

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: FH-048**

**Product names: OCEAL, MINERVE, PONANT,  
VERMEIL, MENDEL**

**Chemical active substance:**

**dicamba, 700 g/kg**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(label extension)**

**Applicant: Rotam Agrochemical Europe Ltd.**

**Date: 2021/03/04**

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

The company Rotam Agrochemical Europe Ltd. has requested a marketing authorisation in France for the product OCEAL (product code: FH-048; authorisation n° 2130066), containing 700 g/kg dicamba<sup>1</sup>, 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 (RR) concerns the evaluation of Rotam Agrochemical Europe Ltd.'s application submitted on 26/04/2019 to extend the existing marketing authorisation for OCEAL (FH-048) 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 label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-3992) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, 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")<sup>3</sup>. 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 OCEAL (FH-048) have been made using endpoints agreed in the EU peer review of dicamba. It also includes assessment of data and information related to OCEAL (FH-048) where those data have not been considered in the EU peer review process.

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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>4</sup>, 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 OCEAL (FH-048).

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<sup>1</sup> REGULATION (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin.

<sup>2</sup> 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

<sup>3</sup> 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](#)

<sup>4</sup> 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

## 1.2 Letters of Access

Not necessary: active substance data are not protected any more.

## 1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

## 1.4 Data protection claims

## 2 Where protection for data is being claimed for information supporting registration of OCEAL (FH-048), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision

### 2.1 Product identity

Product code	FH-048.
Product name in MS	OCEAL. (Second commercial names : MINERVE, PONANT, VERMEIL, MENDEL).
Authorisation number	2130066.
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Herbicide.
Applicant	Rotam Agrochemical Europe Ltd.
Active substance(s) (incl. content)	Dicamba, 700 g/kg.
Formulation type	Water-soluble granule [SG].
Packaging	Packaging not changed.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

### 2.2 Conclusion

**The evaluation of the application for OCEAL (FH-048) 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:	Hazardous to the aquatic environment - Chronic Hazard, category 3.
Hazard pictograms:	None.
Signal word:	None.
Hazard statement(s):	H412 : Harmful 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).
	For other restrictions refer to 2.5.

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

None.

## 2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017<sup>5</sup> 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.

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

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

Finally, the French Order of 26 March 2014<sup>6</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>7</sup> 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.

### 2.5.1 Restrictions linked to the PPP

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

The applicant is required to comply with the current applicable standard for clothing type PPEs, more specifically standard ISO EN 27065<sup>8</sup> for clothing-type PPE.

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 meters to surface water bodies.
SPe 3	To protect non-target plant respect an unsprayed buffer zone of 5 meters to non-agricultural land.
SPe 8	Do not use in presence of bees and other pollinating insects.
Other specific restrictions	

<sup>6</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

<sup>7</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<sup>8</sup> Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

Re-entry period	Six hours.
Storage	-
Risk mitigation measure	-
Agricultural recommendations	Regarding the risk of phytotoxicity on maize strains meant to be used for seed production, it is up to the grower, before any use of OCEAL (FH-048) , to consult the seed company concerned or to respect their recommendations. The product must not be directed toward adjacent dicotyledonous crops.
Bystander and resident protection	For uses on maize, respect an unsprayed zone of 3 meters from the extremity of the boom and : <ul style="list-style-type: none"> <li>- areas where bystanders are present during treatment</li> <li>- areas where residents could be present</li> </ul>

The other conditions of use specified in the previous evaluations are not changed.

### **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.

GAP rev. 1, date: 2021/03/04

PPP (product name/code): OCEAL / FH-048  
Active substance 1: dicamba  
Safener: -  
Synergist: -  
Applicant: Rotam Agrochemical Europe Ltd.  
Zone(s): Southern Zone <sup>(d)</sup>  
Verified by MS: Yes

Formulation type: SG <sup>(a, b)</sup>  
Conc. of a.s. 1: 700 g/kg <sup>(c)</sup>  
Conc. of safener: - <sup>(c)</sup>  
Conc. of synergist: - <sup>(c)</sup>  
Professional use: ☒  
Non-professional use: ☐

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha ( <sup>(i)</sup> )
					Method/ Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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 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. <sup>(e)</sup>	Member state(s)	Crop and/ 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 <sup>(f)</sup>
					Method/ Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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	FR	Maize (fodder and grain)	F	Annual & perennial grasses and broadleaved weeds	Foliar spray	BBCH 12-16 (spring) (1st appl)  BBCH 18-19 (spring) (2nd appl)	a) 1 (mandatory splitting)  b) 1	-	a) 0.270 (1st appl) ; 0.13 (2nd appl)  b) 0.40	a) 189 (1st appl) ; 91 (2nd appl)  b) 280	100 – 400	F – growth stage BBCH 19 at the latest	<b>Acceptable</b> Max. 0.4 kg/ha/crop
2	FR	General weed treatment: inter-cropping / stubble cleaning (use n° 11015924)	F	Annual & perennial grasses and broadleaved weeds	Foliar spray	August - October	a) 1  b) 1	-	a) 0.40  b) 0.40	a) 280  b) 280	150 - 400	n.a.	<b>Not acceptable</b> (groundwater, aquatic organisms and soil macro-organisms)

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

### **3 Background of authorisation decision and risk management**

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

The physico-chemical properties of the formulation were evaluated in the previous dossier (n° 2011-0339), taking into account the in-use concentrations (from 0.125 % to 0.250 % w/v).

The concentrations of uses requested in this extension of use (from 0.1 % to 0.4 % w/v) are not covered by those previously assessed. Nevertheless, the relevant tests of physical and chemical properties for OCEAL (FH-048) evaluated in the initial dossier cover the maximum in-use concentration of this extension of use.

#### **3.2 Efficacy (Part B, Section 3)**

The efficacy of OCEAL (FH-048), applied on dicotyledonous weeds pre- and post-emergence, is considered satisfactory for all the requested uses.

The evaluation of selectivity is not considered pertinent for the use on general weed treatment (i.e., stubble/inter-cropping).

The selectivity of the product is considered satisfactory for the use on maize.

The risk of adverse effects on yield, quality and propagation is considered negligible on maize. Regarding the risk of phytotoxicity on maize strains meant to be used for seed production, it is up to the grower, before any use of OCEAL (FH-048), to consult the seed company concerned or to respect their recommendations.

The risk of adverse effects on succeeding and adjacent crops is considered acceptable. Nevertheless, special attention should be paid to the susceptible succeeding crops.

The risk of adverse effects on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.

The risk of resistance appearing or developing to dicamba does not require monitoring for the requested uses.

#### **3.3 Methods of analysis (Part B, Section 5)**

##### **3.3.1 Analytical method for the formulation**

The analytical methods for the determination of the active substance in the formulation submitted in the product dossier meet the regulatory requirements.

##### **3.3.2 Analytical methods for residues**

New requested uses (maize, inter-cropping/stubble cleaning) are covered by the previous use (maize) already authorised.

The analytical methods for the determination of the active substance residues in matrices (plants and food-stuffs of animal origin) submitted at European level and in the product dossier meet the regulatory requirements.

### 3.4 Mammalian toxicology (Part B, Section 6)

Active substance	<b>Dicamba</b>
AOEL systemic	0.3 mg/kg bw/d
AAOEL	None
Oral absorption	100 %
Vapour pressure	$1.67 \times 10^{-3}$ Pa at 20 °C
Reference	SANCO/829/08 – final rev. 22 (12 July 2016) EFSA Journal 2011;9(1):1965 (14 January 2011)
Dermal absorption	Concentrate: 8 % Spray dilution: 47 % (including <i>pro rata</i> correction for 0.2275 g/L)

#### 3.4.1 Acute toxicity

OCEAL (FH-048), containing 700 g/kg dicamba, has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitiser.

#### 3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model<sup>9</sup>:

Model data		<b>Dicamba</b>
	<b>Level of PPE</b>	<b>% AOEL</b>
<b>Application : Tractor-mounted / downward spraying Outdoor</b> Cereals (maize, maize split applications and inter-cropping/stubble cleaning)		280 g dicamba/ha
<b>Spray application (AOEM; 75th percentile)</b> Body weight: 60 kg	No PPE	<b>17.07 %</b>
	Working coverall and gloves during mix/loading and application	<b>1.33 %</b>

According to the model calculations, it may be concluded that the risk for the operator using OCEAL (FH-048) is acceptable with a working coverall and gloves during mixing/loading and application.

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

<sup>9</sup> AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

### 3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation. Therefore, estimation of worker exposure was calculated according to the AOEM model. Exposure is summarised in the table below:

		Dicamba
Level of PPE		% AOEL
Activity: Irrigation, inspection Outdoor Cereals (maize, inter-cropping/stubble cleaning) Work rate: 2 hours/day Interval between applications: 365 days		
DT <sub>50</sub> : 30 days		
DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha		
Nb applications x Application rate (g a.s./ha)		1 x 280 g dicamba/ha
Body weight: 60 kg	Potential exposure TC: 12 500 cm <sup>2</sup> /person/h	54.83 %
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	6.14 %
Activity: Irrigation, inspection Outdoor Cereals (maize split applications) Work rate: 2 hours/day Interval between applications: 1 day		
DT <sub>50</sub> : 30 days		Dicamba
DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha		% AOEL
Nb applications x application rate (g a.s./ha)		2 x 189 g dicamba/ha
Body weight: 60 kg	Potential exposure TC: 12 500 cm <sup>2</sup> /person/h	73.18 %
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	8.20 %

It may be concluded that there is no unacceptable risk anticipated for the worker.

### 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<sup>10</sup>.

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<sup>1</sup> incorporating a distance of 3 metres from the spray boom. An acceptable risk was determined for residents (adult and/or child):

Model (AOEM) - All pathways (mean)	% AOEL dicamba
<b>Application : Tractor-mounted downward spraying</b> Outdoor Cereals (maize, inter-cropping/stubble cleaning) Nb applications x Application rate (g a.s./ha): 1 x 280 g dicamba/ha	
Resident (children)	11.11
Resident (adults)	4.47
<b>Application : Tractor-mounted downward spraying</b> Outdoor Cereals (maize split applications) Nb applications x Application rate (g a.s./ha): 2 x 189 g dicamba/ha	
Resident (children)	11.85
Resident (adults)	5.35

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

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

The data available are considered sufficient for risk assessment. No exceedence of the current MRL for dicamba as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of dicamba residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses.

<sup>10</sup> 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)

Crop	PHI for OCEAL (FH-048) requested by applicant	PHI/withholding period* sufficiently supported for dicamba	PHI for OCEAL (FH-048) proposed by zRMS	zRMS Comments (if different PHI proposed)
Maize	Period between treatment and harvest is >100 days, no PHI is applicable	Yes	F**	
Inter-crop	-	Yes	Not applicable	

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).

### 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 predicted environment concentration (PEC) values for the active substance and its metabolite 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 of dicamba and its metabolite 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.

PEC<sub>soil</sub> and PEC<sub>sw</sub> derived for the active substance and its metabolite are used for the ecotoxicological risk assessment.

For split application on maize, PEC<sub>gw</sub> for dicamba and its metabolite do not occur at levels exceeding those mentioned in Regulation (EU) No 546/2011.

**For general weed treatment, the PEC<sub>gw</sub> calculations provided by the applicant could not be used to finalise the groundwater risk assessment. The adsorption coefficients were not selected according to current guidance (FOCUS 2014) and the PEC<sub>gw</sub> calculations available cannot be used to cover this use. In addition, the electronic modelling files were not available. As a consequence, the risk of groundwater contamination cannot be finalised for general weed treatment.**

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.7 Ecotoxicology (Part B, Section 9)

#### 3.7.1 Effects on terrestrial vertebrates

The risk assessment for birds showed an acceptable acute and reproductive risk from dicamba when

OCEAL (FH-048) is used at the requested rates.

The risk from drinking water (puddle scenario only, leaf scenario not relevant) was demonstrated to be acceptable as well, and no risk assessment for secondary poisoning is required, due to the low Pow of dicamba. Therefore, the use of OCEAL (FH-048) at the label rates poses an acceptable risk to birds.

The risk assessment for mammals showed all the TERs are above the respective triggers of 10 and 5 at the screening level for the acute and reproductive risks respectively. Therefore, the use of OCEAL (FH-048) at the requested rate poses no unacceptable dietary risk to mammals.

The risk from drinking water was demonstrated to be acceptable as well, and no risk assessment for secondary poisoning is required due to the low Pow of dicamba. Therefore, the use of OCEAL (FH-048) at the label rates poses an acceptable risk to mammals.

### 3.7.2 Effects on aquatic species

Considering valid PEC<sub>sw</sub>, the risk assessment was performed to cover only use 1 intended on “maize (fodder and grain)”. The calculated PEC/RAC<sup>11</sup> ratios, including a non-spray buffer zone of 5 meters, were all lower than 1 for all species and both FOCUS STEP 2 scenarios for dicamba when used at 1 x 350 g dicamba/ha, indicating an acceptable risk from the active substance.

The PEC/RAC ratios were all lower than 1 for all species for the FOCUS STEP 1 scenario for the dicamba metabolite 3,6-dichlorosalicylic acid (DSCA), indicating an acceptable risk from this metabolite.

Therefore, it may be considered that the use of OCEAL (FH-048) at the requested rates poses an acceptable risk to aquatic organisms.

**No pertinent PEC<sub>sw</sub> are available for use 2 (inter-cropping/stubble cleaning), thus it is not possible to finalise the risk for this use, as the PEC<sub>sw</sub> values available for uses 1 do not cover this use.**

### 3.7.3 Effects on bees

The hazard quotient (HQ) calculated for honeybees is lower than the trigger limit of 50, indicating that the use of OCEAL (FH-048) at the requested rates poses an acceptable acute risk to bees.

However, the new data requirement of Reg. (EU) No 284/2013 have to be applied to the current evaluation, due to the submission date of the dossier. According to new requirements of Reg. (EU) No 284/2013, data on acute effects (oral and contact) and chronic effects on adult bees and on development of bees should have been submitted, as exposure of bees to the product cannot be excluded. Therefore, the risk to bees cannot be completely fulfilled. Thus, Member States may consider the risk for bees as not finalised, or required mitigation measures to avoid exposure of bees, and/or request acute and chronic adults and larvae toxicity studies post-authorisation. At national level, France as zRMS will conclude that the risk for bees is not finalised.

It must be highlighted that the toxicity study on larvae must observe the potential effects on emergence to be considered sufficient to address the requirement on development of honeybees. Thus the toxicity study on larvae must be performed according to the recommendation of OECD GD 239 and completed at day 22

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<sup>11</sup> Predicted environmental concentration/regulatory acceptable concentration



to be considered reliable.

#### **3.7.4 Effects on other arthropod species other than bees**

In Tier 1 risk assessment, all HQ values were lower than the trigger of 2. Moreover, the rates with less than 50 % effects measured in Tier 2 studies were lower than the predicted environmental rate. Therefore, the use of OCEAL (FH-048) at the requested rates poses a low risk to non-target arthropods.

#### **3.7.5 Effects on soil organisms**

The acute TER values for dicamba and its metabolite DSCA are higher than the trigger value of 10 for earthworms. Therefore, it is considered that the use of OCEAL (FH-048) poses an acceptable acute risk for earthworms when used at the recommended rates.

**However, the new data requirement of Reg. (EU) No 284/2013 have to be applied to the current evaluation, due to the submission date of the dossier. According to new requirements of Reg. (EU) No 284/2013, data on chronic effects on earthworms should have been provided, as exposure of these organisms to the product cannot be excluded. Therefore, the risk to earthworms cannot be completely fulfilled. Thus, Member States may consider the risk for earthworms as not finalised, or request toxicity studies for earthworms at post-registration. At national level, France concludes that the risk for earthworms is not finalised.**

For the other non-target soil macro-organisms, data are not required, since the risk for non-target arthropods is acceptable in Tier 1.

The maximum concentration with effects  $\leq 25\%$  on nitrogen mineralisation were 6.4 and 2.45 mg a.s./kg soil dw for dicamba and the formulation OCEAL (FH-048) respectively, representing respectively 13.7 and 5.2 times the value of the PECsoil for dicamba. Therefore, the use of OCEAL (FH-048) poses a low risk to soil micro-organisms when used at the requested rates.

#### **3.7.6 Effects on non-target terrestrial plants**

The TER calculated for vegetative vigour is lower than the trigger of 5, indicating a potential risk from the use of OCEAL (FH-048) at the requested rates. However, mitigation measures such as a non-spray buffer zone of 5 m reduce the risk to an acceptable level.

#### **3.7.7 Effects on other terrestrial organisms (Flora and Fauna)**

No data available.

### **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 dicamba 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**

None.

##### **5.1.2 Post-authorisation data requirements**

None.

## Appendix 1 Copy of the product authorisation



### Décision relative à une demande d'extension d'usage d'un produit phytopharmaceutique

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*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 d'extension d'usage majeur du produit phytopharmaceutique **OCEAL***

*de la société **ROTAM AGROCHEMICAL EUROPE LIMITED***

*enregistrée sous le **n°2019-3992***

*Vu les conclusions de l'évaluation de l'Anses du 4 janvier 2021,*

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

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.



Informations générales sur le produit	
Noms du produit	OCEAL MINERVE VERMEIL PONANT MENDEL
Type de produit	Produit de référence
Titulaire	ROTAM AGROCHEMICAL EUROPE LIMITED Hamilton House Mabledon Place London, WC1H 9BB Royaume-Uni
Formulation	Granulé soluble dans l'eau (SG)
Contenant	700 g/kg - dicamba
Numéro d'intrant	2110109
Numéro d'AMM	2130066
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort, le

**04 MARS 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)



## ANNEXE I : Modalités d'autorisation du produit

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Dangers pour le milieu aquatique - Danger chronique, catégorie 3	H412 : Nocif 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.	

### Liste des nouveaux usages autorisés

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)	Mention abeilles
15555901 Maïs*Désherbage	0,4 kg/ha	1/an	entre les stades BBCH 12 et BBCH 19	F (BBCH 19)	5	-	5	-
Uniquement sur maïs. Fractionnement obligatoire de la dose pleine en une première application avant le stade BBCH 16 à la dose maximale de 0,27 kg/ha, suivie d'une seconde application à partir du stade BBCH 18 à la dose maximale de 0,13 kg/ha. Ne pas dépasser la dose totale de 0,4 kg/ha par an et par parcelle, lors de l'utilisation en une application ou en fractionnement.								

### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015924 Traitements généraux* Désherbage /Avi Mise Cult.	0,4 kg/ha	1/an	Non applicable
<b>Motivation du refus :</b> L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les organismes aquatiques.			





## Conditions d'emploi du produit

### Protection de l'opérateur et du travailleur

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit.

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 - Pulvérisation vers le bas**

*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 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A)

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

Pour les usages sur maïs, avec ou sans fractionnement de la dose, 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.



### **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.

### **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.

#### **Protection de la faune**

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

- SPe 8 : Ne pas utiliser en présence d'abeilles et autres pollinisateurs.

#### **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.

### **Recommandations relatives à l'étiquette du produit**

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :

- Il appartient à l'agriculteur multiplicateur, avant toute utilisation du produit, de consulter le semencier concerné ou de respecter les préconisations du prestataire de production concerné.
- Ne pas diriger ce produit vers les cultures de dicotylédones adjacentes.

Les autres modalités d'autorisation du produit restent inchangées.



## 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.

# OCEAL

## Herbicide

### Maïs et traitements généraux

Granulé soluble dans l'eau (SG)  
700 g/kg de Dicamba

AMM n°2130066

#### INFORMATION SANTE

Appel en cas d'urgence : appeler le 15 ou le centre antipoison le plus proche (Paris : 01 40 05 48 48). Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).

#### EMBALLAGE

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Réemploi de l'emballage interdit ; rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur (ou dans la cuve de rinçage pour l'injection directe).

Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique. (Exemple : Adivalor).

#### MODE D'ACTION

Le Dicamba est principalement absorbé par les feuilles puis il se déplace par système, ascendante et descendante. Il agit également par vapeur.

Le Dicamba agit comme régulateur de croissance apparenté à l'auxine (phytohormone) en s'attaquant à différents processus du métabolisme. La plante subit une perturbation de sa croissance avant son dépérissement.

#### USAGES ET DOSES AUTORISÉS :

OCEAL s'utilise en post levée des adventices sur les cultures de maïs (grain et fourrage) du stade 2 feuilles (BBCH 12) au stade 6 feuilles (BBCH 16) en cas d'application unique. En cas d'application fractionnée, la 2<sup>nd</sup> application doit être effectuée à partir du stade 8 feuilles étalées.

OCEAL s'utilise aussi en désherbage en inter-culture contre les dicotylédones, annuelles ou vivaces, à l'automne.

Les détails d'application sont précisés dans le tableau ci-dessous :

Tableau des usages :

CULTURES	USAGE	APPLICATION		
		NOMBRE PAR AN	DOSES KG/HA	STADE D'APPLICATION
MAÏS				
En cas de levées groupées des adventices				
Maïs grain et maïs fourrage	Désherbage, dicotylédones vivaces et annuelles	1	0,4	2 à 6 feuilles
Et en cas de levées échelonnées des adventices				
Maïs grain et maïs fourrage	Désherbage, dicotylédones vivaces et annuelles	2	1 <sup>er</sup> application : 0,270 2 <sup>nd</sup> application : 0,130	2 à 6 feuilles 8 à 10 feuilles
TRAITEMENTS GENERAUX				
Traitements généraux	Inter culture	1	0,4	avant la floraison des adventices

Le délai avant récolte est de 90 jours en maïs grain et de 60 jours en maïs fourrage  
Les limites maximales de résidus sont consultables à l'adresse suivante : <http://e-phy.agriculture.gouv.fr>

### **PRECAUTIONS D'EMPLOI**

En cas de stress hydrique marqué ou de fortes amplitudes thermiques, éviter de traiter les cultures mal implantées ou en situation de sol séchant. Ne pas traiter à partir d'une température de 30°C.

### **MODE D'EMPLOI**

#### **Préparation de la bouillie**

- Verser le produit dans la cuve du pulvérisateur à moitié remplie d'eau, mettre l'agitateur en marche avec modération puis compléter le remplissage de la cuve. En cas de mélange, attendre la dissolution complète d'OCEAL avant d'ajouter l'éventuel herbicide partenaire.
- Maintenir l'agitation jusqu'à la fin de la pulvérisation. Après une interruption, remettre l'agitateur en marche plusieurs minutes avant de reprendre le traitement.

#### **Application**

Avant le traitement s'informer et tenir compte des prévisions météorologiques. Appliquer la bouillie par temps calme, sans vent pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, cultures voisines, chemins, abords de ferme ou bâtiments.

Appliquer OCEAL en conditions poussantes (ciel couvert et humidité élevée durant l'application) et sur maïs en bon état végétatif.

Ne pas traiter par temps de pluie, en présence de rosée ou par risque de gelée prolongée.

Pour une efficacité maximale, 6 heures au minimum sans pluie sont nécessaires.

Utiliser si possible des buses anti-dérive afin d'éviter tout risque de dérive de pulvérisation vers les cultures voisines sensibles : betterave, tournesol, pois, colza, pomme de terre, soja, haricot, tabac, cultures florales, ornementales, maraîchères, vigne et arbres fruitiers.

### **MELANGES**

Ne pas mélanger OCEAL avec des huiles adjuvants ou des engrais liquides.

Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site <http://e-phy.agriculture.gouv.fr>

### **IMPORTANT**

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces.

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

### **PRECAUTIONS A PRENDRE**

#### **Avant l'application**

- Porter des gants pendant la phase de mélange/chargement est recommandé.

- Stocker les produits dans un local phytosanitaire conforme et fermé à clé.
- Bien lire l'étiquette et les précautions avant l'utilisation.
- Se protéger efficacement.
- Vérifier régulièrement, maintenir le bon état et le réglage du matériel d'application.
- Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie
- Rincer les emballages trois fois ou par un système de nettoyage à l'eau sous pression, vider l'eau de rinçage dans la cuve.

**Pendant l'application**

- Ne pas contaminer les étangs, cours d'eau ou fossés avec le produit. Appliquer la bouillie dans les cultures par temps calme, sans vent fort pour éviter, toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
- Diluer les surplus de traitement 10 fois et pulvériser sur la parcelle déjà traitée suivant les prescriptions d'emploi.

**Après l'application**

- Rincer l'intérieur de la cuve à l'eau claire et faire passer au moins un dixième de son volume dans la rampe et les tuyaux.
- Pulvériser le fond de cuve et les eaux de rinçage dans une parcelle déjà traitée.
- Nettoyer le pulvérisateur sur une zone spécialement équipée
- Se laver les mains, prendre une douche.

**Réglementation zones non traitées et délai de rentrée**

Zone non traitée : 5 mètres par rapport aux points d'eau et à la zone non cultivée adjacente.

Délai de réentrée dans la culture : 6 heures

## OCEAL - AMM n° 2130066

(Contient 700g/kg de ~~Dicamba~~)

Formulation : Granulé soluble dans l'eau (SG)



Mention d'avertissement : Aucune

Mention de danger :

H411	Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401	Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Conseils de Prudence :

Prévention :	
P273	Éviter le rejet dans l'environnement.
Intervention :	
P391	Recueillir le produit répandu.
Élimination :	
P501	Éliminer le contenu/récipient dans un point de collecte des déchets spéciaux ou dangereux.
SP1	
Ne pas polluer d'eau avec le produit ou son emballage. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.	
SPe3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
SPe3	Pour protéger les plantes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Détenteur de l'homologation :

ROTAM AGROCHEMICAL EUROPE LIMITED

Hamilton House, ~~Mableton~~ Place, London, WC1H 9BB, ANGLETERRE

Conditionnement: XXXXX

Lot N° : XXXX

