REGISTRATION REPORT
Part A
Risk Management

Product code: GF-3706
Product name(s): REXADE 275

Chemical active substance(s):

Halauxifen-methyl, 52.1 g as/kg (50 g ae/kg)

Florasulam, 37.5 g as/kg

Pyroxsulam, 187.5 g as/kg

Safener Cloquintocet acid, 266 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(new application)

Applicant: CORTEVA
Date: 12/04/2024

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

The company CORTEVA has requested a marketing authorisation in France for the product REXANE 275(formulation code: GF-3706), containing 52.1 g/kg Halauxifen methyl[1] , 37.5 g/kg Florasulam[2] , 187.5 g/kg Pyroxsulam[3] and safener 266 g/kg Cloquintocet acid as a 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's application submitted on 04/08/2020 to market REXADE 275 (GF-3706) 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 (2020-2651) 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 REXADE 275 (GF-3706) has been made using endpoints agreed in the EU peer reviews of halauxifen methyl, florasulam and pyroxsulam. It also includes assessment of data and information related to REXADE 275(GF-3706) 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.

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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) 2015/1397 of 14 August 2015 renewing the approval of the active substance florasulam 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

3 Commission Implementing Regulation (EU) No 1176/2013 of 20 November 2013 approving the active substance pyroxsulam, 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

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

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.

This document also describes the specific conditions of use and labelling required for France for the registration of REXADE 275 (GF-3706).

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance(s).

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 REXADE (GF-3706), 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-3706
Product name in MS	REXADE 275
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	Corteva
Active substance(s) (incl. content)	halauxifen-methyl, 52.1 g/kg pyroxsulam, 187.5 g/kg florasulam, 37.5 g/kg cloqunintocet acid, 266 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-

[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

Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

The evaluation of the application for REDAXE 275 resulted in the **decision to refuse** the authorisation.

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

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.

[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

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
- 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.

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

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 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.

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.

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

[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):	REXADE 275 / GF-3706	Formulation type:	WG [a, b]
Active substance 1:	Halauxifen-methyl	Conc. of a.s. 1:	52.12 g/kg (50 g ae/kg) (c)
Active substance 2:	Florasulam	Conc. of a.s. 2:	37.5 g/kg (c)
Active substance 3:	Pyroxsulam	Conc. of a.s. 3:	187.5 g/kg (c)
Safener:	*Cloquintocet acid*	Conc. of safener:	266 g/kg (c)
Applicant:	CORTEVA	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:** 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													

GF-3706/ REXADE 275
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	FR	**Winter cereals:** Soft wheat (TRZAW) *MRL code: 0500090* Durum wheat (TRZDU) *MRL code: 0500090* Spelt (TRZSP) *MRL code: 0500090* Rye (SECCE) *MRL code: 0500070* Triticale (TTLWI) *MRL code: 0500090*	F	**Grasses:** Alopecurus myosuroides (ALOMY) Lolium spp (LOLSS) Avena spp (AVESS) Bromus spp. (BROSS) and other species **+ Broadleaf weeds:** Galium aparine (GALAP) Matricaria spp (MATSS) Veronica spp (VERSS) Fumaria officinalis (FUMOF) and other species	Overall, Broadcast foliar spray	BBCH 12-32	a) 1 b) 1	n/a	a, b) 0.1	a, b) 5,21 (5ae) + 3.75 + 18.75	100-400	N/a	**Not acceptable** (no national evaluation dedicated to cloquintocet acid, groundwater, benefits of combining active substances, selectivity in spring)

GF-3706/ REXADE 275
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		
2	SZ (BG, FR, IT, EL, HR)	**Winter cereals:** Soft wheat (TRZAW) *MRL code: 0500090* Durum wheat (TRZDU) *MRL code: 0500090* Spelt (TRZSP) *MRL code: 0500090* Rye (SECCE) *MRL code: 0500070* Triticale (TTLWI) *MRL code: 0500090*	F	Grasses: *Bromus* spp. (BROSS)	Overall, Broadcast foliar spray	BBCH 12 to 32	a) 2 b) 2	14 days	a) 0.05 b) 0.1	a) 2.62 (= 2.5 ae) + 1.875 + 9.38 b) 5.21 (= 5.0 ae) + 3.75 + 18.75	100-400	N/a	**Not acceptable** (no national evaluation dedicated to cloquintocet acid, groundwater, benefits of combining active substances, selectivity in spring)

* 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.

GF-3706/ REXADE 275
Part A - National Assessment
FRANCE

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)

REXADE (GF-3706) is Water dispersible granule (WG). 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 a a tan granule . It is not explosive and has no oxidising properties. It has a self- ignition temperature of 400°C. In aqueous solution (1%), it has a pH value of 4.51 at 20.3°C. There is no effect of low and high temperature on the stability of the formulation, since after 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 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

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)

The level of efficacy of the product REXADE 225 (GF-3706) applied at the rate of 0.1 kg / ha in post-emergence in spring is considered satisfactory for the control of broadleaf weeds and grasses for all the claimed uses. **However, the assessment of the benefit of the combination of active substances for positioning in spring on winter cereals could not be finalized due to insufficient data.**
The level of effectiveness of the product REXADE 225 (GF-3706) applied at a rate of 0.1 kg / ha in post-emergence in the fall is considered satisfactory for controlling bromine only for all the claimed uses. However, the combination of active substances and in particular the presence of halauxyfen and florasulam in the combination is not of interest for this positioning in the fall to fight only against bromines.

The selectivity level of REXADE 225 (GF-3706) applied post-emergence in autumn or spring is considered satisfactory on soft winter wheat, hard winter wheat and winter triticale and winter rye.
In the absence of data, the assessment of the selectivity of the product REXADE 225 (GF-3706) applied post-emergence in spring could not be finalized on soft spring wheat, hard spring wheat, spring triticale and spring rye.

Risks of negative impact on yield, quality, breadmaking processes and multiplication are considered acceptable.

The risk of negative impact on the following crops is considered acceptable. However, special attention should be paid to the conditions for establishing the following crops and replacement crops.
The risk of negative impact on adjacent crops is considered acceptable. However, special attention should be paid to the conditions of application of the product near adjacent crops.
There is a risk of the appearance or development of resistance to florasulam, in particular on poppy (*Papaver rhoeas*), chickweed (*Stellaria media*), matricaria (*Matricaria sp*.), Groundsel (*Senecio vulgaris*) requiring monitoring.
There is a risk of the appearance or development of resistance to pyroxsulam, in particular on black grass

(*Alopecurus myosuroides*), wild oats (A*vena sp*.), Bromes (*Bromus* sp.), Ray grass (*Lolium sp.)* .) requiring supervision.
There is a risk of the appearance or development of resistance to halauxyfen methyl, especially in poppy (*Papaver rhoeas*) requiring monitoring.

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 substance and the relevant impurities in the formulation are available and validated Analytical methods for the determination of the active substances in the formulation are available and validated. As the active substances pyroxsulam and Halauxifen-methyl do not contain relevant impurity, no analytical method is required. A method has been provided and validated for Florasulam.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of pyroxsulam, Halauxifen-methyl and Florasulamin plants (high water, oily, acidic and dry content commodities), food of animal origin, soil, water (surface and drinking), air and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

Product name and code	REXADE 275 (GF-3706)			
Formulation type	WG			
Category	Herbicide			
Active substance(s) (incl. content)	**Halauxifen-methyl** 52.12 g as/kg; 50 g ae/kg	**Florasulam** 37.5 g as/kg;	**Pyroxsulam** 187.5 g/kg	**Cloquintocet-acid** 266 g/kg
AOEL systemic	0.058 mg/kg bw/d	0.05 mg/kg bw/d	0.7 mg/kg bw/d	Not established
Inhalation absorption	100%	100%	100%	
Oral absorption	100%	100%	75%	
Dermal absorption (EFSA Defaults)[a,b]	Concentrate: 10% Dilution: 50%	Concentrate: 50% Dilution: 50%	Concentrate: 10% Dilution: 50%	Concentrate: Dilution:

[a] EFSA Journal 2017; 15(6):4873
[b] SANTE/ 2018/ 10591 rev 1

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

REXADE 275 (GF-3706) containing 52,116 g/kg of halauxifen-methyl, 37,5 g/kg of florasulam, 187,5 g/kg of pyroxsulam and 266 g/kg of cloquintocet acid 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 sensitiser.

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 REXADE 275 (GF-3706) cannot be established.

3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

Critical use: Cereals			
Tractor mounted outdoor, downward application			
Halauxifen methyl		Application rate: 0,0052 kg a.s./ha	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves	0,0006	1,09%
Florasulam		Application rate: 0,0038 kg a.s./ha	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves	0,0006	1,27%
Pyroxsulam		Application rate: 0,0188 kg a.s./ha	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves	0,0011	0,15%

Based on the exposure assessment using the EFSA model, operator exposure to REXADE 275(GF-3706) is below the AOEL value of active substances halauxifen methyl, florasulam, pyroxsulam for all intended uses, considering the use of workwear and gloves during mixing and loading and application.

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

3.4.3 Worker exposure

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

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

Critical use: Cereals			
Inspection/irrigation, outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3µg/cm²/kg a.s./ha Interval between multiple applications: 14 days			
Halauxifen methyl		Number and rate of application: 1 x 0,0052 kg a.s./ha (2 x 0,0026 kg a.s./ha)	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0,0004 (0,0003)	0,63% (0,54%)
Florasulam		Number and rate of application: 1 x 0,0038 kg a.s./ha (2 x 0,0019 kg a.s./ha)	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0,0003 (0,0002)	0,53% (0,46%)
Pyroxsulam		Number and rate of application: 1 x 0,0188 kg a.s./ha (2 x 0,0099 kg a.s./ha)	
Model	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0,0013 (0,0012)	0,19% (0,17%)

Based on the exposure assessment using the EFSA model, worker exposure to REXADE 275 (GF-3706) is below the respective AOEL value of halauxifen methyl, florasulam, pyroxsulam for all intended uses, taking into account that work wear (arms, body and legs covered) are worn.

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[12].
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 without mitigation measures (i.e. without drift reduction technology and with a buffer zone of 3 meters).

Critical use: Cereals			
Vehicle-mounted, downward spraying, outdoor Buffer zone: 2-3 meters Drift reduction technology: No DT_{50}: 30 days DFR: 3 µg/cm^2 of foliage/kg a.s. applied/ha Vapour pressure of active substance: Low volatile substances having a vapour pressure of <5x10^{-3} Pa Interval between multiple applications: 14 days Minimum volume water: 100 L/ha			
Halauxifen methyl		Number and rate of application	1 x 0,0052 kg a.s./ha (2 x 0,0026 kg a.s./ha)
Model	**Exposure pathways**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Resident child: EFSA model 2014 (AOEM Excel calculator) Body weight: 10 kg	Drift (75th perc.)	0,0007 (0,0003)	1,2% (0,6%)
	Vapour (75th perc.)	0,0011 (0,0011)	1,84% (1,84%)
	Deposits (75th perc.)	0,00002 (0,00002)	0,07% (0,06%)
	Re-entry (75th perc.)	0,0004 (0,0004)	0,76% (0,65%)
	Sum (mean)	0,0018 (0,0016)	3,16% (2,74%)
Resident adult: EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Drift (75th perc.)	0,0002 (0,0001)	0,29% (0,14%)
	Vapour (75th perc.)	0,0002 (0,0002)	0,4% (0,4%)
	Deposits (75th perc.)	0,00002 (0,00002)	0,03% (0,03%)
	Re-entry (75th perc.)	0,0002 (0,0002)	0,42% (0,36%)

[12] 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)

	Sum (mean)	0,0005 (0,0004)	0,89% (0,77%)
Florasulam		Number and rate of application	1 x 0,0038 kg a.s./ha (2 x 0,0019 kg a.s./ha)
Model	**Exposure pathways**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Resident child: EFSA model 2014 (AOEM Excel calculator) Body weight: 10 kg	Drift (75th perc.)	0,0005 (0,0003)	1,02% (0,51%)
	Vapour (75th perc.)	0,0011 (0,0011)	2,14% (2,14%)
	Deposits (75th perc.)	0,00001 (0,00001)	0,06% (0,05%)
	Re-entry (75th perc.)	0,0003 (0,0003)	0,64% (0,55%)
	Sum (mean)	0,0016 (0,0015)	3,26% (2,9%)
Resident adult: EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Drift (75th perc.)	0,0001 (0,0001)	0,24% (0,12%)
	Vapour (75th perc.)	0,0002 (0,0002)	0,46% (0,46%)
	Deposits (75th perc.)	0,00001 (0,00001)	0,03% (0,02%)
	Re-entry (75th perc.)	0,0002 (0,0002)	0,36% (0,31%)
	Sum (mean)	0,0004 (0,0004)	0,88% (0,78%)
Pyroxsulam		Number and rate of application	1 x 0,0188 kg a.s./ha (2 x 0,0099 kg a.s./ha)
Model	**Exposure pathways**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Resident child: EFSA model 2014 (AOEM Excel calculator) Body weight: 10 kg	Drift (75th perc.)	0,0025 (0,0013)	0,36% (0,19%)
	Vapour (75th perc.)	0,0011 (0,0011)	0,15% (0,15%)
	Deposits (75th perc.)	0,0001 (0,0001)	0,02% (0,02%)
	Re-entry (75th perc.)	0,0016 (0,0014)	0,23% (0,21%)
	Sum (mean)	0,0038 (0,003)	0,55% (0,44%)
Resident adult: EFSA model 2014 (AOEM Excel calculator) Body weight: 60 kg	Drift (75th perc.)	0,0006 (0,0003)	0,09% (0,05%)
	Vapour (75th perc.)	0,0002 (0,0002)	0,03% (0,03%)
	Deposits (75th perc.)	0,0001 (0,0001)	0,01% (0,01%)

	Re-entry (75th perc.)	0,0009 (0,0008)	0,13% (0,11%)
	Sum (mean)	0,0013 (0,0011)	0,18% (0,15%)

Based on the exposure assessment using the EFSA model, the resident exposure (adult and child) to REXADE 275 (GF-3706) is **below the AOEL** value of active substances halauxifen methyl, florasulam and pyroxsulam for all intended uses.

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, florasulam, pyroxsulam, 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 and 0.01 mg/kg for florasulam and pyroxsulam, as laid down in Reg. (EU) 396/2005 are not expected.

The chronic intakes of halauxifen-methyl, florasulam and pyroxsulam 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 florasulam and pyroxsulam.
The short-term intakes of halauxifen-methyl residues 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, FR zRMS does not agree with the authorization of the intended use.

Summary for REXADE 275 (GF-3706)

Crop	**PHI for REXADE 275 (GF-3706) proposed by applicant**	**PHI/ Withholding period sufficiently supported for**				**PHI for REXADE 275 (GF-3706) proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Halauxifen-Methyl	**Pyroxsulam**	**Florasulam**	**Cloquintocet Acid**		
cereals: Wheat, Rye and	F-BBCH 32	Yes	Yes	Yes	**No**	F-BBCH 32	-

Crop	PHI for REXADE 275 (GF-3706) proposed by applicant	PHI/ Withholding period sufficiently supported for				PHI for REXADE 275 (GF-3706) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Halauxifen-Methyl	Pyroxsulam	Florasulam	Cloquintocet Acid		
Triticale							

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 halauxifen-methyl, florasulam, pyroxsulam, cloquintocet-acid 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 and PECsw derived for halauxifen-methyl, florasulam, pyroxsulam and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for halauxifen-methyl, florasulam and their metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000[13].

PECgw for pyroxsulam and its metabolites were not considered reliable due to major deviations identified in the selection of the plant uptake factor and in the implementation of the pH-dependence of pyroxsulam sorption, that are not in accordance with the recommendations of the current guidance documents (EFSA, 2013[14] and EFSA, 2013[15]). **Therefore, the assessment of the risk of groundwater contamination for pyroxsulam and its metabolites cannot be finalized.**

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 conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed

[13] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.
[14] EFSA Journal 2013;11(6):329, Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers1
[15] EFSA Journal 2013;11(2):3114, Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers1

endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly

In the absence of a national assessment dedicated to the safener cloquintocet acid, the risk assessment for **non-target aquatic organisms, birds, mammals, bees, earthworms and other non-target soil macro-organisms and non-target soil microorganisms cannot be conducted for this safener.**

For the intended uses of the product REXADE 275 (GF-3706), the exposure levels of the active substances halauxifen-methyl, pyroxsulam and florasulam and their metabolites, estimated for aquatic non-target species, birds, mammals, bees, earthworms and other non-target soil macro-organisms and the non-target soil microorganisms, are lower than the reference toxicity values for each group of organisms, in the conditions of uses described under 2.5.

Regarding the other non-target species (non-target terrestrial plants and non-target arthropods), the risk assessment was carried out on the basis of toxicity data with the product REXADE 275 (GF-3706) in accordance with the in force guidance documents. The exposure levels of the product REXADE 275 (GF-3706) are lower than the reference toxicity values for these organisms. Risk mitigations are required for terrestrial non-target plants.

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.

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

Halauxifen-methyl, pyroxsulam and florasulam are not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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 ***REXADE 275***

de la société	*CORTEVA AGRISCIENCE FRANCE S.A.S.*
enregistrées sous les	*n° 2020-2651, 2021-2344 et 2023-0206*

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 de contamination des eaux souterraines, 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	REXADE 275
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	Granulé dispersable (WG)
Contenant	52,1 g/kg - halauxifène-méthyl 187,5 g/kg - pyroxsulam 37,5 g/kg - florasulame 266 g/kg - cloquintocet acide
Numéro d'intrant	678-2020.01
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	0,1 kg/ha	1/an	F (BBCH 32)
	Motivation du refus : L'usage est refusé car, en l'absence d'évaluation nationale des risques liés au 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 ni d'exclure un risque inacceptable de contamination des eaux souterraines, ni de justifier l'intérêt de l'association des substances actives dans le produit pour une application après reprise de végétation sur céréales d'hiver, ni de démontrer la sélectivité du produit en post levée sur céréales de printemps. Les autres modalités de traitement sont refusées pour les mêmes motifs.		
15105915 Seigle*Désherbage	0,1 kg/ha	1/an	F (BBCH 32)
	Motivation du refus : L'usage est refusé car, en l'absence d'évaluation nationale des risques liés au 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 ni d'exclure un risque inacceptable de contamination des eaux souterraines, ni de justifier l'intérêt de l'association des substances actives dans le produit pour une application après reprise de végétation sur céréales d'hiver, ni de démontrer la sélectivité du produit en post levée sur céréales de printemps. Les autres modalités de traitement sont refusées pour les mêmes motifs.		

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-3706