REGISTRATION REPORT
Part A
Risk Management

Product code: ALB 083
Product name(s): ARVENS DUO
Chemical active substance(s):
Tribenuron-methyl, 250 g/kg
Florasulam, 104 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(new application)

Applicant: Albaugh UK Ltd.
Date: 2018/10/12

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PART A
RISK MANAGEMENT

1 Details of the application

The company ALBAUGHT UK Ltd has requested marketing authorisation in France for the product ARVENS DUO (formulation code: ALB 083), containing 250 g/kg tribenuron-methyl and 104 g/kg florasulam for use as a herbicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to ARVENS DUO (ALB 083) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ARVENS DUO (ALB 083) have been made using endpoints agreed in the EU peer review of tribenuron-methyl and florasulam.

This document describes the specific conditions of use and labelling required for France for the registration of ARVENS DUO (ALB 083).

Appendix 1 of this document provides a copy of the product authorisation.

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

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

1.1 Application background

The present registration report concerns the evaluation of ALBAUGH UK Ltd's application to market ARVENS DUO (ALB 083) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

The present application (2016-2529) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] 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")[2] – the highest application rates over 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 1107/2009[3], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU)

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] 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
[3] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letter(s) of access.

1.3 Justification given for submission of tests and studies

According to the applicant:
"ARVENS DUO (ALB 083) is a new formulation. The following tests have been generated with ARVENS DUO (ALB 083) and submitted within the current application: product data on physical and chemical properties, analytical methods, efficacy, acute toxicity and dermal absorption and ecotoxicological data. These new tests have been generated as ARVENS DUO (ALB 083) is a new formulation."

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

[4] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

2 Details of the authorisation decision

2.1 Product identity

Product code	ALB 083
Product name in MS	ARVENS DUO
Authorisation number	-
Function	Herbicide
Applicant	ALBAUGHT UK Ltd
Active substance(s) (incl. content)	tribenuron-methyl, 250 g/kg florasulam, 104 g/kg
Formulation type	Water soluble granule (SG)
Packaging	- Professional user.
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 ARVENS DUO (ALB 083) resulted in the decision to refuse the authorization.

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:	Aquatic acute 1 Aquatic chronic 1
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects

Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains tribenuron-methyl. May cause an allergic reactions [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: not registered in France.

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

N/A: not registered in France.

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 4th May 2017 [5] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift 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[6] provides that:

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

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

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[5] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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

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

2.5.1 Restrictions linked to the PPP

N/A: not registered in France.

2.5.2 Specific restrictions linked to the intended uses

N/A: not registered in France.

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" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP, date: 2018-10-12

PPP (product name/code):	ARVENS DUO (ALB 083)	Formulation type:	SG [a, b]
Active substance 1:	tribenuron-methyl	Conc. of as 1:	250 g/kg[c]
Active substance 2:	florasulam	Conc. of as 2:	104 g/kg[c]
Applicant:	Albaugh UK Ltd	Professional use:	☒
Zone(s):	southern	Non professional use:	☐
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 / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/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	FR	Winter cereals (wheat, spelt, triticale, barley, oat and rye)	F	Broadleaved weeds	Spray	BBCH 13 – 39 1st January to early July	1	-	0.06 kg/ha	6.25 g florasulam/ha – 15 g tribenuron-methyl/ha	200 - 400	F	**Not acceptable** (groundwater contamination risk, no sufficient selectivity data on oat and rye)
2	FR	Spring cereals (wheat, spelt, triticale, barley, oat and	F	Broadleaved weeds	Spray	BBCH 12 – 39 1st February to	1	-	0.06 kg/ha	6.25 g florasulam/ha – 15 g tribenuron-	200 – 400	F	**Not acceptable** (groundwater contamination risk, no suffi-

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 / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		rye)				July				methyl/ha			cient selectivity data on oat and rye)

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/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)

ARVENS DUO (ALB 083) is a water soluble granule (SG). 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 a light brown free flowing granule free from foreign matter. It is not explosive and has no oxidising properties. The product is not flammable. No self-ignition is observed (>400 °C)**.** In aqueous solution (1%), it has a pH value of 9.4 at 22°C. There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35 °C, neither the active ingredient content nor the technical properties were changed. The formulation is considered stable 2 years at ambient temperature when stored in HDPE/PA and polyester/aluminium/LDPE.. Its technical characteristics are acceptable for an SG formulation.

The formulation is not classified for the physico-chemical aspect. The preparation should not be stored at a temperature higher than 35°C.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of ARVENS DUO (ALB 083) is considered as satisfactory for all the claimed uses.
- the selectivity level of ARVENS DUO (ALB 083) is considered as satisfactory for winter soft wheat, winter hard wheat, winter barley, triticale, spring barley, spring hard wheat and spring soft wheat. No data was submitted on rye and oat. Consequently the evaluation of the selectivity on these crops can't be finalized.
- the risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
- 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.
- There is a risk of resistance development or appearance to tribenuron-methyl or florasulam for all the claimed uses requiring a survey of resistance on the basis of field failure.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substances and the relevant impurity 2,6-DFA in the formulation are available and validated.
Analytical methods are available in the Renewal Assessment Report/this dossier and validated for the determination of residues of tribenuron-methyl and florasulam in plants (cereals), food of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in the Renewal Assessment Report and validated for the determination of residues of florasulam in tissues and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: **florasulam**			
ADI	0.05 mg kg bw/d		EU (2016)
ARfD	not applicable		
AOEL	0.05 mg/kg bw/d		
AAOEL	not applicable		
Dermal absorption	Based on an *in vitro* human study performed on formulation:		
		Concentrate (tested) 104 g/kg	Diluted formulation (tested) 0.015625 g/L
	In vitro (human) %	0.5%	9%
		Concentrate (used in formulation) 104 g/kg	Spray dilution (used in formulation) 0.0156 - 0.0312 g/L
	Dermal absorption endpoints %	**0.5%**	**9%**
Oral absorption	90%*		EFSA (2015)

Active Substance: **tribenuron-methyl**			
ADI	0.01 mg kg bw/d		EU (2006)
ARfD	0.2 mg/kg bw		
AOEL	0.07 mg/kg bw/d		
AAOEL	not applicable		
Dermal absorption	Based on an *in vitro* human study performed on formulation:		
		Concentrate (tested) 250 g/kg	Diluted formulation (tested) 0.0375 g/L
	In vitro (human) %		
		Concentrate (used in formulation) 250 g/kg	Spray dilution (used in formulation) 0.0375 - 0.075 g/L
	Dermal absorption endpoints %	**3**	**6**
Oral absorption	80%*		EFSA (2004)

*data entry in EFSA model: 100%

3.4.1 Acute toxicity

ARVENS DUO (ALB 083) containing 104 g/kg florasulam and 250 g/kg tribenuron-methyl has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[8]	Equipment *Application method*	Maximum application rate kg as /ha	Spray dilution (L/ha)
Cereals (wheat, spelt, triticale, barley, oat and rye)	F	Vehicle mounted *Downward spraying*	0.06 kg/ha florasulam: 0.00625 kg/ha tribenuron-methyl: 0.015 kg/ha	200-400 L/ha

Considering proposed uses, operator systemic exposure was estimated using EFSA model[9]:

Crop	Equipment	PPE and/or working coverall	% AOEL florasulam (0.05 mg/kg bw/d)	% AOEL tribenuron-methyl (0.07 mg/kg bw/d)
Cereals (wheat, spelt, triticale, barley, oat and rye)	Vehicle mounted / *downward spraying*	Working coverall and gloves during mixing/loading and application	0.98%	0.92%

According to the model calculations, it can be concluded that the risk for the operator using ARVENS DUO (ALB 083) 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 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection and irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 0.16% of the AOEL of florasulam and 0.18% of the AOEL of tribenuron-methyl with PPE (work wear).
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.

3.4.4 Bystander and resident 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[10].
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 Jour-

[8] Open field or glasshouse
[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)
[10] 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)

nal 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."*

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 florasulam**	**% AOEL tribenuron-methyl**
Resident (children)	2.39%	1.82%
Resident (adults)	0.57%	0.45%

Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.
A cumulative assessment for operators, residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	**florasulam**	0.0098
		tribenuron-methyl	0.0092
	Cumulative risk operators (HI)		**0.019**
Bystanders /Residents	Children - All pathways (mean)	**florasulam**	0.0239
		tribenuron-methyl	0.0182
	Cumulative risk residents (child) (HI)		**0.0421**
	Adults - All pathways (mean)	**florasulam**	0.0057
		tribenuron-methyl	0.0045
	Cumulative risk residents (adult) (HI)		**0.0102**
Worker	Working coverall	**florasulam**	0.0016
		tribenuron-methyl	0.0018
	Cumulative risk workers (HI)		**0.0034**

The Hazard Index is < 1. Thus combined exposure to all active substances in ARVENS DUO (ALB 083) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

Overal conslusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of for tribenuron-methyl and florasulam as laid down in Reg. (EU) 2015/1040 and Reg. (EU) No 1317/2013, respectively, is not expected.
The chronic and the short-term intakes of tribenuron-methyl and florasulam residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.
According to available data, no specific mitigation measures should apply.

Data gaps

Some data gaps were identified at EU level during renewal of florasulam (EFSA, 2015):

- 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.

Summary of the evaluation

Summary for florasulam

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EC) 2013/1317	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Cereals	Yes	Yes	Yes	Yes	Yes	No	No

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

As residues of florasulam do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.
Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. Nonetheless, submission of additional rotational crop data at EU level, addressing a plant-back interval of 365 days and taking into account persistent metabolites TSA and ASTCA, are desirable to address residue definition in rotational crops.
Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. However, it should be noted that further evidence with regard to occurrence, behaviour and/or toxicity of 4-OH-phenyl-florasulam is still required to finalise livestock residue definition for risk assessment and determine potential exposure of livestock and subsequently the consumer through animal commodities to metabolite 4-OH-florasulam (EFSA, 2015).

Summary for tribenuron-methyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2015/1040	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Cereals	Yes	Yes	Yes	Yes	Yes	No	No

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

As residues of tribenuron-methyl do not exceed the trigger values defined in Reg. (EU) 2015/1040, there is no need to investigate the effect of industrial and/or household processing.
Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.
Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for ARVENS DUO (ALB 083)

Crop	PHI for ALB 083 proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for ALB 083 proposed by zRMS	zRMS Comments (if different PHI proposed)
		florasulam	tribenuron-methyl		
Cereals	NR**	NR**/ Yes	NR**/ Yes	F**	/

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant.

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. 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 tribenuron-methyl, florasulam 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.
PEC soil and PECsw derived for both active substances and their metabolites are used for the ecotoxicological risk assessment.

PECgw for florasulam and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[11]. No unacceptable risk of groundwater contamination is expected for florasulam and its metabolites according to the intended uses.
The PECgw calculations proposed by the applicant for tribenuron-methyl and its metabolites cannot be validated by zRMS: the entire degradation pathway of the active substance was not considered, a crop uptake factor of 0 was not used for all metabolites and a non-relevant pH dependence for metabolites' degradation and mobility was considered by the notifier although it was not pointed out at European level. The notifier's input parameters differ from those already validated in other dossiers containing tribenuron-methyl assessed at the zonal level. Therefore, the groundwater risk assessment cannot be finalized for tribenuron-methyl and its metabolites.

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

3.7 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 terrestrial vertebrates, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms can be considered acceptable for the intended uses.

The risks to aquatic organisms following the intended use of ARVENS DUO (ALB 083) can be considered acceptable with the following mitigation measure:

- To protect aquatic organisms, do not apply on winter cereals before BBCH 20.
- To protect aquatic organisms do not apply to artificially drained soils with clay content higher than or equal to 45% for the uses on winter cereals.
- To protect aquatic organisms respect an unsprayed buffer zone of 5 m with an unsprayed vegetated buffer zone of 5 m to surface water bodies for the uses on winter cereals.
- To protect aquatic organisms respect an unsprayed buffer zone of 5m to surface water bodies for the uses on spring cereals.

The risk to non-target plants following the intended use of ARVENS DUO (ALB 083) can be considered acceptable with a 5m non-sprayed buffer zone.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites ASTCA and TSA predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B Section 8). Assessment of the relevance of these metabolites has already realised in EFSA Journal 2015 of florasulam.

For tribenuron-methyl, no reliable PECgw calculations are available for both intended uses on spring and winter cereals (please refer to dRR Part B Section 8 for more details).

[11] 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.

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

Active substances tribenuron-methyl and florasulam are not approved as a candidate of 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

N/A: not registered in France.

5.1.1 Post-authorisation monitoring

N/A: not registered in France.

5.1.2 Post-authorisation data requirements

N/A: not registered in France.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

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

de la société	*ALBAUGH UK Ltd*
enregistrée sous le	*n°2016-2529*

Vu les conclusions de l'évaluation de l'Anses du 25 mai 2018,

Considérant que les paramètres d'entrée utilisés dans les modélisations pour le tribénuron-méthyl et ses métabolites diffèrent de ceux validés au niveau européen et que l'intégralité de la voie de dégradation du tribénuron-méthyl n'est pas prise en compte dans l'estimation des concentrations de la substance active dans les eaux souterraines fournie par le demandeur,

Considérant que l'estimation des concentrations dans les eaux souterraines en tribenuron-méthyl et ses métabolites ne peut être finalisée,

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

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

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Informations générales sur le produit	
Nom du produit	ARVENS DUO
Type de produit	Produit de référence
Titulaire	ALBAUGH UK Ltd 1 Northumberland Avenue Trafalgar Square LONDON WC2N 5BW ROYAUME-UNI
Formulation	Granulé soluble dans l'eau (SG)
Contenant	104 g/kg - florasulame 250 g/kg - tribénuron-méthyl
Numéro d'intrant	720-2016.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 12 OCT. 2018

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105911 Avoine*Désherbage	0,06 kg/ha	1/an	F (BBCH 39)
	Motivation du refus : L'usage est refusé en raison d'un manque de données relatives à la sélectivité du produit et à l'estimation des concentrations dans les eaux souterraines en tribénuron-méthyl et ses métabolites.		
15105912 Blé*Désherbage	0,06 kg/ha	1/an	F (BBCH 39)
	Motivation du refus : L'usage est refusé en raison d'un manque de données relatives à l'estimation des concentrations dans les eaux souterraines en tribénuron-méthyl et ses métabolites.		
15105913 Orge*Désherbage	0,06 kg/ha	1/an	F (BBCH 39)
	Motivation du refus : L'usage est refusé en raison d'un manque de données relatives à l'estimation des concentrations dans les eaux souterraines en tribénuron-méthyl et ses métabolites.		
15105915 Seigle*Désherbage	0,06 kg/ha	1/an	F (BBCH 39)
	Motivation du refus : L'usage est refusé en raison d'un manque de données relatives à la sélectivité du produit et à l'estimation des concentrations dans les eaux souterraines en tribénuron-méthyl et ses métabolites.		

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.

ARVENS DUO®

Granulés solubles dans l'eau (SG) utilisés en post-emergence pour contrôler les dicotylées en céréales d'hiver et de printemps
Numéro d'AMM : XXXX
Arvens Duo contient : 250 g/kg (25.0% w/w) de tribenuron-méthyle et 104 g/kg (10.4% w/w) de florasulam
Usage : Professionnel
Mentions d'avertissements **H410** Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme. **EUH208** Contient du Tribenuron-methyle. Peut produire une réaction allergique. **EUH401** Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement. **Conseils de prudence** **P391** Recueillir le produit répandu. **P501** Éliminer le contenu/récipient dans des points de ramassage réservés à l'élimination des déchets dangereux, sauf pour les conteneurs vides qui ont été rincés à trois reprises qui peuvent être éliminés comme des déchets non dangereux. **SP1** Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface./ Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.) **SPe2** Pour protéger les organismes aquatiques, ne pas appliquer sur des sols artificiellement drainés avec un taux d'argile supérieur ou égal à 45%. **SPe 3** Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres ou des mesures de réduction de la dérive de 90% par rapport à la zone non cultivée adjacente. Délai de rentrée : 6 heures en cohérence avec l'arrêté du 12 juin 2015
Information santé : Fiche de données de sécurité également disponible sur le site web : www.albaugh.eu **Appel en cas d'urgence** : Appeler le +44 1235 239 670 (24 h/24), le 15 ou le centre antipoison de Paris : 01 40 05 48 48. Puis signaler les symptômes au réseau Phyt'attitude, n° vert 0800 887 887 (appel gratuit depuis un poste fixe).
Date de fabrication, n° de lot, référence : Inscrits ailleurs sur l'emballage pour des raisons techniques.

Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve dupulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.

ATTENTION

CONTENU : 20, 100, 125, 150, 200, 250, 300, 400, 500, 1000, 1500 g

Détenteur d'agréation:
Albaugh UK Ltd
Northumberland Avenue 1, Trafalgar Square, London, W2CN 5 BW, UK
Tel: +44 (0) 20 3551 2580 Fax: +44 (0) 20 7872 5611

Lire attentivement l'étiquette.

ARVENS DUO®

ARVENS DUO est un herbicide de contact qui agit par absorption via les racines. ARVENS DUO est prévu pour être utilisé seul ou en mélange et en séquences pour lutter contre des dicotylées en céréales d'hiver et de printemps. ARVENS DUO peut être appliqué en post-emergence de la culture au printemps à partir de 3 feuilles étalées (BBCH 13) jusqu'au stade où le limbe de la dernière feuille est entièrement étalé, la ligule est visible (BBCH 39) en céréales d'hiver et au printemps à partir de 2 feuilles étalées (BBCH 12) jusqu'au stade où le limbe de la dernière feuille est entièrement étalé, la ligule est visible (BBCH 39) en céréales de printemps. L'efficacité est la meilleure lorsque le produit est appliqué tôt en post-émergence et sur des mauvaises herbes de petite taille et en croissance active.

Doses et usages autorisés

Culture	Dose maximum	Nombre de traitements maximum	Période d'application
Blé d'hiver, Orge d'hiver, Orge de printemps, Blé de printemps	60 g/ha	1	Au plus tard au stade où le limbe de la dernière feuille est entièrement étalé, la ligule est visible (BBCH 39)

- **Préparation de la bouillie de pulvérisation**

Remplir à moitié d'eau le réservoir du pulvérisateur et démarrer le système d'agitation. Ajouter la quantité requise de produit au réservoir et pulvériser entièrement. Pulvériser immédiatement après la préparation du mélange, ne pas laisser stagner le mélange dans le pulvérisateur. Lors d'utilisation en mélange, respecter l'ordre d'ajout spécifié sur l'étiquette du produit associé.

Volume d'eau à utiliser : 200 à 400 L d'eau/ha.

- **Remarques importantes**
  - Avant utilisation, s'assurer que le pulvérisateur ne contient pas de reste des utilisations précédentes et qu'il est réglé de manière à appliquer le volume et la pression de pulvérisation recommandée. Procéder directement après l'utilisation au nettoyage de l'équipement de pulvérisation (cfr. section « Nettoyage du matériel de pulvérisation » et « Emballages vides et surplus de traitement »).
  - ARVENS DUO peut être utilisé sur tous types de sols. Une humidité du sol suffisante garantit un contrôle des mauvaises herbes optimal.
  - Eviter toute dérive de la pulvérisation en dehors de la zone à traiter. Traiter par temps calme afin de protéger les cultures voisines. Eviter les chevauchements de rampe.
  - Ne pas utiliser sur des cultures de semences.
  - Ne pas labourer ni retourner le sol après application.
  - Ne pas utiliser sur des sols présentant une structure pauvre ou compacte ou sur des sols sujets à engorgements.
  - Eviter toute pulvérisation dans les 5 mètres sur les bords du champ afin de minimiser l'impact sur les insectes et arthropodes non ciblés.
  - Une plus faible efficacité peut être observée après une période de sécheresse prolongée suivant l'application.
  - Sous certaines conditions climatiques, une décoloration temporaire du feuillage peut être observée, cette décoloration peut être forte en cas de fortes pluies suivant l'application. Ces symptômes temporaires disparaissent rapidement et n'ont aucun impact sur le rendement de la culture.
  - Ne pas appliquer sur des cultures soumisses à un stress (endommagées par des parasites, souffrant du gel ou de carences en substances nutritives). Ne pas appliquer dans des périodes de gel prolongées ou importantes car cela risque d'endommager provisoirement la culture.

- **Protection de l'utilisateur**

Pour l'opérateur porter :

• Pendant le mélange / Chargement :

- Gants en nitrile certifiés EN-374-3 ;
- Combinaison de travail cotte en polyester 65% / coton 35% avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Vêtement imperméable (tablier ou blouse à manches longuescertifiés cat. III type 3 (PB3) à porter par-dessus la combinaison précitée ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- Lunettes norme EN 166 (CE, sigle 3)

• Pendant l'application :

- Gants en nitrile certifiés EN 374-3. Nécessaires uniquement lors d'interventions sur le matériel 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 ;
- Combinaison de travail cotte en polyester 65% / coton 35% avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Lunettes norme EN 166 (CE, sigle 3) dans le cas d'une intervention sur le matériel ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- En cas de risque d'exposition à des particules pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou demimasqueconnecté à un filtre à particules (EN 140 + 143). Le masque doit être stocké à l'extérieur de la cabine.

• Pendant le nettoyage du matériel de pulvérisation :

- Gants en nitrile certifiés EN 374-3.
- Combinaison de travail cotte en polyester 65% / coton 35% avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- Vêtement imperméable (tablier ou blouse à manches longues certifiés cat. III type 3 (PB3) à porter par-dessus la combinaison précitée ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- Lunettes norme EN 166 (CE, sigle 3) ;

Pour protéger le travailleur, porter une combinaison de travail tissée en polyester 65% / coton 35% avec un grammage de 230g/m² ou plus avec traitement déperlant.

Laver tous les vêtements après utilisation, en particulier l'intérieur des gants.
Ne pas manger, boire ni fumer pendant l'utilisation.
Se laver les mains après manipulation.
En cas de malaise, consulter un médecin.

Efficacité

L'application de ARVENS DUO à la dose de 60 g/ha en post-émergence permet de contrôler les mauvaises herbes suivantes :

Très sensibles	Sensibles	Moyennement sensibles
Mouron des oiseaux (*stellaria media*)	Gaillet gratteron *(galium aparine)*	Chardon des champs *(cirsium arvense)*
Coquelicot (*papaver rhoeas*)	Chénopode *(chenopodium)*	
Matricaire (*matricaria*)	Bleuet centaurée *(centaurea cyanus)*	
Sanve, moutarde	Lamier pourpre *(lamium purpureum)*	
Capselle bourse à pasteur (*capsella bursa pastoris*)	Véronique de Perse (*veronica persica*)	

	Pensée des champs *(viola arvensis)*	

Nettoyage du matériel de pulvérisation

Afin d'éviter tout dommage aux cultures traitées ultérieurement avec le même matériel, il est nécessaire de nettoyer soigneusement le pulvérisateur, dès la fin de l'application, soit en utilisant un mélange d'hypochlorite de sodium et la potasse caustique formulée à cet effet, soit une solution d'ammoniaque (0.3 L/100 L de réservoir).

Gestion du risque d'apparition de résistances

Il existe un risque modéré de développement de la résistance des mauvaises herbes au ARVENS DUO avec des herbicides exerçant des modes d'action différents et ayant le même spectre d'efficacité.

Ne pas utiliser ARVENS DUO comme seul traitement contre vulpin des champs. Utiliser en mélanges ou en séquences avec d'autres herbicides homologués contre le vulpin des champs et exerçant un autre mode d'action. Ne pas utiliser ARVENS DUO comme seul traitement herbicide sur des cultures successives.

Restrictions particulières

- **Cultures suivantes**

Seuls des céréales, des haricots et du colza peuvent être semés dans la même année calendrier de la récolte d'une culture de céréales traitée avec ARVENS DUO.

- **Cultures de remplacement**

En cas d'échec de la culture, quelle qu'en soit la raison, seuls des céréales peuvent être semés dans les 3 mois suivant l'application du produit ARVENS DUO. Après 6 mois, des haricots et du colza peuvent également être semés.

Mélanges

Les mélanges doivent être mis en oeuvre conformément à la législation en vigueur (arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015) et aux recommandations des guides de bonnes pratiques officiels. Il est de la responsabilité de l'utilisateur de s'informer auprès du détenteur de l'agréation de la miscibilité possible avec d'autres produits à base des substances actives mentionnées sur l'étiquette.
Consulter le site : https://ephy.anses.fr/

Stockage

Conserver à l'écart de la nourriture, des boissons et y compris ceux pour animaux.
Tenir hors de portée des enfants.
Conserver dans l'emballage d'origine bien fermé, en lieu sûr.
Conserver au sec et protéger du gel dans un lieu adapté aux pesticides.

Emballages vides et surplus de traitement

Réemploi de l'emballage interdit. L'emballage de ce produit, soigneusement vidé, doit être rincé à l'eau suivant un système manuel (trois agitations successives) ou par un système de nettoyage à l'eau sous pression placé sur le pulvérisateur. Les eaux de ce nettoyage devront être versées dans la cuve de pulvérisation.
L'élimination des déchets, des emballages contaminés et de tout produit de pulvérisation dilué non utilisé doit se faire en conformité avec l'arrêté du 20 septembre 2002 sur l'incinération et la co

incinération des déchets dangereux (JO, 1er décembre 2002) et l'arrêté du 30 décembre 2002 sur le stockage des déchets dangereux (JO, 16 avril 2003).

L'emballage de ce produit peut être éliminé dans le cadre de la filière ADIVALOR.

Clause de non-responsabilité

Plusieurs facteurs peuvent affecter ou influencer l'activité de ce produit, parmi lesquels le climat, les conditions du sol, la variété cultivée, le calendrier du traitement, la quantité d'eau, les taux d'application, les techniques de pulvérisation, la rotation des cultures, les spécificités régionales et la présence ou le développement de souches résistantes au principe actif.
Dans certaines circonstances, il peut se produire des modifications de l'activité ou des dommages sur la plante cultivée. Le fabricant ou le fournisseur ne sauraient être tenus responsables dans de telles circonstances. Tous les produits que nous fournissons sont de très grande qualité et nous estimons qu'ils sont tout à fait adaptés à l'usage auquel nous les destinons expressément. Toutefois, comme nous ne sommes pas en mesure d'exercer de contrôle sur les opérations de mélange, utilisation et application pouvant affecter les performances de nos produits, toutes les conditions et garanties, légales ou autres, relatives à la qualité ou l'aptitude à tout usage de nos produits sont exclues, et nous ne pouvons être tenus responsables de quelque dommage ou blessure que ce soit, résultant de leur stockage, manipulation, application ou emploi. Ces conditions ne peuvent être modifiées par notre personnel ou nos agents, ni par les revendeurs de nos produits, qu'ils fournissent ou non des activités de supervision ou d'assistance technique pour l'utilisation de ces produits.

Appendix 3 Letter of Access

Provided upon request.

Appendix 4 Lists of data considered for national authorisation

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in joined excel file. Studies highlighted in grey cannot be protected (not GLP, nor GEP, calculations, etc.).