

REGISTRATION REPORT

Part A

Risk Management

Product code: GF-4320

Product name(s): FENCADE

Chemical active substance(s):

Mesosulfuron-methyl, 140 g/kg

Pyroxsulam, 140 g/kg

cloquintocet-acid, 248 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Corteva Agriscience

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 FENCADE (formulation code: GF-4320), containing 140 g/kg Mesosulfuron-methyl¹, 140 g/kg Pyroxsulam² and 248 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 Agriscience's application submitted on 28/09/2021 to market FENCADE (GF-4320) 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 (2021-1774) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009³, 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")⁴. 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 FENCADE (GF-4320) has been made using endpoints agreed in the EU peer reviews of Mesosulfuron-methyl and Pyroxsulam. It also includes assessment of data and information related to FENCADE (GF-4320) 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 546/2011⁵, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 renewing the approval of the active substance mesosulfuron 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 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

³ 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

⁴ 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](#)

⁵ 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

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This document also describes the specific conditions of use and labelling required for France for the registration of FENCADE (GF-4320).

1.2 Letters of Access

The applicant has provided letters of access for active substance . These letters of access 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 FENCADE (GF-4320), 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-4320
Product name in MS	FENCADE
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)	Mesosulfuron-methyl, 140 g/kg Pyroxsulam, 140 g/kg Cloquintocet-acid, 248 g/kg
Formulation type	Water-dispersible granule [WG]
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 FENCADE (GF-4320) 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.

2.4.2 Standard phrases under Regulation (EU) No 547/201

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 2017⁶ 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 April 2021⁷ provides that:

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

⁶ 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/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁷ <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 extrapolation⁸ 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 2021⁹ 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 crop⁹ 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.

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

⁹ 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)

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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): FENCADE / GF-4320
Active substance 1: Mesosulfuron-methyl
Active substance 2: Pyroxsulam
Safener : cloquintocet-acid:
Applicant: Corteva Agriscience
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Herbicide

Formulation type: WG ^(a, b)
Conc. of a.s. 1: 140 g/kg ^(c)
Conc. of a.s. 2: 140 g/kg ^(c)
Conc. of safener: 248 g/kg ^(c)
Professional use:
Non-professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop 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/Ki nd	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/ma x		
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 or situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	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/ma x		
1	France	Winter cereals: Soft wheat (TRZAW) Triticale (TTLWI) Durum wheat (TRZDU)	F	Grasses: <i>Alopecurus myosu- roides</i> (ALOMY) <i>Lolium spp</i> (LOLSS) <i>Avena spp</i> (AVESS) <i>Bromus spp</i> (BROSS) <i>Poa annua</i> (POAAN) <i>Phalaris spp</i> (PHASS) + Broadleaf weeds: <i>Veronica hederifolia</i> (VERHE) <i>Stellaria media</i> (STEME)	Overall, Broadcas t spray	BBCH 21 to 32	a) 1 b) 1	NA	a) 0.1 b) 0.1	a) b) 14 + 14	80-400	N/A	Not acceptable (no national evaluation dedicated to cloquintocet acid, selectivity for durum winter wheat, groundwater, aquatic organisms, soil organisms, efficacy)
2	France	Winter cereals: Soft wheat (TRZAW) Triticale (TTLWI) Durum wheat (TRZDU)	F	Grasses: <i>Bromus spp</i> (BROSS)	Overall, Broadcas t spray	BBCH 21 to 32	a) 2 b) 2	14	a) 0.05 b) 0.1	a) 7 + 7 b) 14 + 14	80-400	N/A	Not acceptable (no national evaluation dedicated to cloquintocet acid, selectivity for durum winter wheat, groundwater, aquatic organisms, soil organisms, efficacy)

* 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.

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Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	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.	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)

FENCADE (GF-4320) is a Water dispersible granule (WG). All studies have been performed in accordance with the current ret is not explosive and has no oxidizing properties. The product is not flammable. It has a self- ignition temperature below 400°C. In aqueous solution (1%), it has a pH value of 4.39 at 20.6 °C. There is no effect high temperature on the stability of the formulation, 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 and Foil Laminate. Its technical characteristics are acceptable for a WG formulation. The report of long term storage stability should be provided in post-authorisation.

The formulation is not classified for the physico-chemical part 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 ratio in active ingredient has been demonstrated, the use of safener is necessary and the rate of this one in the formula is acceptable.

However, no data has been submitted in order to demonstrate the interest of the association between pyroxsulam and mesosulfuron-methyl. Both active ingredients belong to the inhibitor of ALS. Resistance issues for this class of herbicide is very important. The combinaison of 2 ALS inhibitors could get worse rapidly the resistance situation. Data are necessary in order to define the benefit of use of the association of pyroxsulam and mesosulfuron-methyl regarding solo active ingredient applied alone. This data gap on the demonstration of the interest of the association is very critical.

The level of efficacy of the product FENCADE (GF-4320) applied post-emergence in the spring is considered satisfactory for all of the claimed uses.

The level of selectivity of the product FENCADE (GF-4320) in post-emergence in the spring is considered acceptable for soft winter wheat and triticale. The risk of negative impact on yield is considered acceptable.

The level of selectivity of the product FENCADE (GF-4320) in post-emergence in spring is considered non-compliant for hard winter wheat because high phytotoxicity symptoms are observed following the use of the product FENCADE (GF-4320) as well as yield losses.

The risks of negative impact on quality, bread-making processes and multiplication are considered negligible.

The risk of negative impact on subsequent crops is considered acceptable. However, special attention should be paid to the conditions for setting up replacement crops.

The risk of negative impact on adjacent crops is considered acceptable. However, particular attention must

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be paid to the conditions of application of the product near sensitive adjacent crops.

There is a risk of resistance to pyroxsulam for blackgrass (*Alopecurus myosuroides*), wild oats (*Avena sp.*), bromes (*Bromus sp.*), Ray grass (*Lolium sp.*), *Stellaria media* and *Matricaria species* in straw cereal crops requiring a survey of resistance monitoring. Moreover, considering the current resistance status of grass weeds to inhibitors of ALS, the authorisation of the product should be linked to the following safety precautions related to good agricultural practice (SPa):

SPa1 : As part of the management of resistance of grass weeds in straw cereals to ALS inhibitors, the use of products based on such active substances should be limited to 1 application per campaign, all products combined. However, in the context of *Bromus sp.* management, a double application of the product GF 4320 is possible at half doses with 3 weeks interval between the applications. It is also allowed to use the product GF4320 to carry out a second intervention in outing of winter in a weeding program.

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, relevant impurity are not necessary.

3.3.2 Analytical methods for residues

Analytical methods are available in the monographs and in this dossier and validated for the determination of residues of pyroxsulam and mesosulfuron-methyl in plants, food of animal origin, soil, water (surface and drinking).

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints			
Active substance	Pyroxsulam	Mésosulfuron-méthyl	Cloquintocet acid*
AOEL systemic	0.7 mg kg bw/d	0.13 mg kg bw/d	Not established
Inhalation absorption	100%	100%	
Oral absorption	75%	2%	
Dermal absorption	Concentrate : 10% Spray dilution : 50%	Concentrate : 10% Spray dilution : 50%	Concentrate : Spray 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

FENCADE (GF-4320) containing 140g/kg Pyroxsulam, 140 g/kg Mesosulfuron-methyl, and 248 g/kg Cloquintocet acid has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin and 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 FENCADE (GF-4320) cannot be established.

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model¹⁰:

Model data		Pyroxsulam	Mesosulfuron-methyl
	Level of PPE	% AOEL	% AOEL
Application : Tractor mounted boom spray application outdoors to low crops Cereals			
Application rate: max. 100g / kg product/ha		0.014 kg a.s./ha	0.014 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Potential exposure	0.75%	4.01%
	Work wear (arms, body and legs covered) M/L and A	0.45%	2.44%
	Work wear (arms, body and legs covered) M/L and A + gloves M/L and A	0.14%	0.73%

Based on the exposure assessment using the EFSA model, operator exposure to FENCADE (GF-4320) is below the AOEL value of active substances pyroxsulam and mesosulfuron-methyl 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.

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

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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 AOEM model.

Model data			Pyroxsulam	Mesosulfuron-methyl
		Level of PPE	% AOEL	% AOEL
Activity: inspection, irrigation Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Number of applications : 1 Interval between treatments: 365 days				
Number of applications and application rate			1 x 0.014 kg a.s./ha	1 x 0.014 kg a.s./ha
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h		1.25%	6.73%
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h		0.14%	0.75%

Based on the exposure assessment using the EFSA model, worker exposure to FENCADE (GF-4320) is below the AOEL value of active substances pyroxsulam and mesosulfuron-methyl 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 set¹¹.

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 the EFSA model

¹¹ 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		Pyroxsulam	Mesosulfuron-methyl
		% AOEL	% AOEL
Scenario: Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 (m) DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Drift reduction technology: no Number of applications : 1 Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.014 kg a.s./ha	1 x 0.014 kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	0.34%	1.81%
	Vapour (75th percentile)	0.15%	0.82%
	Surface deposits (75th percentile)	0.02%	0.08%
	Entry into treated crops (75th percentile)	0.17%	0.91%
	All pathways (mean)	0.48%	2.6%
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	0.08%	0.43%
	Vapour (75th percentile)	0.03%	0.18%
	Surface deposits (75th percentile)	0.01%	0.04%
	Entry into treated crops (75th percentile)	0.09%	0.5%
	All pathways (mean)	0.15%	0.81%

Based on the exposure assessment using the EFSA model, the resident exposure (adult and child) to FENCADE (GF-4320) is below the AOEL of each of the active substances pyroxsulam and mesosulfuron-methyl 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, mesosulfuron-methyl, 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 be performed.

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

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The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for pyroxsulam, 0.01 mg/kg for mesosulfuron-methyl as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and intakes of pyroxsulam and mesosulfuron-methyl 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 pyroxsulam and mesosulfuron-methyl.

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 do not agree with the authorization of the intended use.

Table 3.5-6: Information on FENCADE (GF-4320) (KCA 6.8)

Crop	PHI for FEN-CADE (GF-4320) proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for FEN-CADE (GF-4320) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyroxsulam	Mesosulfuron-methyl	Cloquintocet acid		
Winter cereals: Soft wheat (TRZAW) Triticale (TTLWI) Durum wheat (TRZDU)	F**-BBCH 32	Yes	Yes	No	F**-BBCH 32	

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

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 mesosulfuron-methyl, pyroxsulam 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.

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PEC soil derived for mesosulfuron-methyl, pyroxsulam and their metabolites, with the exception of pyroxsulam metabolite PSA¹², are used for the ecotoxicological risk assessment, and mitigation measures are proposed. **In the absence of exposure assessment in soil for PSA required according to regulation 284/2013, the risk assessment for this metabolite cannot be finalized.**

Since no PEC_{gw} modelling files were made available by the Applicant, groundwater exposure calculations cannot be validated. In addition, no PEC_{gw} calculations were provided for the relevant¹³ metabolite BCS-CV14885¹⁴. PEC_{gw} 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, 2013¹⁵ and 2013¹⁶). **Therefore, the assessment of the risk of groundwater contamination for mesosulfuron-methyl, pyroxsulam and their metabolites cannot be finalized for all intended uses.**

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.

Since no PEC_{sw/sed} modelling files were made available to zRMS, surface water exposure calculations cannot be validated. **In addition, in the absence of exposure assessment for relevant¹⁷ metabolite PSA, the risk assessment for non-target aquatic organisms cannot be finalized for this metabolite. Consequently, the exposure assessment for surface water compartment for mesosulfuron-methyl, pyroxsulam and their metabolites cannot be finalized for all intended uses.**

In the absence of a national assessment dedicated to the safener cloquintocet acid, the exposure assessment for surface water compartment cannot be conducted for this safener.

No groundwater and surface water exposure calculations were provided for multiple applications. Consequently, the risk assessment cannot be finalised for the active substances and their metabolites for the multiple applications. Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

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 other non-target arthropods, is acceptable for the intended uses.

¹² 2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonic acid

¹³ Regulation (EC) n°284/2013

¹⁴ Methyl2-[(carbamimidoylcarbonyl)sulfamoyl]-4-[[methylsulfonyl]amino]methyl]benzoate; metabolite of mesulfuron-methyl

¹⁵ EFSA Journal 2013;11(6):329, Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers1

¹⁶ EFSA Journal 2013;11(2):3114, Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of lower tiers1

¹⁷ Regulation (EC) n°284/2013

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For aquatic organisms, in absence of acceptable PEC_{sw}, the aquatic risk assessment cannot be finalized. Please refer to point 9.5.2 and registration report of Section B8 for details.

For soil macro and micro organisms, in absence of PEC_{sw} for the metabolite of pyroxsulam PSA, the risk assessment cannot be finalized.

In addition, no evaluation of the toxicity data of the safener cloquintocet-acid can be performed by zRMS as part of this dossier application. Thus, the toxicity data and risk assessment related to the cloquintocet-acid reported in the core dossier are presented for information only. **Therefore, the risk assessment for birds, mammals, aquatic organisms, bees and soil organisms cannot be finalized.** Considering the non-target arthropods and non-target terrestrial plants, the risk assessment is based on toxicity data for the formulation as usually done at EU or zonal level

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)

Mesosulfuron-methyl and pyroxsulam 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.

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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 réglementaire,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **FENCADE***

de la société CORTEVA AGRISCIENCE FRANCE S.A.S.

enregistrée sous le n° 2021-1774

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 également 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	FENCADE
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	140 g/kg - pyroxsulam 140 g/kg - mésosulfuron-méthyl 248 g/kg - cloquintocet acide
Numéro d'intrant	511-2021.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 12/04/2024

DocuSigned by:

Charlotte Grastilleur

AE281A955A442454

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	100 g/ha	1/an	F (BBCH 32)
	<p>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 refusé car la sélectivité du produit sur blé dur d'hiver n'a pas été démontrée. L'usage est refusé car les données disponibles ne permettent pas de déterminer l'intérêt de l'association des substances actives. L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque de contamination des eaux souterraines, d'effet inacceptable pour les espèces non-cibles aquatiques, les vers de terre et autres organismes du sol.</p>		

Appendix 3 : 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-4320

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