.0002	0.4%	0.0002	1%	0.0002	0.2%
	Deposits (75th perc.)	0.0000	0.03%	0.0001	1%	0.0003	0.3%
	Re-entry (75th perc.)	0.0003	0.5%	0.002	9%	0.004	4%
	Sum (mean)	**0.0005**	**1%**	**0.002**	**11%**	**0.005**	**5%**

Based on the exposure assessment using the EFSA model, the resident exposure (adult and child) to ELIPRIS (GF-3678) is below the AOEL of each of the active substances Halauxifen-methyl, Flufenacet, Diflufenican for all intended uses considering 3 meters buffer strip.

3.4.6 Combined exposure

A cumulative assessment for operators, residents (adult and child) and workers is necessary to take into account all active substances, Halauxifen-methyl, Flufenacet, Diflufenican, and the safener cloquintocet acid.

However, the risk assessment of the safener cloquintocet acid for operators, workers, residents and bystanders could not be conducted since this safener has not been evaluated at a national level and no specific request has been submitted.

Therefore, the combined exposure could not been performed.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.02* mg/kg for halauxifen-methyl in cereals, as laid down in Reg. (EU) 396/2005 is not expected. An exceedance of the current MRL of 0.1 mg/kg for flufenacet in wheat and barley, 0.05* mg/kg in rye and 0.02 mg/kg for diflufenican, as laid down in Reg. (EU) 396/2005 is also not expected.

The chronic intakes of halauxifen-methyl, flufenacet, diflufenican and cloquintocet acid residues are unlikely to present a public health concern.
The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for diflufenican.
The short-term intakes of halauxifen-methyl and flufenacet residue are unlikely to present a public health concern.

The consumer exposure of the safener cloquintocet acid could not be conducted since this safener has not been evaluated at a national level and no specific request has been submitted.

As far as consumer health protection is concerned, France, zRMS does not agree with the authorization of the intended uses.

Crop	PHI for ELIPRIS GF-3678 proposed by applicant	PHI/ Withholding period* sufficiently supported for				PHI for ELIPRIS GF-3678 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Halauxifen-Methyl	Flufenacet	Diflufenican	Cloquintocet Acid		
Soft Wheat, Durum Wheat, Barley, Spelt, Rye, Triticale	NR	Yes	Yes	Yes	**No**	F	

NR: not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of flufenacet, diflufenican, halauxifen-methyl and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

In the absence of a national assessment dedicated to the safener cloquintocet acid, PEC for cloquintocet-acid cannot be assessed for any of the environmental compartments.

PEC_{SOIL} derived for the flufenacet, diflufenican, halauxifen-methyl and their metabolites are used for the ecotoxicological risk assessment.

For application before dormancy only (BBCH 00-20), PEC_{SW} derived for the flufenacet, diflufenican, halauxifen-methyl and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{GW} for flufenacet, diflufenican, halauxifen-methyl and their metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Only autumn applications are covered by the notifier simulations. Therefore, no unacceptable risk of groundwater contamination with these susbtances is expected for the intended uses for application before dormancy only (BBCH 00-20). **However, in the absence of a national assessment dedicated to the safener cloquintocet acid, the risk assessment for groundwater contamination cannot be conducted for this safener.**

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, honey bees and non-target arthropods other than bumble bees, soil macro-organisms other than earthworms, soil micro-organisms and non-target terrestrial plants are acceptable for the intended uses. Mitigation measures are required for non-target plants.

For aquatic organisms, according to E-fate section, exposure assessment for cloquintocet-acid and its metabolites cannot be used for risk assessment in any of the compartments. Moreover, a potential risk was identified from exposure to diflufenican based on PECsw FOCUS Step 3 and 4 in first-tier risk assessment. A refined risk assessment, based on a toxicity study with algae including recovery was proposed by applicant. However, comparison with exposure profiles were not provided by applicant. **Therefore, in accordance with the European approach[14], the risk assessment for aquatic organisms cannot be finalized.**

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document (2013)[15]. No data is available for bumblebees. However the applicant proposed a risk assessment for these organisms based on honey bee toxicity values divided by 10 in accordance with the EFSA Guidance Document (2013). A potential risk was triggered for bumble bees at Tier 1 for use on cereals. **The refined risk assessment proposed by the applicant is not in accordance with the EFSA Guidance Document (2013). Therefore, the risk assessment for bumble bees could not be finalized for use on cereals.**

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

[14] Addendum – Volume 3, April 2007 et EFSA Scientific report No. 122 (2007)

[15] European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

ELIPRIS (GF-3678) contains diflufenican and flufenacet which are approved as candidates for substitution because they fulfill two of PBT criteria (Persistent and Toxic).
Preliminary Step / Request for derogation from comparative assessment:
The information submitted to comply with Article 50(3) of Regulation (EC) No 1107/2009 is considered acceptable.
As it is necessary to acquire experience first through using the product in practice, comparative assessment will not be put in place for any of the requested uses.
Therefore, the authorisation would be granted once only, for a period not exceeding five years.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

Appendix 1 Copy of the product authorisation DAMM

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le règlement (UE) n° 284/2013 établissant les exigences en matière de données applicables aux produits phytopharmaceutiques,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***ELIPRIS***

de la société	*CORTEVA AGRISCIENCE FRANCE S.A.S.*
enregistrées sous les	*n° 2021-0230, 2021-2351 et 2023-0205*

Vu les conclusions de l'évaluation de l'Anses du 15 novembre 2023,

Considérant qu'en l'absence des données nécessaires, il n'a pas été possible d'établir des spécifications pour le cloquintocet acide,

Considérant l'absence d'évaluation nationale du phytoprotecteur cloquintocet acide,

Considérant en conséquence que le respect des limites maximales de résidus en vigueur au niveau national n'a pas pu être vérifié et l'évaluation des risques ne peut pas être conduite,

Considérant de plus, qu'un risque inacceptable pour les espèces non-cibles aquatiques et les vers de terre, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

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Informations générales sur le produit	
Nom du produit	ELIPRIS
Type de produit	Produit de référence
Titulaire	CORTEVA AGRISCIENCE FRANCE S.A.S. Immeuble Equinoxe II 1 bis avenue du 8 mai 1945 78280 GUYANCOURT France
Formulation	Suspension concentrée (SC)
Contenant	240 g/L - flufénacet 180 g/L - diflufénican 11,7 g/L - halauxifène-méthyl 7,8 g/L - cloquintocet acide
Numéro d'intrant	049-2021.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 12/04/2024

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105912 Blé*Désherbage	0,5 L/ha	1/an	F (BBCH 21)
	Motivation du refus : L'usage est refusé car, en l'absence d'évaluation nationale des risques du cloquintocet acide, le respect des limites maximales de résidus en vigueur au niveau national n'a pas pu être vérifié et l'évaluation des risques liés à l'utilisation du produit ne peut pas être conduite. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les espèces non-cibles aquatiques et les vers de terre. L'usage est refusé car la sélectivité du produit sur blé dur d'hiver n'a pas été démontrée. Enfin, l'usage est refusé en prélevée et entre les stade BBCH 13-21 car le ratio en substances actives n'est pas justifié , et car l'intérêt de l'association des substances actives n'a pas été déterminé.		
15105913 Orge*Désherbage	0,5 L/ha	1/an	F (BBCH 21)
	Motivation du refus : L'usage est refusé car en l'absence d'évaluation nationale des risques du cloquintocet acide, le respect des limites maximales de résidus en vigueur au niveau national n'a pas pu être vérifié et l'évaluation des risques liés à l'utilisation du produit ne peut pas être conduite. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les espèces non-cibles aquatiques et les vers de terre. Enfin, l'usage est refusé en prélevée et entre les stade BBCH 13-21 car le ratio en substances actives n'est pas justifié , et car l'intérêt de l'association des substances actives n'a pas été déterminé.		

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105915 Seigle*Désherbage	0,5 L/ha	1/an	F (BBCH 21)
	Motivation du refus : L'usage est refusé car en l'absence d'évaluation nationale des risques du cloquintocet acide, le respect des limites maximales de résidus en vigueur au niveau national n'a pas pu être vérifié et l'évaluation des risques liés à l'utilisation du produit ne peut pas être conduite. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les espèces non-cibles aquatiques et les vers de terre. Enfin, l'usage est refusé en prélevée et entre les stade BBCH 13-21 car le ratio en substances actives n'est pas justifié , et car l'intérêt de l'association des substances actives n'a pas été déterminé.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

1G.1 projet d'étiquette_GF-3678