

REGISTRATION REPORT

Part A

Risk Management

Product code: 102000025797

Product name(s): VALDOR TRIO

Chemical active substance(s):

foramsulfuron, 240 g/kg

iodosulfuron-methyl-sodium, 24 g/kg

thiencarbazone-methyl, 100 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal according to Art. 43)

Applicant: 2022 ENVIRONMENTAL SCIENCE FR SAS

Date: 27/11/2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company 2022 ENVIRONMENTAL SCIENCE FR SAS has requested a marketing authorisation in France for the product VALDOR TRIO (formulation code: 102000025797), containing 240 g/kg foramsulfuron¹, 24 g/kg iodosulfuron-methyl-sodium²¹ and 100 g/kg thiencazone-methyl³ 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 2022 ENVIRONMENTAL SCIENCE FR SAS's application submitted on 28/08/2020 to market VALDOR TRIO (102000025797) 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 re-registration of authorisation after the renewal of approval of the active(s) substance(s) foramsulfuron of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2020-2279) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009⁴, 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 VALDOR TRIO (102000025797) has been made using endpoints agreed in the EU peer review of foramsulfuron. It also includes assessment of data and information related to VALDOR TRIO 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.

¹ Commission Implementing Regulation (EU) 2020/616 of 5 May 2020 renewing the approval of the active substance foramsulfuron 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 540/2011 of 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 145/2014 of 14 February 2014 approving the active substance thiencazone, 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](#)

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In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to foramsulfuron following its renewal of approval. For iodiosulfuron-methyl-sodium and thiencarbazone-methyl, provisions of the initial authorisation remain.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁶, 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 VALDOR TRIO (102000025797).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of VALDOR TRIO (102000025797), 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	102000025797
Product name in MS	VALDOR TRIO
Authorisation number	2200279
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	2022 ENVIRONMENTAL SCIENCE FR SAS
Active substance(s) (incl. content)	foramsulfuron, 240 g/kg. iodiosulfuron-methyl-sodium, 24 g/kg. thiencarbazone-methyl, 100 g/kg.
Formulation type	Water-dispersible granule, WG.

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

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Packaging	100 ml, 250 ml, 500 ml, 1 L, (HDPE/EVOH) 250 ml, 500 ml, 1 L, 3 L, 5 L, 10 L (HDPE/PA)
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 VALDOR TRIO resulted in the decision **to grant** 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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Carcinogenicity, category 2 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H351: Suspected of causing cancer H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	-

See Part C for justifications of the classification and labelling proposals.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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	For other restrictions refer to 2.5
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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 2017⁷ 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.

Moreover, the French Order of 12 April 2021⁸ 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 extrapolation⁹ 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 2021¹⁰ 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 crop¹¹ 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.

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>

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

¹⁰ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹¹ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

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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

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Bystander and resident protection	
	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 2	To protect bees, do not apply to surroundings of railways for uses in railways.
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies for uses in pathways, sidewalks, cemeteries, industrial sites and railways.
SPe 4	To protect aquatic organisms do not apply on impermeable surfaces such as asphalt, concrete, cobblestones, and other situations with a high risk of run-off for uses in pathways, sidewalks, cemeteries and industrial sites.
	Avoid spray drift to nearby plants for uses in railways (surroundings of railways).
SPe 8	To protect bees and other pollinating insects, do not use in presence of bees and other pollinating insects, do not apply when flowering weeds are present.
Other specific restrictions	
Re-entry period	48 hours
Storage	-
SPa 1	-
Risk mitigation measures	- To prevent any risk of phytotoxicity, specify the optimum conditions for application in relation to adjacent crops.
Agricultural recommendations	-

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2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

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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 26 March 2014 (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.

PPP (VALDOR TRIO/code):	VALDOR TRIO / 102000025797	Formulation type:	GAP rev. 1, date: 27-11-2024 WG ^(a, b)
Active substance 1:	foramsulfuron	Conc. of as 1:	240 g/kg ^(c)
Active substance 2:	iodosulfuron-methyl-sodium	Conc. of as 2:	24 g/kg ^(c)
Active substance 3:	thiencarbazone-methyl	Conc. of as 3:	100 g/kg ^(c)
Safener:	Not applicable	Conc. of safener:	Not applicable ^(c)
Synergist:	Not applicable	Conc. of synergist:	Not applicable ^(c)
Applicant:	2022 ENVIRONMENTAL SCIENCE FR SAS	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	southern ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Herbicide		

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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 and/ 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. 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	South zone Central zone	IVM: Industrial area, Non crop Land, Fallow land	F	Total weed control annual weeds and perennial weeds	Spray (broadcast or band or spot) Knapsack + lance, Knapsack + boom, Tank + lance, Tank + boom, Tractor + boom, Vehicle mounted boom	Feb to Oct - Early to mid post of weeds	1 per season	n/a	0.150 kg/ha	36 g/ha FSN 3.6 g/ha IMS 15 g/ha TCM	100-600 (150-600 in case of knapsack use)	n/a	Acceptable
2	South zone Central zone	IVM: Soft Surfaces	F	Total weed control annual weeds and perennial weeds	Spray (broadcast or band or spot) Knapsack + lance, Knapsack + boom, Tank + lance, Tank + boom, Tractor + boom, Vehicle mounted boom	Feb to Oct - Early to mid post of weeds	1 per season	n/a	0.150 kg/ha	36g/ha FSN 3.6 g/ha IMS 15 g/ha TCM	100-600 (150-600 in case of knapsack use)	-	Acceptable
3	South zone Central zone	IVM: Railway	F	Total weed control annual weeds and perennial weeds	Spray (broadcast or band or spot) Knapsack + lance, Knapsack + boom, Spray train, 'Unimog'	Feb to Oct - Early to mid post of weeds	1 per season	n/a	0.150 kg/ha	36g/ha FSN 3.6 g/ha IMS 15 g/ha TCM	100-600 (150-600 in case of knapsack use)	-	Acceptable

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Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(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	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)

The appearance of the product is that of grey-green granule, with a weak synthetic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 375 °C. In 1% aqueous solution, it has a pH value around 9.2 at ambient temperature. There is no effect of 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 a HDPE/EVOH bottle, as the formulation is WG, the HDPE/PA packaging can be considered as acceptable. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.025 % to 0.15 % w/v.

The product can be mixed in the tank together with the adjuvant Mero. Studies regarding the combination with Mero were submitted.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of VALDOR TRIO (102000025797) is considered satisfactory for all the claimed uses for the control of dicotyledonous and grass weeds.
- the risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.
- There is a risk of resistance development or appearance to foramsulfuron, iodosulfuron methyl sodium and thiencarbaone methyl requiring a monitoring for the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Sufficiently sensitive and selective analytical methods are available for the active substance(s) and relevant impurities in the plant protection product.

3.3.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions in plants, matrices of animal origin, water (surface and drinking), soil, air and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

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Agreed EU endpoints	
Active substance	foramsulfuron
AOEL systemic	0.1 mg/kg bw/d (corrected for 20 % oral absorption)
AAOEL	none
Oral absorption	20%
Vapour pressure	5.8×10^{-12} Pa \times m ³ \times mol ⁻¹
Reference	EFSA Journal 2016;14(3):4421
	SANTE/2016/11214 Rev 2– 24/03/2020
Dermal absorption	Concentrate: 0.31% Dilution: 9.7% (Dilution rate: 1:4000) Based on product (formulation).

3.4.1 Acute toxicity

VALDOR TRIO (102000025797) containing 240 g/kg foramsulfuron, 24 g/kg iodosulfuron-methyl-sodium and 100 g/kg thiencarbazone-methyl 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 but is classified as carcinogen cat 2.

3.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹²:

Model data	Level of PPE	foramsulfuron
		% AOEL
Application : Downward spraying, Vehicle-mounted / Outdoor Critical use: fallow land		
Application rate: 0.15 kg PPP /ha		0.036 kg foramsulfuron / ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	0.88
Application : Downward spraying, Handheld / Outdoor Critical use: fallow land		
Application rate: 0.15 kg PPP /ha		0.036 kg foramsulfuron / ha
Spray	Working coverall and	15.2

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

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ap-plica-tion (AOEM; 75th per- centile) Body weight: 60 kg	gloves during mix/loading and application	
Application : Downward spraying, Knapsack / Outdoor Critical use: fallow land		
Application rate: 0.15 kg PPP /ha		0.036 kg foramsulfuron / ha
Spray ap-plica-tion (AOEM; 75th per- centile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	15.27

Considering proposed uses, operator systemic exposure was estimated using the ZNA model¹³:

Model data	Level of PPE	foramsulfuron
		% AOEL
Application : Downward spraying, Vehicle-mounted / Outdoor Critical use: fallow land		
Application rate: 0.15 kg PPP /ha		0.036 kg foramsulfuron / ha
Spray ap-plica-tion (AOEM; 75th per- centile) Body weight: 60 kg	Working coverall during mix/loading and application and gloves during M/C	0.35
Application : Downward spraying, Handheld / Outdoor Critical use: fallow land		
Application rate: 0.15 kg PPP /ha		0.036 kg foramsulfuron / ha
Spray ap-plica-tion (AOEM;	Working coverall and gloves during mix/loading	0.52

¹³ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

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75th percentile) Body weight: 60 kg	and application	
Application : Downward spraying, Knapsack / Outdoor		
Critical use: fallow land		
Application rate: 0.15 kg PPP /ha	0.036 kg foramsulfuron / ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	0.03

According to the model calculations, it can be concluded that the risk for the operator using VALDOR TRIO (102000025797) is acceptable with a working coverall and gloves during mixing/loading and application.

Regarding weeder train operator exposure, data have been submitted by the applicant (refer to RR section B6). However, in absence of quantitative data for operator exposition under real exposure conditions, the risk for the operator cannot be finalised.

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

3.4.3 Worker exposure

Worker risk assessment has been evaluated as per EFS model by zRMS :

		foramsulfuron
Level of PPE		%AOEL
Activity: Maintenance Outdoor Work rate: 8 hours/day Interval between applications: 365 days		
DT50: xxx days		30
DFR: xxx µg/cm ² /kg a.s./ha		3
Nb applications x Application rate (kg as/ha)		0.036 kg foramsulfuron / ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC:2500cm ² /person/h	3.49

It is concluded that there is no unacceptable risk anticipated for the worker without PPE, when re-entering crops treated with VALDOR TRIO (102000025797).

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 .

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

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) incorporating a buffer zone of 3 meters from the spray boom and without drift reduction technology:

Model (AOEM) - All pathways (mean)	foramsulfuron
	% AOEL
Resident (children)	2.10
Resident (adults)	0.62

According to the model calculation, for each active substance, an acceptable risk was determined for residents (adult and/or child).

3.4.6 Combined exposure

Not performed since the submission is related to foramsulfuron only.

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

As Garden, Vegetated Areas and Infrastructure crops are not intended for human or animal consumption, the assessment of residue levels and the risk to consumers associated with use on these crops is 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. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from

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

The PEC of foramsulfuron and its 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 or with specific models (*e.g.* HardSPEC), and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

For uses on hard surfaces, the estimation of PEC_{gw} is not considered relevant. For other uses, PEC_{gw} for foramsulfuron and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure and DT₅₀ in air 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 product VALDOR TRIO (102000025797) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the 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, aquatic organisms, other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and non-target terrestrial plants are acceptable for the intended uses.

For bees, according to new requirements of Reg. No. 284/2013, information on chronic effects on adult bees and on development of bees should have been submitted as exposure of bees to the formulation cannot be excluded for uses in pathways, sidewalks and cemeteries. In absence of these data, the risk for bees can not be finalized for uses in pathways, sidewalks, cemeteries.

Mitigation measures are needed for aquatic organisms, bees and non-target terrestrial 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)

The active substance foramsulfuron is 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

A survey of resistance to foramsulfuron,iodosulfuron methyl sodium and thiencarbazone methyl should be put in place, in particular on bromus species, searia species and hordeum murinum (one monitoring for all products based on foramsulfuron, iodosulfuron methyl sodium and thiencarbazone methyl) based on analysis of field efficacy failure. A report on the results of the monitoring put in place should be provided at the time of the renewal of the product VALDOR TRIO (102000025797).

5.1.2 Post-authorisation data requirements

The French decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Provide the results of an operator exposure study under actual exposure conditions using a weeding train, in accordance with the dedicated OECD protocol. As well as an updated registration report for this section.

Appendix 1 Copy of the product authorisation DAMM

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Décision relative à une demande de renouvellement de l'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 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 de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active foramsulfuron, du produit phytopharmaceutique **VALDOR TRIO***

de la société 2022 ENVIRONMENTAL SCIENCE FR SAS

enregistrée sous le n° 2020-2779

Vu les conclusions de l'évaluation de l'Anses du 16 février 2024,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	VALDOR TRIO
Type de produit	Produit de référence
Titulaire	2022 ENVIRONMENTAL SCIENCE FR SAS 1 place Giovanni Da Verrazzano 69009 LYON France
Formulation	Granulé dispersable (WG)
Contenant	24 g/kg - iodosulfuron-méthyl-sodium 100 g/kg - thiencarbazon-méthyl 240 g/kg - foramsulfuron
Numéro d'intrant	115-2017.01
Numéro d'AMM	2200279
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 septembre 2025.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 27/11/2024

DocuSigned by:

 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 : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité / éthylène alcool vinylique	100 mL ; 250 mL ; 500 mL ; 1 L
Bouteilles en polyéthylène haute densité / polyamide	250 mL ; 500 mL ; 1 L
Bidons en polyéthylène haute densité / polyamide	3 L ; 5 L ; 10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Cancérogénicité - Catégorie 2	H351 : Susceptible de provoquer le cancer
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
 En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
10015907 JEVI*Désherb. Total*Sites industriels et autres infrastructures	0,15 kg/ha	1/an	-	Non applicable	5	-	-	Non concerné
10015908 JEVI*Désherbage*PJT	0,15 kg/ha	1/an	-	Non applicable	5	-	-	Non concerné
01001001 JEVI*Désherbage*Voies ferrées	0,15 kg/ha	1/an	-	Non applicable	5	-	-	Non concerné

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à dos ou d'une lance

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 5/6 ;

OU

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

• pendant l'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection non tissée de catégorie III type 5/6 ;
- Bottes de protection certifiées EN 13 832-3.

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection non tissée de catégorie III type 5/6 ;

OU

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe ou d'un train désherbeur

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

• pendant l'application

Si application avec tracteur avec cabine ou train désherbeur

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

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Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation.

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 48 heures

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 2 : Pour protéger les abeilles, ne pas appliquer ce produit sur les bandes de proximité pour l'usage voies ferrées.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
- SPe 4 : Pour protéger les organismes aquatiques, ne pas appliquer sur des surfaces imperméables telles que le bitume, le béton, les pavés et dans toute autre situation où le risque de ruissellement est important pour les usages PJT, sites industriels et autres infrastructures.
- SPe 8 : Pour protéger les abeilles et autres insectes pollinisateurs, ne pas utiliser en présence d'abeilles et autres pollinisateurs, ne pas appliquer lorsque des adventices ou des broussailles en fleur sont présentes.

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Protection de la flore

- Eviter toute dérive de pulvérisation vers les plantes voisines pour l'usage voies ferrées (bande de proximité).

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision pendant une période de 6 mois.

Pour la mise sur le marché français, la fabrication du produit s'opère exclusivement selon la composition intégrale figurant en annexe des conclusions de l'évaluation, dans un délai maximum de 12 mois à compter de la présente décision.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Poursuivre le suivi de la résistance au foramsulfuron. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Poursuivre le suivi de la résistance au iodossulfuron. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Poursuivre le suivi de la résistance au thiencarbazon-méthyl. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-
Fournir les résultats d'une étude d'exposition des opérateurs dans les conditions réelles d'exposition à l'aide d'un train désherbeur, selon le protocole OCDE dédié. Ainsi qu'un registration report actualisé pour cette partie	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'application par rapport aux cultures adjacentes.

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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.



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2_0005570290_0004;