

REGISTRATION REPORT
Part A
Risk Management

Product code: BARC 100/2

Product name: VALENTIA

Chemical active substances:

florasulam, 2 g/L

fluroxypyr, 144 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: BARCLAY CHEMICALS R&D LTD

Date: 31/12/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company BARCLAY CHEMICALS R&D LTD has requested a marketing authorisation in France for the product VALENTIA (formulation code: BARC 100/2), containing 2 g/L florasulam and 144 g/L fluroxypyr as a herbicide for professional uses.

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 information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to VALENTIA (BARC 100/2) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of VALENTIA (BARC 100/2) have been made using endpoints agreed in the EU peer reviews of florasulam and fluroxypyr.

This document describes the specific conditions of use and labelling required for France for the registration of VALENTIA (BARC 100/2).

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).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of BARCLAY CHEMICALS R&D LTD's application to market VALENTIA (BARC 100/2) in France as an herbicide (product uses described under point 2.6). France acted as 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.

The present application (2018-0446 & 2018-0451) 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 applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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.

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 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

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The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letters of access for active substances florasulam and fluroxypyr.

1.3 Justification for submission of tests and studies

According to the applicant: « VALENTIA (BARC 100/2) was not the representative formulation for Annex I inclusion of florasulam and/or fluroxypyr and was not evaluated at EU level. In addition VALENTIA (BARC 100/2) has not been submitted or evaluated according to Uniform Principles in any other Member State. Consequently, new Annex III data is submitted to support the registration of VALENTIA (BARC 100/2) and are considered necessary for first authorisation. »

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of VALENTIA (BARC 100/2), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7..

2 Details of the authorisation decision

2.1 Product identity

Product code	BARC 100/2
Product name in MS	VALENTIA
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No
Function	herbicide
Applicant	BARCLAY CHEMICALS R&D LTD
Active substances) (incl. content)	florasulam, 2 g/L fluroxypyr, 144 g/L
Formulation type	Suspo-emulsion [SE]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

³ 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

2.2 Conclusion

The evaluation of the application for VALENTIA (BARC 100/2) resulted in the decision **not 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 classes, categories:	Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 2.
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statements:	H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May produce an allergic reaction.[EUH208]

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

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

N/A: no marketing autorisation granted.

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

N/A: no marketing autorisation granted.

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 2017⁴ 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 meters;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Finally, the French Order of 26 March 2014⁵ 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 “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 extrapolation⁶ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.6) 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

N/A : no marketing autorisation granted.

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing autorisation granted.

⁴ 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/AGR1632554A/jo/texte>

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

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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.

PPP (product name/code):	VALENTIA / BARC 100/2	Formulation type:	Suspo-emulsion (SE) ^(a, b)	GAP rev. 1, date: 2019-12-31
Active substance 1:	florasulam	Conc. of a.s. 1:	2 g/L ^(c)	
Active substance 2:	fluroxypyr	Conc. of a.s. 2:	144 g/L ^(c)	
Applicant:	BARCLAY CHEMICALS R&D LTD	Professional use:	<input checked="" type="checkbox"/>	
Zone:	Southern Zone ^(d)	Non-professional use:	<input type="checkbox"/>	
Verified by MS:	Yes			

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Winter wheat, barley	F	Annual + perennial broadleaf weeds	Medium Foliar spray	20-45	1	-	1.2 - 1.6 L/ha	fluoroxypr 0.16 florasulam 0.0032 fluoroxypr 0.12 florasulam 0.0024	150/400	F (BBCH 45)	Not acceptable (risk for aquatic organisms and non-target terrestrial plants)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2	France	Spring wheat, barley	F	Annual + perennial broadleaf weeds	Medium Foliar spray	20-39	1	-	1.2 - 1.5 L/ha fluoroxypyr 0.15 florasulam 0.003 fluoroxypyr 0.12 florasulam 0.0024	150/400	F (BBCH 39)	Not acceptable (risk for aquatic organisms and non-target terrestrial plants)	
3	France	Durum Wheat	F	Annual + perennial broadleaf weeds	Medium Foliar spray	20-45	1	-	1.2 - 1.6 L/ha fluoroxypyr 0.16 florasulam 0.0032 fluoroxypyr 0.12 florasulam 0.0024	150/400	F (BBCH 45)	Not acceptable (risk for aquatic organisms and non-target terrestrial plants)	
4	France	Oats	F	Annual + perennial broadleaf weeds	Medium Foliar spray	20-31	1	-	1.2 - 1.6 L/ha fluoroxypyr 0.16 florasulam 0.0032 fluoroxypyr 0.12 florasulam 0.0024	150/400	F (BBCH 31)	Not acceptable (risk for aquatic organisms and non-target terrestrial plants)	
5	France	Rye, Triticale	F	Annual + perennial broadleaf weeds	Medium Foliar spray	20-39	1	-	1.2 - 1.5 L/ha fluoroxypyr 0.15 florasulam 0.0030 fluoroxypyr 0.12 florasulam 0.0024	150/400	F (BBCH 39)	Not acceptable (risk for aquatic organisms and non-target terrestrial plants)	

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6	France	Maize	F	Annual + perennial broadleaf weeds	Medium Foliar spray	12-16	1	-	1.2 - 1.2 L/ha	fluoroxypyrr 0.18 florasulam 0.0036 fluoroxypyrr 0.12 florasulam 0.0024	150/400	F (BBCH 16)	Not acceptable (efficacy, risk for aquatic organisms and non-target terrestrial plants)

- 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
- 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.
- (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.
- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

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

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

The formulation VALENTIA (BARC 100/2) is suspo-emulsion formulation (SE). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogeneous free flowing opaque white liquid. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 377°C. In aqueous solution (1%), it has a pH value of 5.9 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a SE formulation.

The HDPE packaging claimed cannot be accepted without a long term stability study in this packaging.

The formulation is not classified for the physical-chemical part.

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

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

3.2.1 **Efficacy data**

Considering the data submitted the efficacy level of VALENTIA (BARC 100/2) is considered as satisfactory for all the claimed uses.

However, the products authorized for a use on maize with the same active substances and a similar efficacy level bring less florasulam per hectare. **Hence, the provided data do not allow considering the use on maize as acceptable.**

The selectivity level of VALENTIA (BARC 100/2) is considered as acceptable for all the claimed uses on maize.

The selectivity level of VALENTIA (BARC 100/2) is considered as acceptable for the use on straw cereals, for an application at BBCH 20 or higher. **Given the lack of data, the evaluation of the selectivity of the product for an application from BBCH 13 to BBCH 20 is not possible.**

The risks of negative impact on yield, quality, propagation are acceptable.

The risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.

The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

N/A : not registered in France.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of florasulam and fluroxypyr in plants (cereals), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

VALENTIA (BARC 100/2) containing 2 g/L of florasulam and 100 g/L of fluroxypyr has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is not a skin sensitisier.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁷	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Maize	F	Vehicle mounted <i>Downward spraying</i>	fluroxypyr 0.18 florasulam 0.0036	150

Considering proposed uses, operator systemic exposure was estimated using the EFSA model⁸:

Crop	Equipment	PPE and/or working coverall	% AOEL fluroxypyr	% AOEL florasulam

⁷ Open field or glasshouse

Maize	Vehicle-mounted	Working coverall and gloves during mixing/loading and application	0.73	1.18
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According to the model calculations, **it can be concluded that the risk for the operator using BARC 100/2 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.

3.4.3 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 set⁹.

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.*”

3.4.1 Resident exposure

Residential exposure was assessed according to EFSA model. **An acceptable risk was determined for residents (adult and/or child):**

Model (AOEM) - All pathways (mean)	% AOEL fluroxypyr	% AOEL florasulam
Resident (children)	4.26 %	3.46%
Resident (adults)	1.72%	1.00%

3.4.2 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 2.36% of the AOEL of fluroxypyr with PPE and to 0.76% of the AOEL of florasulam with working clothes.

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

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

⁹ 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)

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

The data available for cereals (wheat, barley, oat, rye and triticale) and maize are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg for fluroxypyr and 0.01* mg/kg for florasulam as laid down in Reg. (EU) 396/2005 is not expected.

The chronic intakes of both active substances residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS, agrees with the authorization of the intended uses on cereals and maize.

Regarding fluroxypyr, in the framework of the re-registration dossier of a PPP belonging to the main applicant of fluroxypyr, France received at the end of 2017 (after the publication of the revised Review Report) a new metabolism study in which goats were exposed to radiolabelled fluroxypyr methylheptyl ester. Contrary to the previous conclusions, the new metabolism study carried out with fluroxypyr-MHE demonstrates the formation of the fluroxypyr glucuronide conjugate. Furthermore, fluroxypyr 2-pyridinol has been detected in all tissues with the exception of muscle and was also detected in the urine, faeces and milk. Significant levels were detected in liver and kidney. According to FR, zRMS, as animals are mostly exposed to the esters rather than the acid, fluroxypyr 2-pyridinol (free and conjugated) should be included in the residue definition for Risk Assessment. However, in the absence of toxicological data on fluroxypyr 2-pyridinol, it is not possible to conclude whether the toxicity of this metabolite is covered by the parent compound. A TTC approach as a surrogate for toxicological data has been performed and allowed to assess the dietary risk linked to metabolite fluroxypyr-2-pyridinol. Risk linked to dietary exposure to fluroxypyr-2-pyridinol is considered acceptable.

It should be noted that the requirement of a representative metabolism study to address the fate of fluroxypyr esters in ruminants' matrices was also identified as a data gap in the framework of the MRL review under Article 12. For this reason, this study was transmitted by France to EFSA in order to be assessed and peer reviewed at EU level.

Waiting for the conclusions at EU levels, it is up to each member states to take a decision on these feeds.

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

- Following the use of fluroxypyr, a plant back interval of 10 months should be applied for crops belonging to the root and tuber crop group.

Data gaps

- A feeding study on ruminant with fluroxypyr-MHE would be desirable to confirm estimated concentrations of fluroxypyr-2-pyridinol in products of animal origin.

Noticed data gaps at EU level for florasulam are:

- Data and/or information addressing the toxicity of the major plant metabolite 4-OH-florasulam and the potential exposure of livestock and subsequently the consumer through animal commodities to metabolite 4-OH-florasulam.

- Rotational crop data considering the crop groups and plant back intervals as required by current guidance.

Noticed data gaps at EU level for fluroxypyr are:

- Data on the toxicity of fluroxypyr-methoxypyridine is required as this metabolite is susceptible to accumulate in soil and therefore, data on its plateau concentration and the transfer to plants.
- Information about the storage conditions of the samples from the fluroxypyr livestock feeding study is required in order to confirm the validity of the results of the reported ruminant feeding study. According to the Regulation CE n°2015/1040, this confirmatory data has to be submitted by 1st july of 2017.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active 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 of florasulam, fluroxypyr 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.

3.6.1 Predicted environmental concentrations in soil (PEC_{soil}) and surface water (PEC_{sw})

PEC soil derived for the active substances and their metabolites are used for the ecotoxicological risk assessment. PEC_{sw} were provided for the active substances and their metabolites. **However, no STEP 3 PEC_{sw} calculations were provided with FOCUS SWASH for florasulam and fluroxypyr, therefore the risk assessment on aquatic organisms cannot be finalized for this preparation.**

3.6.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} for florasulam, fluroxypyr and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹⁰. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

¹⁰ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

3.6.3 Predicted environmental concentrations in air (PEC_{air})

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/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.

Risk is not finalized for non-target terrestrial plants since no toxicity study on seedling emergence has been submitted for the formulation VALENTIA (BARC 100/2).

3.8 Relevance of metabolites (Part B, Section 10)

The PEC_{GW} of two florasulam metabolites (ASTCA and TSA) are above 0.1 µg/L. Their relevance has been assessed as per SANCO 221/2000, February 2003 and these two metabolites have been considered not toxicologically relevant.

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

N/A : not registered in France.

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

N/A : not registered in France.

4.1.1 Post-authorisation monitoring

N/A : not registered in France.

4.1.2 Post-authorisation data requirements

N/A : not registered in France.

Appendix 1 Copy of the product authorisation



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 réglementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique VALENTIA

de la société BARCLAY CHEMICALS R&D LTD
enregistrées sous les n°2018-0446 et 2018-0451

Vu les conclusions de l'évaluation de l'Anses du 4 novembre 2019,

Considérant qu'un risque inacceptable pour les organismes aquatiques et les plantes non cibles ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas autorisée en France.

VALENTIA / BARC 100/2
Part A - National Assessment
FRANCE



Informations générales sur le produit

Noms du produit	VALENTIA ORPEN
Type de produit	Produit de référence
Titulaire	BARCLAY CHEMICALS R&D LTD Damastown Way Damastown Industrial Park Mulhuddart 15 DUBLIN Irlande
Formulation	Suspo-émulsion (SE)
Contenant	2 g/L - florasulame 144 g/L - fluroxypyr-méthyl (équivalent à 100 g/L de fluroxypyr)
Numéro d'intrant	9991-2018.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 31 DEC. 2019

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)

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105911 Avoine*Désherbage	1,6 L/ha	1/an	F (BBCH 31)
15105912 Blé*Désherbage	1,5 L/ha	1/an	F (BBCH 39)
15555901 Mais*Désherbage	1,2 L/ha	1/an	F (BBCH 16)

VALENTIA
 AMM n°-



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105913 Orge*Désherbage	1,5 L/ha	1/an	F (BBCH 39)
Motivation du refus : L'usage est refusé au motif que l'absence de données ne permet pas d'exclure un risque inacceptable pour les organismes aquatiques et les plantes non cibles. L'usage est refusé sur orge d'hiver à la dose de 1,6 L/ha et pour un stade d'application plus tardif (BBCH 45) au même motif.			
15105915 Seigle*Désherbage	1,5 L/ha	1/an	F (BBCH 39)
Motivation du refus : L'usage est refusé au motif que l'absence de données ne permet pas d'exclure un risque inacceptable pour les organismes aquatiques et les plantes non cibles.			

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.



<p>Valentia</p> <p>H411 Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme. EUH 208 Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.</p> <p>Recommandations de sécurité</p> <p>P273 Éviter le rejet dans l'environnement. P391 Recueillir le produit répandu. P501 Éliminer le contenu/récipient conformément aux dispositions en vigueur</p> <p>SP1 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.</p> <p>SPe 2 Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45%.</p> <p>SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.</p> <p>SPe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.</p> <p>EUH401 Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.</p> <p>Délai de rentrée sur la parcelle traitée : 6 heures.</p>		<p>A.M.M. n° XXXXXX délivrée le DD/MM/YYY</p> <p><i>Suspo-émulsion (SE) contenant 100 g/L de fluroxypyr (10% m/m) + 2 g/L de florasulam (0.2% m/m)</i></p> <p>Valentia est un herbicide de post-levée pour la maîtrise des dicotylédones, en cultures de maïs et céréales à paille</p> <p>RÉSERVÉ À UN USAGE STRICTEMENT PROFESSIONNEL</p>
<p>Fabriqué par : Barclay Chemicals Manufacturing Ltd. Damastown Way, Damastown Industrial Park, Mulhuddart, Dublin 15, Irlande Tél. : +353 1 811 2900 Fax : +353 1 822 4678 E-mail : info@barclay.ie Site Internet : www.barclay.ie</p> <p>Détenteur de l'A.M.M. : Barclay Chemicals (R&D) Ltd. Damastown Way, Damastown Industrial Park, Mulhuddart, Dublin 15, Irlande Tél. : +353 1 811 2900 Fax : +353 1 822 4678 E-mail : info@barclay.ie Site internet : www.barclay.ie</p> <p>Copyright © Barclay Chemicals (R&D) Ltd, 2019</p> <p>Distribué par : XXX</p> <p>En cas d'urgence,appelez le 15 ou le centre anti-poison puis signalez vos symptômes au réseau Phyt'Attitude, N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).</p> <p>Fiche de données de sécurité disponible sur demande pour les professionnels : consulter notre site internet www.barclay.ie</p> <p>Le fabricant garantit uniquement la qualité du produit. Ne pouvant contrôler l'application et l'emploi, il ne peut garantir les résultats et n'accepte aucune responsabilité pour les dégâts qui pourraient résulter de l'application.</p> <p>N° de lot et date de fabrication : voir emballage</p>		<p>LIRE ATTENTIVEMENT L'ETIQUETTE AVANT EMPLOI</p>

USAGES ET DOSES AUTORISÉS

Culture	Cible	Dose homologuée	Stade d'application	Nombre maximal de traitements par an	ZNT Organismes aquatiques
Blé tendre d'hiver, orge d'hiver et blé dur	Désherbage des dicotylédones	1.6 L/ha	Avant le stade BBCH 45	1	5 m
Blé tendre de printemps, orge de printemps	Désherbage des dicotylédones	1.5 L/ha	Avant le stade BBCH 39	1	5 m
Avoine	Désherbage des dicotylédones	1.6 L/ha	Avant le stade BBCH 31	1	5 m
Seigle, triticale	Désherbage des dicotylédones	1.5 L/ha	Avant le stade BBCH 39	1	5 m
Maïs	Désherbage des dicotylédones	1.2 L/ha	Avant le stade BBCH 16	1	5 m

RESPECT DES LIMITES MAXIMALES DE RESIDUS (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

NOUVEAU CATALOGUE DES USAGES ET USAGES MINEURS

Barclay Chemicals ne préconise l'utilisation de ce produit que sur les cultures et usages mentionnés dans le tableau ci-dessus et décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures ou usages tels que prévus par le catalogue des usages en vigueur.

PRÉCONISATIONS D'EMPLOI

IMPORTANT : Toutes les instructions de cette section doivent être lues attentivement afin d'utiliser ce produit en toute sécurité et d'obtenir une efficacité adaptée.

Valentia est un herbicide destiné à la maîtrise des adventices dicotylédones annuelles et vivaces en cultures de céréales et de maïs. Valentia est un mélange de deux substances actives principalement à action foliaire. Il est indispensable de l'appliquer sur des adventices levées, de préférence jeunes et en croissance active, et de s'assurer que la pulvérisation recouvre bien le feuillage.

ADVENTICES MAÎTRISÉES en culture de céréales

Adventice		Sensibilité à la dose maximum ¹
Repousses de colza	<i>Brassica napus</i>	S
Capselle bourse-à-pasteur	<i>Capsella bursa-pastoris</i>	TS
Bleuet	<i>Cyanus segetum</i>	MS
Gaillet gratteron	<i>Galium aparine</i>	S
Lamier amplexicaule	<i>Lamium amplexicaule</i>	TS
Lamier pourpre	<i>Lamium purpureum</i>	S
Matricaire camomille	<i>Matricaria chamomilla</i>	TS
Matricaire inodore	<i>Tripleurospermum inodorum</i>	TS
Coquelicot	<i>Papaver rhoeas</i>	MS
Renouée liseron	<i>Fallopia convolvulus</i>	S
Sanve	<i>Sinapis arvensis</i>	S

Adventice		Sensibilité à la dose maximum ¹
Mouron des oiseaux	<i>Stellaria media</i>	S

¹TS = très sensible (>95%); S = sensible (85-94%); MS = moyennement sensible (70-84%); PS=Peu sensible (50-69.9%)

ADVENTICES MAÎTRISÉES en culture de maïs

Adventice		Sensibilité à la dose maximum ¹
Abutilon	<i>Abutilon theophrasti</i>	TS
Amarante réfléchie	<i>Amaranthus retroflexus</i>	S
Liseron des champs	<i>Convolvulus arvensis</i>	S
Renouée liseron	<i>Fallopia convolvulus</i>	MS
Renouée persique	<i>Persicaria maculosa</i>	S
Sanve	<i>Sinapis arvensis</i>	S
Morelle noire	<i>Solanum nigrum</i>	TS
Pourpier	<i>Portulaca oleracea</i>	S

¹TS = très sensible (>95%); S = sensible (85-94%); MS = moyennement sensible (70-84%); PS=Peu sensible (50-69.9%)

Culture	Stade d'application	Dose d'emploi
Blé tendre d'hiver, orge d'hiver et blé dur	BBCH 13-45	Pour la majorité des adventices :1.2-1.6 L/ha <i>Brassica napus</i> , <i>Papaver rhoeas</i> , <i>Matricaria sp.</i> , <i>Cyanus segetum</i> : 1.5-1.6 L/ha Appliquer dans 150 à 400 L/ha d'eau
Blé tendre de printemps, orge de printemps	BBCH 13-39	Pour la majorité des adventices :1.2-1.5 L/ha <i>Brassica napus</i> , <i>Papaver rhoeas</i> , <i>Matricaria sp.</i> , <i>Cyanus segetum</i> : 1.5 L/ha Appliquer dans 150 à 400 L/ha water
Avoine	BBCH 13-31	Pour la majorité des adventices :1.2-1.6 L/ha <i>Brassica napus</i> , <i>Papaver rhoeas</i> , <i>Matricaria sp.</i> , <i>Cyanus segetum</i> : 1.5 L/ha Appliquer dans 150 à 400 L/ha water
Seigle, triticale	BBCH 13-39	Pour la majorité des adventices :1.2-1.5 L/ha <i>Brassica napus</i> , <i>Papaver rhoeas</i> , <i>Matricaria sp.</i> , <i>Cyanus segetum</i> : 1.5-1.6 L/ha Appliquer dans 150 à 400 L/ha water
Maïs	Avant BBCH 16	1-1.2 L/ha Appliquer dans 150 à 400 L/ha water

CULTURES SUIVANTES

Aucune restriction ne s'applique concernant l'implantation d'une culture suivante au-delà de 30 jours après application de Valentia.

CULTURES DE REMPLACEMENT

Dans le cas où une culture de remplacement doit être mise en place, bien respecter les intervalles suivants après application de Valentia :

- 14 jours pour l'implantation d'une culture de carotte, concombre, tomate ou oignon ;
- 30 jours pour l'implantation d'une culture de tournesol, colza, radis ou betterave.

PRÉPARATION DE LA BOUILLIE

Porter des équipements de protection individuels pendant toutes les phases de mélange/chargement, de traitement et de nettoyage du matériel de pulvérisation (cf. Précautions de l'utilisateur).

Bien agiter le bidon avant utilisation. Remplir à moitié la cuve avec de l'eau et mettre en marche l'agitation. Verser la quantité nécessaire de Valentia dans la cuve. Remplir la cuve avec de l'eau au volume requis. Maintenir l'agitation durant toute la durée de l'application.

QUALITÉ DE LA PULVÉRISATION

Appliquer en pulvérisation de finesse moyenne à une pression de 2-2.5 bars avec un pulvérisateur à jets projetés conventionnel. Éviter tout risque de dérive de pulvérisation. Ne pas laisser la bouillie dans la cuve du pulvérisateur pendant de longues périodes, par exemple le temps des repas.

Appliquer dans 150 à 400 L/ha d'eau afin d'assurer une bonne couverture du feuillage. Utiliser le volume d'application maximum pour les cultures à feuillage dense ou lorsque les adventices sont développées.

Appliquer sur feuillage sec. Ne pas appliquer en cas de prévision de pluie imminente. Éviter la dérive de pulvérisation sur les cultures ou surfaces voisines. Éviter les recouvrements de pulvérisation.

Aucun impact négatif de Valentia n'est attendu sur plantes non-cibles et cultures adjacentes en respectant une zone non traitée de 5 m.

PRÉCAUTIONS D'EMPLOI

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, 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.

PRÉCAUTIONS POUR L'UTILISATEUR

Éviter le contact du produit avec les yeux, la peau et les voies respiratoires.

Ne pas porter les gants ou tout autre objet souillé à la bouche.

Ne pas déboucher les buses du pulvérisateur en soufflant dessus.

Après application, rincer ses équipements de protection, jeter les gants avec les emballages vides (via une collecte organisée), se laver les mains au savon et prendre une douche.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe :

Pendant le mélange/chargement et le nettoyage du matériel de pulvérisation, porter :

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III type PB (3) à porter par-dessus la combinaison précitée.

Pendant l'application porter :

- Combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperlant ;

Si application avec tracteur sans cabine :

- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

Si application avec tracteur avec cabine :

- Gants en nitrile certifiés EN 374-2 à usage unique dans le cadre 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.

PRÉCAUTIONS POUR LE TRAVAILLEUR

Dans les cas où le travailleur serait amené à intervenir sur les parcelles traitées : combinaison de travail polyester 65%/coton 35% avec un grammage d'au moins 230 g/m² avec traitement déperlant et gants en nitrile certifiés EN 374-3.

PREMIERS SOINS

Enlever immédiatement les vêtements contaminés par le produit.

En cas de contact avec la peau : laver abondamment à l'eau et au savon.

En cas d'inhalation : transporter la victime à l'extérieur et la maintenir au repos dans une position où elle peut confortablement respirer.

En cas de contact avec les yeux : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

En cas d'ingestion, ne PAS faire vomir. Appeler un médecin. Garder la victime au repos et la maintenir au chaud.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

COMPATIBILITÉ

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.

Pour plus d'information sur la compatibilité des mélanges à base de Valentia, prendre contact avec :

Barclay Chemicals (R&D) Ltd., Damastown Way, Damastown Industrial Park, Mulhuddart, Dublin 15, Irlande.

Tel: +353 1 8112900 Fax: +353 1 8224678 E-mail: info@barclay.ie

STOCKAGE

Conserver à l'abri du gel.

Toujours conserver le produit dans son emballage d'origine. Le stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur.

EMBALLAGES VIDES ET SURPLUS DE TRAITEMENT

Éviter toute contamination de rivières, étangs et canaux d'irrigation avec le produit. Rincer les bidons, verser dans la cuve de pulvérisation et épandre les reliquats sur la parcelle traitée selon la réglementation en vigueur. Rendre inutilisables les emballages vides.

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

Ne pas réutiliser les emballages vides et les éliminer via une collecte organisée par les distributeurs partenaires de la filière Adivalor ou un autre service de collecte spécifique.

NETTOYAGE DU PULVÉRISATEUR

Après utilisation de Valentia, nettoyer soigneusement le pulvérisateur. S'assurer que la rampe et les tuyaux sont bien rincés.

Un mauvais nettoyage pourrait entraîner des dégâts sur les cultures traitées ultérieurement.

RÉSISTANCE

Il existe un risque général d'apparition d'adventices résistantes aux herbicides. Afin de limiter ce risque, il convient de prendre les dispositions suivantes :

- Respecter les préconisations d'emploi de cette étiquette (dose, conditions d'application...) ;
- Adopter des méthodes prophylactiques de lutte contre les adventices ;
- Limiter la dispersion des adventices et de leur graines ;
- Adopter de bonnes pratiques de pulvérisation afin d'atteindre un niveau de contrôle maximum ;
- Utiliser des buses adaptées pour assurer une bonne couverture des adventices lors de la pulvérisation ;
- Appliquer dans des conditions météorologiques adaptées ;
- Surveiller le comportement du produit et informer Barclay Chemicals (R&D) Ltd de résultats non conformes.

L'utilisation répétée d'herbicides de même mode d'action peut augmenter le risque d'apparition de résistance. A chaque fois que c'est possible, il est recommandé de varier les substances chimiques et d'alterner avec des produits à mode d'action différent.

Vous pouvez demander conseil à votre technicien ou à votre distributeur.

IMPORTANT

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les 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 mise sur le marché délivrée par les autorités françaises compétentes. 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.

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Appendix 3 Letter of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.