REGISTRATION REPORT

Part A

Risk Management

Product code: GF-2545 SC

Product name: TRIVALDI

Active substances:

metazachlor, 500 g/L

picloram, 13.3 g/L

Aminopyralid, 5.3 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: CORTEVA AGRISCIENCE FRANCE S.A.S.

Date: 15/04/2021

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PART A – Risk Management

The company CORTEVA AGRISCIENCE FRANCE S.A.S. has requested marketing authorisation in France for the product TRIVALDI (product code: GF-2545 SC), containing 500g/L metazachlor, 13.3g/L picloram and 5.3g/L aminopyralid, for use as an herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to TRIVALDI (GF-2545 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TRIVALDI (GF-2545 SC) have been made using endpoints agreed in the EU peer review(s) of the active substances.

This document describes the specific conditions of use and labelling required for France for the registration of TRIVALDI (GF-2545 SC).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Dow AgroSciences S.A.S.'s application to market TRIVALDI (GF-2545 SC) in France as an herbicide (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 MSs of the Southern zone.

1.2 Active substance approval

Metazachlor

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. Commission Implementing Regulation (EU) No 127/2012 of 14 February 2012 amending Implementing Regulation (EU) No 540/2011 as regards an extension of the use of the active substance metazachlor.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only uses as herbicide may be authorised; application max. of 1.0 kg/ha only every third year on the same field. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metazachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms,

— the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.

Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate.

If metazachlor is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer', the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer.

They shall ensure that the notifiers provide that information to the Commission within six months from the notification of such a classification decision.

Specific provisions of Regulation (EU) No 127/2012 were to amend Part A above as follows:

PART A

Only uses as herbicide may be authorised. Applications shall be limited to a total dose of not more than 1.0 kg metazachlor/ha in a three-year period on the same field.

Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme) extended the approval's expiration date to 31 July 2021.

An EFSA conclusion is available (EFSA Scientific Report (2008) 145, 1-132 Conclusion on the peer review of metazachlor), as amended by the Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for metazachlor in light of confirmatory data (EFSA supporting publication 2016:EN-1086) and Peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data submitted (EFSA Journal 2017;15(6):4833).

A Review Report is available (SANCO/140/08 – final rev. 2 24 January 2012).

Picloram

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.

Specific provisions of Regulation (EU) No 540/2011 were as follows:

PART A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picloram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account.

In the overall assessment Member States must pay particular attention to:

— the potential for ground water contamination where picloram is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate;

The Member States concerned shall ensure that the notifier submits to the Commission:

— further information to confirm that the monitoring analytical method applied in residue trials correctly

quantifies the residues of picloram and its conjugates; — a soil photolysis study to confirm the evaluation of picloram degradation. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.
An EFSA conclusion is available (EFSA Journal 2009; 7(12):1390), as amended by the Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for picloram in light of confirmatory data (EFSA Supporting publication 2017:EN-1258). A Review Report is available (SANCO/835/08 – final rev. 2 26 January 2018).

Aminopyralid

Commission Implementing Regulation (EU) No 891/2014 of 14 August 2014 approving the active substance aminopyralid, 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.
Specific provisions of Regulation (EU) No 891/2014 were as follows: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aminopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; (b) the risk to aquatic macrophytes and terrestrial non-target plants; (c) chronic risk to fish. Conditions of use shall include risk mitigation measures, where appropriate.
An EFSA conclusion is available (EFSA Journal 2013;11(9):3352). A Review Report is available (SANCO/11423/2014 rev 1 11 July 2014).

1.3 Regulatory approach

The present application (2013-0534) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

[1] 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

[2] 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" 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 "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TRIVALDI (GF-2545 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary for the other two active substances.

[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] 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

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	TRIVALDI (GF-2545 SC)
Authorisation number	2210146
Function	Herbicide
Applicant	CORTEVA AGRISCIENCE FRANCE S.A.S.
Composition	500 g/L metazachlor 13.3 g/L picloram 5.3 g/L aminopyralid
Formulation type (code)	Suspension concentrate (SC)
Packaging	High-density polyethylene (5 L, 10 L, 15 L and 20 L) Polyethylene terephthalate (5 L, 10 L, 15 L and 20 L)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Carcinogenicity, category 2	
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1 Hazardous to the aquatic environment, Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 1,2-benzisothiazol-3 (2H)-one and metazachlor. May produce an allergic reaction.'

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

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

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.
SPe 1	To protect groundwater, do not apply this or any other product containing aminopyralid more than once every third year.
SPe 1	To protect groundwater, do not apply this or any other product containing metazachlor more than once every 3 years at the application rate of 500 g / ha or more than once every 4 years at the dose of 750 g / ha.
SPe 2	To protect aquatic organisms, do not apply to artificially drained soil with clay content greater than or equal to 45 %.
SPe 2	To protect groundwater, do not apply this product on a field with referenced naturel well or gulf
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[7] incorporating an unsprayed vegetative buffer zone of 5 metres to surface water bodies for post-emergence applications.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details *The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)*[9]		
Re-entry period[10]: 48 hours		
Pre-harvest interval[11]:	Oilseed rape (OSR)	F (BBCH 15)
Other mitigation measures: - The product must be stored at a temperature below 40 °C. - For succeeding crops, respect the following plant back interval • a waiting period of 365 days for leafy crops, • a waiting period of 120 days for other crops,		
The label may include the following recommendations: - EUH208 : Contains 1,2-benzisothiazol-3(2H)-one and metazachlor. May cause an allergic reaction. - Specify the measures limiting the transfer, in particular: • In clayey soils with large shrinkage cracks, surface cultivation is necessary in order to limit rapid flow to groundwater. • Use should be avoided in plots with areas of rapid infiltration (other than the referenced naturel well or gulf). • In areas with karstic subsoils, the use of the active substance must be accompanied by measures to slow down its		

[7] The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[8] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[9] Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

[10] The legal basis for this is **Titre I Article 3** of the French Order of 4 May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[11] According to the French Order of 4 May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

transfer to groundwater, such as grassing of sinkholes.

The label must reflect the conditions of authorisation.

2.3 Product uses

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.

GAP rev. 1, date: 2021-04-15

PPP (product name/code)	**TRIVALDI (GF-2545 SC)**	**Formulation type:**	**SC**
active substance 1	**metazachlor**	**Conc. of a.s. 1:**	**500 g/L**
active substance 2	**picloram**	**Conc. of a.s. 2:**	**13.3 g/L**
active substance 3	**aminopyralid**	**Conc. of a.s. 3:**	**5.3 g/L**
Applicant:	**Dow AgroSciences S.A.S.**	**professional use**	☒
Zone:	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		

Crop and/or situation (a)	Member State or Country	Product Code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	g a.s./ha min max		
Winter oilseed rape	SZ France	GF-2545	F	Broad-leaved weeds	SC	13.3 g ae/L picloram (23.84 g a.s./L picloram-triisopropanolammonium); 5.3 g ae/L aminopyralid (10.2 g/L aminopyralid triisopropanolammonium); 500 g a.s./L metazachlor	Spray - foliar	BBCH 00-08, Autumn, 1 Aug- 15 Sep (pre-emergence)	1	N/A	0.004+ 0.0016+ 0.15 to 0.016+ 0.006+ 0.6	100-400	16 g **ae** + 6.36 g **ae** + 600 g **a.s.** (28.6 + 12.2 + 600)	N/A	**Acceptable** 1.2 L/ha One application every three years. Only 1 application (pre-emergence or post-emergence)/crop
Winter oilseed rape	SZ France	GF-2545	F	Broad-leaved weeds	SC	13.3 g ae/L picloram (23.84 g a.s./L picloram-triisopropanolammonium); 5.3 g ae/L aminopyralid (10.2 g/L aminopyralid triisopropanolammonium); 500 g a.s./L metazachlor	Spray - foliar	BBCH 10-15, Autumn, 15 Aug- 30 Sep (post-emergence)	1	N/A	0.005 + 0.002 + 0.188 to 0.02+ 0.008+ 0.75	100-400	200 g **ae** + 8 g **ae** + 750 g **a.s.** (358 + 15.3 + 750)	N/A	**Acceptable** 1.5 L/ha One application every **four** years. Only 1 application (pre-emergence or post-emergence)/crop

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure).
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I).
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989.
(f) All abbreviations used must be explained.
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
(i) g/kg or g/l.
(j) Growth stage at 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.
(k) The minimum and maximum number of application possible under practical conditions of use must be provided.
(l) PHI - minimum pre-harvest interval.
(m) Remarks may include: Extent of use/economic importance/restrictions.

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

TRIVALDI (GF-2545 SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a white liquid, with a sweet odour. It is not explosive, has no oxidising properties and is not flammable. It has a flash point above 100°C and a self-ignition temperature above 400°C. In 1 % aqueous solution, it has a pH value 6.7 at 22°C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0°C and 18 weeks at 40°C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE and PET. As the stability tests were performed on these packaging types, all packaging may be considered acceptable. The technical characteristics are acceptable for an SC formulation.

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

The product must be stored at a temperature below 40 °C.

3.1.2 Methods of analysis

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

3.1.2.1 Analytical method for the formulation

3.1.2.2 Analytical methods for residues

Aminopyralid:

Analytical methods are available in the Draft Assessment Report (DAR) and validated for the determination of residues of aminopyralid in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

Nevertheless, as there is a hydrolysis step in the analytical method in plants, it is not in accordance with Reg. (EU) No 2017/171. Therefore a fully validated method (with confirmatory data) and its ILV for the determination of aminopyralid residues in oily matrices (aminopyralid parent according to Reg. (EU) No 2017/171)) must be provided post-authorisation.

Picloram:

Analytical methods are available in the DAR/this dossier and validated for the determination of residues of picloram in plants (oily matrices), foodstuffs of animal origin, soil, water (surface and drinking) and air.

Metazachlor:

Analytical methods are available in the DAR and this dossier and validated for the determination of residues of metazachlor in plants (high-oil-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

The active substances are neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

TRIVALDI (GF-2545 SC), containing 5.3 g/L aminopyralid, 500 g/L metazachlor and 13.3 g/L picloram, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[12]	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Oilseed rape	F	Tractor-mounted boom sprayer, hydraulic nozzles	1.5 L product/ha aminopyralid: 8g/ha metazachlor: 750 g/ha picloram: 20 g/ha	100-400	BBA, POEM

Considering the proposed uses, operator systemic exposure was estimated using the German BBA model and/or UK-POEM model/ French study from UPJ 2009-2010[13] dedicated to non-agricultural areas / French study 2005 dedicated to amateur use

Crop	Equipment	PPE and/or working coverall	% AOEL aminopyralid	% AOEL metazachlor	% AOEL picloram
Oilseed rape	Tractor-mounted boom sprayer hydraulic nozzles	Working coverall and gloves during mixing/loading and application	0.3	7.4	0.7

According to the model calculations, it may be concluded that the risk for the operator using TRIVALDI (GF-2545 SC) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be less than 0.1 % of the AOEL of aminopyralid and picloram and 0.8 % of the AOEL of metazachlor.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to TRIVALDI (GF-2545 SC).

3.1.3.4 Worker Exposure

TRIVALDI (GF-2545 SC) is used as an herbicidal treatment on a crop where there is no need to re-enter the treated area after application. Worker exposure is considered to be not relevant.

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

[12] Open field or glasshouse

[13] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al* (2008). Exposure is estimated to be:

0.1 and 0.2 % of the AOEL of aminopyralid for children and adults respectively;

0.5 and 0.9 % of the AOEL of metazachlor for children and adults respectively; and

0.1 and 0.2 % of the AOEL of picloram for children and adults respectively.

It may be concluded that there is no unacceptable risk to the resident exposed to TRIVALDI (GF-2545 SC).

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure for active substance metazachlor of people living near sprayed areas was estimated, as follows:

		% ADI	% AOEL
Maximum daily measurement (0.58 ng/m³)	Adult	<0.1	<0.1
	Child	<0.1	<0.1
Maximum weekly measurement (3.54 ng/m³)	Adult	<0.1	<0.1
	Child	<0.1	<0.1

3.1.3.6 Relevance of metabolites

The PECgw of Metazachlor metabolites are as follows:

Metabolite	**Maximum PEC_{gw} value (µg/L)**	**Relevant**
BH479-4	5.188	N
BH479-8	12.089	N
BH479-9	3.032	Y
BH479-11	1.068	Y
BH479-12	12.619	N

The metabolites BH479-9 and BH479-11 are above the threshold of 0.1 µg/L and are relevant from a toxicological point of view.

Insert summary of the evaluation of the relevance of metabolites only if :

the concentrations of a metabolite in groundwater for a certain intended use are not covered by the EU assessment of the active substance.

new data on the properties of active substance and/or metabolites trigger a reassessment of metabolite relevance

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Summary of the evaluation

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs on oilseed rape for aminopyralid, metazachlor and picloram as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of aminopyralid, metazachlor and picloram residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.

According to available data, the following specific mitigation measures are recommended:

- Do not grow new crop in the treated field less than 120 days after application of GF-2545 SC except for leafy vegetables for which the plant back interval must be extended to 365 days

Data gaps

Noticed data gaps are:

- None

Data required in post-authorization

- None

Summary of the evaluation

3.1.5 Summary for TRIVALDI (GF-2545 SC)

Table 0-1: Information on TRIVALDI (GF-2545 SC) (KCA 6.8)

Crop	PHI for TRIVALDI (GF-2545 SC) proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for TRIVALDI (GF-2545 SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		aminopyralid	metazachlor	picloram		
Oilseed rape	F (BBCH 15)	F	F	F	F	

NR: not relevant
* 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).

Table 0-2: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for TRIVALDI (GF-2545 SC)
Crop group	Led by Aminopyralid	Led by Metazachlor	Led by Picloram	
Leafy vegetables	90 days (all crops)	365 days	120 days (all crops)	Do not grow leafy vegetables in the treated field less than 365 days after application of TRIVALDI (GF-2545 SC)
Root vegetables		120 days		Do not grow root vegetables in the treated field less than 120 days after application of TRIVALDI (GF-2545 SC)
Cereals		NR		Do not grow cereals in the treated field less than 120 days after application of TRIVALDI (GF-2545 SC)

NR: not relevant

Environmental fate and behaviour

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 substances and their metabolites 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.

The PEC values of picloram, aminopyralid, metazachlor 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.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

The PECgw values calculated for aminopyralid for an application every third year are below the threshold values defined in the guidance SANCO 221/2000, after the use of the preparation TRIVALDI (GF-2545 SC).

PECgw values for picloram for an application every third year exceed the trigger value for all FOCUS scenarios (maximum value of 0.636 µg/L). Refined calculations as proposed by the applicant, using the DT_{50} value of 6.71 days rejected by RMS UK, were not deemed acceptable. Consequently, the groundwater risk assessment cannot be finalised for picloram.

The PECgw calculations reported for metazachlor were performed for an application of 750 g a.s./ha every third year on oilseed rape. The PECgw calculated for metazachlor and for its soil metabolite are below the threshold values defined in the guidance SANCO 221/2000. The PECgw calculated for four metazachlor metabolites are above the threshold values defined in SANCO 221/2000, after the use of the preparation TRIVALDI (GF-2545 SC).

Additional data were provided with a groundwater monitoring for the five soil metabolites of metazachlor, dedicated to the intended use on oilseed rape. The design of the monitoring study was considered appropriate in terms of well selection (vulnerability and representativeness of the use of metazachlor on oilseed rape). The results from the PECgw calculations and the data from French monitoring show a groundwater contamination by metazachlor metabolites. Moreover, some uncertainties have been pointed out about the limited number of analyses. Therefore an important groundwater contamination by the non-relevant metazachlor metabolites and an occasional exceedence of the regulatory threshold for the metabolite BH479-9 cannot be excluded.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

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(s) 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, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended uses.

For aquatic organisms and non-target plants, mitigation measures are required to make the risk acceptable.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of TRIVALDI (GF-2545 SC) is considered satisfactory for all the requested uses.
- the selectivity level of TRIVALDI (GF-2545 SC) is considered satisfactory for all the requested uses.

- o the risks of negative impact on yield, quality, propagation and adjacent crops are considered acceptable.
- o the risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible replacement crops.
- o the risk of resistance developing or appearing to picloram, metazachlor and aminopyralid does not require monitoring for the requested use.

Restrictions: none

Resistance monitoring data: none

Post-authorisation data: none

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

Continue to monitor relevant and irrelevant metabolites in groundwater, particularly those intended for human consumption.

If the water quality limit for human consumption is observed, notify the competent authorities and quickly put in place additional measures to protect the supply areas of the catchment areas.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments (see label in Appendix 2):

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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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 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 **TRIVALDI***

de la société	*CORTEVA AGRISCIENCE FRANCE S.A.S.*
enregistrées sous les	*n°2013-0534, 2017-1682, 2018-2335, 2019-5523 et 2020-1479*

Vu les conclusions de l'évaluation de l'Anses du 14 février 2020,

Vu le procès-verbal de la réunion du comité de suivi des AMM en date du 24 septembre 2020,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** 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	
Noms du produit	TRIVALDI LASIDOR
Type de produit	Produit de référence
Titulaire	CORTEVA AGRISCIENCE FRANCE S.A.S. 1 bis avenue du 8 mai 1945 Immeuble Equinoxe II 78 280 Guyancourt France
Formulation	Suspension concentrée (SC)
Contenant	10,2 g/L - aminopyralide sel de triisopropanolamine (équivalent à 5,3 g/L d'aminopyralide) 23,84 g/L - piclorame sel de triisopropanolamine (équivalent à 13,3 g/L de piclorame) 500 g/L - métazachlore
Numéro d'intrant	9873-2013.01
Numéro d'AMM	2210146
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 31 juillet 2022.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 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 15 AVR. 2021

Caroline SEMAILLE
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 I : 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**
Bidons en polyéthylène haute densité	5 L ; 10 L ; 15 L ; 20 L
Bidons en polyéthylène téréphtalate	5 L ; 10 L ; 15 L ; 20 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
EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one et du métazachlore. Peut produire une réaction allergique.	
Pour les phrases P se référer à la règlementation 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

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)	Mention abeilles
15205901 Crucifères oléagineuses* Désherbage	**1,2 L/ha**	**1/an**	Jusqu'au stade BBCH 08	F (BBCH 08)	-	-	5	-
	Uniquement sur colza d'hiver. 1 application maximum par culture et par parcelle.							
	1,5 L/ha	**1/an**	entre les stades BBCH 10 et BBCH 15	F (BBCH 15)	5 (dont DVP 5)	-	5	-
	Uniquement sur colza d'hiver. 1 application maximum par culture et par parcelle.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40 °C.

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 rampe

- **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

- 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 ;

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.

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Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

- Afin d'éviter la présence de résidus dans les cultures suivantes, ne pas implanter :
  • De cultures de légumes feuilles ou tiges moins de 365 jours après traitement,
  • D'autres cultures moins de 120 jours après traitement.

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

- SPe 1 : Pour protéger les eaux souterraines ne pas appliquer ce produit ou tout autre produit contenant de l'aminopyralide plus d'une fois tous les 3 ans.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du métazachlore plus d'une fois tous les 3 ans à la dose de 500 g métazachlore/ha ou plus d'une fois tous les 4 ans à la dose de 750 g métazachlore/ha.

- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit sur une parcelle comportant une bétoire référencée.

Protection de la faune

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 %.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour des applications en post-levée.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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)	Récurrence (mois)
Mettre en place un monitoring des métabolites pertinents et non pertinents du métazachlore dans les eaux souterraines notamment celles destinées à la consommation humaine. En cas de dépassement observés des limites de qualité de l'eau destinée à la consommation humaine, prévenir les autorités compétentes et mettre en place rapidement des mesures complémentaires de nature à protéger les aires d'alimentation de captage.	-	-

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Recommandations relatives à l'étiquette du produit

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

- Préciser les mesures limitant le transfert du métazachlore et de ses métabolites, comme notamment :
  - Dans les sols argileux présentant des fentes de retrait importantes, un travail superficiel du sol est nécessaire afin de limiter les écoulements rapides vers les eaux souterraines.
  - L'utilisation est à éviter dans les parcelles qui présentent des zones d'infiltration rapide (autres que les bétoires référencées).
  - Dans les zones karstiques, l'utilisation doit être accompagnée de mesures permettant de freiner les transferts vers les eaux souterraines (comme l'enherbement des dolines par exemple).

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Appendix 2 – Copy of the draft product label as proposed by the applicant

Not applicable.

Appendix 3 – Letter(s) of Access

Provided upon request.