REGISTRATION REPORT

Part A

Risk Management

Product code: AVADEX CS, TRI-ALLATE CS, GWN-3189B

Product name(s): AVADEX FACTOR

Active Substance(s):

tri-allate, 450 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: GOWAN France

Date: 2018/01/16

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PART A – Risk Management

The company GOWAN France has requested marketing authorisation in France for the product AVADEX FACTOR (formulation code: TRI-ALLATE CS, GWN-3189B), containing 450 g/L tri-allate for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) have been made using endpoints agreed in the EU peer review of tri-allate.

This document describes the specific conditions of use and labelling required for France for the registration of AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of GOWAN France's application to market AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) 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.

1.2 Active substance approval

tri-allate

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tri-allate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: —the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, —the dietary exposure of consumers to residues of tri-allate in treated crops as well as in succeeding rotational crops and in products of animal origin —the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate,

—the potential for ground water contamination by the degradation products TCPSA when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate.

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

— further information to assess the primary plant metabolism,

— further information on the fate and behaviour of the soil metabolite diisopropylamine,

— further information on the potential for biomagnification in aquatic food chains,

—information to further address the risk to fish-eating mammals and the long-term risk to earthworms.

They shall ensure that the notifier provides such information to the Commission by 31 December 2011.

An EFSA conclusion is available (EFSA Scientific Report (2008) 181, 1-100).

A Review Report is available (SANCO/4437/09 final, 22 October 2009).

1.3 Regulatory approach

The present applications (2013-1723) were 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.

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[3] 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.

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[4], 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] 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

[4] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B)
Authorisation number	N/A : no acceptable use in FR
Function	herbicide
Applicant	GOWAN France
Composition	450 g/L tri-allate
Formulation type (code)	Capsule suspension (CS)
Packaging	HDPE/PA CoEx (5L, 10L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

[5] 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

[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

Physical hazards		
Health hazards	Skin sensitisation cat. 1B, Specific target organ toxicity - Repeated exposure cat. 2	
Environmental hazards	Aquatic Chronic 1; Aquatic Acute 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction
	H373	May cause damage to organs through prolonged or repeated exposure via the oral route
	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

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

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

N/A: no acceptable use

2.2.4 Other phrases linked to the preparation

N/A: no acceptable use

2.3 Product uses

Please note:
When the conclusion is "not acceptable" , the intended use is highlighted in grey and the main reason(s) reported in the remarks.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2018-01-16

PPP (product name/code) **AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B)** **Formulation type:** **CS**
(TRIALLATE CS, GWN-3189B) **Conc. of as 1:** **450 g/L**
active substance 1 **tri-allate**

Applicant: **GOWAN France** **professional use** ☒
Zone(s): **southern EU** **non professional use** ☐
Verified by MS: **yes**

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	Cereals (winter barley, spring barley)	F	ALOMY, AVESS, LOLMU, BROST,	Overall spray (incorporation)	Pre-sowing	1		3.6	1620	220-400	-	Not acceptable (risks of groundwater contamination and for aquatic organisms)
2	FR	Beets (Sugar Beet, Fodder Beet, Red beet)	F	ALOMY, AVESS, LOLMU, BROST	Overall spray (incorporation)	Pre-sowing	1		3.6	1620	220-400	-	Not acceptable (risks of groundwater contamination and for aquatic organisms)

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		
3	FR	Spinach	F	ALOMY, AVESS, LOLMU, BROST	Overall spray (incorporation)	Pre-sowing	1		3.6	1620	220-400	-	Not acceptable (risks of groundwater contamination and for aquatic organisms and for consumer)
4	FR	Chicoree witloof	F	ALOMY, AVESS, LOLMU, BROST	Overall spray (incorporation)	Pre-sowing	1		3.6	1620	220-400	-	Not acceptable (risks of groundwater contamination and for aquatic organisms)
5	FR	Flax fiber	F	ALOMY, AVESS, LOLMU, BROST	Overall spray (incorporation)	Pre-sowing	1		3.6	1620	220-400	-	Not acceptable (risks of groundwater contamination and for aquatic organisms)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization 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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) is a capsule suspension (CS) containing 450 g/L of Tri-allate. 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 a homogeneous brown fluid with a characteristic odour. It is not explosive and has no oxidizing properties. The product is not flammable and has a self-ignition temperature of 372°C. In aqueous solution (1% dilution), it has a pH value of 8.33.
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. The content of active substance is unchanged by 6 months storage in PE at ambient temperature. A provisional shelf-life of 6 months is proposed, pending the results of the final 2 years study.

The preparation should be stored at temperatures below 40°C.
To update the dossier, the finalized two years-storage study at room temperature is required.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurity N-nitrosodiisopropylamine (NDIPA) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of tri-allate in plants, products of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Tri-allate</td></tr>
<tr><td>ADI</td><td colspan="2">0.025 mg kg bw/d</td><td rowspan="3">EU agreed endpoint (2010)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.6 mg/kg bw/d</td></tr>
<tr><td>AOEL</td><td colspan="2">0.032 mg/kg bw/d</td></tr>
<tr><td rowspan="4">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation and in vivo monkey study (dermal absorption values from the DAR of tri-allate):</td></tr>
<tr><td></td><td>Concentrate (tested)
446 g/L</td><td>Diluted formulation (tested)
3.6 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.4 %</td><td>3% (not used)*</td></tr>
<tr><td></td><td>Concentrate (used in formulation)
450 g/L (pure)</td><td>Spray dilution (used in formulation)
4.05 g/L (pure)</td></tr>
</table>

	Dermal absorption endpoints %	**0.4 %**	**12 % (*)**

* Considering the skin washes and the low recoveries in the diluted formulation, values could not be used for the diluted formulation. The value of 12% is retained for the diluted formulation, taking from the endpoints of dermal absorption in the DAR of tri-allate. The dermal absorption value is based in an *in vivo* study in a group of 6 monkeys using an EC formulation, although performed pre-GLP, is considered to provide a reasonable basis for deriving a dermal absorption value. Penetration through monkey skin would be expected to be greater than through human skin. Therefore, the value of 12% for the EC formulation is likely to be an adequately precautionary value for the dermal penetration of tri-allate.

(*) from *in vivo* monkey study on a EC formulation 480 g/L

3.1.3.1 Acute Toxicity

TRI-ALLATE CS, GWN-3189B (AVADEX FACTOR) containing 450 g/L tri-allate (479 g/L technical) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Cereals, beets, flax fiber, chicory witloof and spinach	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3.6 (1723 g sa/ha)	220-400	BBA model

Considering proposed uses, operator systemic exposure was estimated using the German BBA:

Crop	Equipment	PPE and/or working coverall	% AOEL Tri-allate
Cereals, beets, flax fiber, chicory witloof and spinach	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	52 %

According to the model calculations, it can be concluded that the risk for the operator using TRI-ALLATE CS, GWN-3189B (AVADEX FACTOR) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 5.4 % of the AOEL of tri-allate.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to TRI-ALLATE CS, GWN-3189B (AVADEX FACTOR).

3.1.3.4 Resident Exposure

Residential exposure was assessed according to Martin et al.. Exposure is estimated to 1 % of the AOEL of tri-allate for resident adult and 2% of the AOEL of tri-allate for resident child.

[8] Open field or glasshouse

It is concluded that there is no unacceptable risk to the resident exposed to TRI-ALLATE CS, GWN-3189B (AVADEX FACTOR).

3.1.3.5 Worker Exposure

TRI-ALLATE CS, GWN-3189B (AVADEX FACTOR) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

3.1.3.6 Relevance of metabolites

The metabolite diisopropylamine (DIPA) is > 10 µg/L in groundwater (max. 112 µg/L). No data is available, no conclusion is possible on its relevance (EFSA Scientific Report (2008) 181, 1-100).

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

Overall conclusion

The data available are not considered sufficient for risk assessment.

A peer review is proposed to further address the plant residue definition for risk assessment, the plant residue definition for monitoring (identification of suitable markers) and to define whether some of the plant metabolites could be relevant in food and feed commodities. Pending a conclusion regarding the plant residue definition for risk assessment, the relevance of livestock exposure to tri-allate residues, the need for livestock metabolism studies, the relevance of rotational crop residues and a need for rotational crops studies in line with the risk assessment need to be addressed. A revised risk assessment would be needed once the residue definition has been concluded on.

No conclusion can be reached regarding consumer risk assessment at this stage (peer review proposed by EFSA).

Summary of the evaluation

The preparation AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) is composed of tri-allate.

Summary for tri-allate

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Cereals (winter barley, spring barley)	Yes	Yes	Yes	No	Yes	Not finalised	Not finalised	Acceptable
2	Beets (Sugar Beet, Fodder Beet, Red beet)	No	Yes	Yes	No	Y		Not finalised	Acceptable
3	Spinach	No	No	No	-	-		-	Not acceptable
4	Chicoree witloof	No	Yes	Yes	No	Y		Not finalised	Acceptable
5	Flax fiber	As flax fiber is not intended for human or livestock consumption, no assessment was therefore performed. Flax fiber by-products should not be used as an animal feedstuff.							

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its 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 tri-allate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

For all intended uses, PECgw for tri-allate does not occur at levels exceeding those mentioned in regulation EC 1107/2009. PECgw for metabolites TPCSA and DIPA do occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[9] for at least one FOCUS scenario. **Therefore, no acceptable risk of groundwater contamination is expected for the intended uses even when either mitigation measures were proposed or national scenarios were considered.**

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

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and 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.
The risks for aquatic organisms could not be finalized as the TER values are below the trigger values with FOCUS Step 3 PECsw and since the refinement option proposed by the applicant is not accepted by zRMS.
The risk for non-target plants is acceptable if a non-sprayed buffer zone of 20 meters is respected.

3.1.7 Efficacy

This conclusion concerned the product AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B), composed of 450g/L of triallate. This active substance is already registered in Europe and used in France as a selective herbicide for pre-sowing application followed by harrowing. It is a new formulation as a capsule suspension. France is zRMS on this dossier.

Considering the data submitted:

- The efficacy of AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) is considering as satisfactory for the claimed uses.

[9] 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.

Given the lack of data or possible extrapolation on chicory, evaluation for this purpose cannot be finalized.

- The selectivity of AVADEX FACTOR (TRI-ALLATE CS, GWN-3189B) is considered as satisfactory for the claimed uses except for chicory witloof (no data)
- The risks of negative impact on yield, quality, transformation processes, propagation, are considered as acceptable
- The risks of negative impact on succeeding crops and adjacent crops are considered as acceptable
- The risks of resistance development or appearance are considered as low to medium depending on weeds

Agronomic recommendation from the evaluation:
Do not sow oats or grass crops within a year after treating with TRI-ALLATE CS, GWN-3189B *(AVADEX FACTOR), and then only after ploughing. Do not undersow grass species in crops that have been treated with this product. It is safe to undersow with clover and other legumes.*
In the event of crop failure following application of TRI-ALLATE CS, GWN-3189B *(AVADEX FACTOR), only sow winter or spring barley, and only after ploughing prior to sowing.*

Missing data:
Chicory witloof's data on selectivity and negative impacts on yield and quality

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted (risks for aquatic organisms and consumer, Chicory witloof's data on selectivity and negative impacts on yield and quality and toxicological relevance of DIPA). A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

-

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

3.4.1 Post-authorisation monitoring

N/A

3.4.2 Post-authorisation data requirements

N/A

3.4.3 Label amendments (see label in Appendix 2):

N/A

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire
alimentation, environnement, travail

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 ***AVADEX FACTOR***

de la société *GOWAN FRANCE*

enregistrée sous le *n°2012-2204*

Vu les conclusions de l'évaluation de l'Anses du 2 septembre 2016,

Considérant les risques de contamination des eaux souterraines et les risques pour les organismes aquatiques,

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.

AVADEX FACTOR
AMM n°-

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RÉPUBLIQUE FRANÇAISE

anses
agence nationale de sécurité sanitaire
alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	AVADEX FACTOR
Type de produit	Produit de référence
Titulaire	GOWAN FRANCE 5, Rue du Gué 77139 PUISIEUX FRANCE
Formulation	Suspension de capsules (CS)
Contenant	450 g/L – tri-allate
Numéro d'intrant	932-2012.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 16 JAN. 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)

AVADEX FACTOR
AMM n°-

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ANNEXE I : Conditions de mise sur le marché demandées

Classification du produit	
Catégorie de danger	**Mention de danger**
Sensibilisation cutanée, catégorie 1B	H317 : Peut provoquer une allergie cutanée
Toxicité spécifique pour certains organes cibles - Exposition répétée, catégorie 2	H373 : Risque présumé d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH066 : L'exposition répétée peut provoquer dessèchement ou gerçures de la peau Pour les phrases P se référer à la règlementation en vigueur.	

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
1505911 Betterave industrielle et fourragère*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines et pour les organismes aquatiques.	1/an	-
1617901 Betterave potagère*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines et pour les organismes aquatiques.	1/an	-
1635901 Chicorées - Production de racines*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines et pour les organismes aquatiques.	1/an	-
1650901 Epinard*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines, pour les organismes aquatiques et pour les consommateurs.	1/an	-
1550902 Lin*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines et pour les organismes aquatiques.	1/an	-
1510913 Orge*Désherbage	3,6 L/ha **Motivation du refus :** L'usage est refusé en raison des risques pour les eaux souterraines et pour les organismes aquatiques.	1/an	-

AVADEX FACTOR
AMM n°-

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

Gowan

AVADEX FACTOR

AVADEX FACTOR est un herbicide sélectif de pré-semis sur orges, betteraves, épinard, chicorée witloof et lin textile.
Autorisation de Mise sur le Marché (A.M.M.) N° XXXXXXX
Délivrée le XX/XX/XXXX
Détenteur de l'A.M.M. : Gowan France
5 rue du Gué, 77139 Puisieux, France

Suspension de capsules (CS)
contenant 450 g/L (39.8% m/m) de triallate.

AVADEX FACTOR
Peut déclencher une réaction allergique

SGH07 SGH08 SGH09

ATTENTION

H317	**Peut provoquer une allergie cutanée.**
H373	**Risque présumé d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée (par ingestion).**
H411	**Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
EUH066	**L'exposition répétée peut provoquer dessèchement ou gerçures de la peau.**
EUH401	**Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.**
P260	Ne pas respirer les brouillards de pulvérisation.
P273	Éviter le rejet dans l'environnement.
P280	Porter des gants de protection.
P302 + P352	EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon.
SPe3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

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. Une attention particulière doit être apportée pour éviter la dérive de pulvérisation sur les cultures non-cibles adjacentes à la culture traitée.

Distribué par: GOWAN France SAS - 5, rue du Gué - 77139 PUISIEUX
Tél : 01 64 36 61 61 - Fax : 01 60 44 70 61

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).
Fiche de Données de Sécurité disponible sur le site internet : www.quickfds.com.

N° de lot et date de fabrication : voir emballage
5 ou 10 L ℮

Tableau des usages :

Cultures	Usage	Dose d'emploi	Nombre maximal d'applications	Zone Non Traitée (ZNT)
Orge d'hiver et de printemps	Désherbage	3.6 L/ha	1 application à pleine dose / an	5 m
Betteraves (industrielles, fourragères et potagères)				
Épinard				
Chicorée witloof				
Lin textile				

Pas de Délai Avant Récolte (DAR) : celui-ci est couvert par les conditions d'application et le cycle de croissance de la culture.

Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Mélanges
Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Consulter le site:
http://e-phy.agriculture.gouv.fr

Efficacité et mode d'action
- AVADEX FACTOR est particulièrement efficace contre les principales graminées adventices : folle avoine, vulpin des champs, ray-grass, agrostide épi du vent, pâturin annuel et brome stérile.
- AVADEX FACTOR agit sur les mauvaises herbes au moment de leur germination, il est absorbé par le coléoptile et empêche leur développement. Une bonne incorporation du produit est indispensable pour obtenir des performances maximales.

Période d'emploi
En pré-semis incorporé contre les graminées sur toutes les cultures : orge d'hiver, orge de printemps, betteraves, épinard, chicorée witloof et lin textile.

AVADEX FACTOR doit être appliqué à la dose de 3.6 L/ha pendant la préparation du lit de semences, avant la levée des adventices.
Un sol finement préparé et non motteux est recommandé. AVADEX FACTOR peut être appliqué directement sur un labour régulier, aplani et dépourvu de grosses mottes. Incorporer dans la couche superficielle du sol dans un délai de 2 heures au maximum et à une profondeur de 2-3 cm. L'incorporation se fera grâce à un combiné herse + semoir, un passage d'outil à dents souples, un vibroculteur + cage ou deux passages croisés à la herse lourde. Le semis peut être effectué immédiatement après ou différé de plusieurs jours. Semer à une profondeur d'au moins 2.5 cm.

Remarque : pour la gestion des adventices dicotylédones, AVADEX FACTOR doit être utilisé en programme avec les produits complémentaires adaptés à chaque type de flore et à chaque culture.

Résistance
La résistance des adventices à certains herbicides est devenue un problème critique dans de nombreuses cultures. Le principal atout du triallate est son mode d'action différent des familles herbicides les plus utilisées. Le triallate est un inhibiteur de la synthèse lipidique ; il appartient au groupe N tel que défini par le HRAC (Herbicide Resistance Action Committee).
Le triallate est utilisé depuis plus de quarante ans dans de nombreux pays. À ce jour, en France, aucune population de graminées n'a développé de résistance au triallate. Cependant, dans la mesure du possible, varier les substances chimiques et alterner avec des produits ayant des modes d'action différents.

Préparation
Bien agiter le bidon avant emploi. Verser la quantité nécessaire d'AVADEX FACTOR dans la cuve du pulvérisateur à demi remplie d'eau. Compléter le remplissage en faisant fonctionner le système d'agitation.

Volume d'eau à l'hectare : 220 à 400 litres. Veiller à assurer une couverture homogène du sol avec la bouillie.

Possibilité de remplacement d'une culture accidentée (climat, parasites, ...) :
Ne ressemer que de l'orge d'hiver ou de printemps, et seulement après un labour du sol. Cependant, quelles que soient les conditions de ré-implantation, il existe toujours un risque de ne pas atteindre le rendement escompté.

Cultures suivantes :
Ne pas semer d'avoine ou toute autre culture de graminées moins d'un an après un traitement avec AVADEX FACTOR et ressemer seulement après un labour. Ne pas semer sous couvert de graminées dans les cultures qui ont été traitées avec AVADEX FACTOR. Il peut être semé du trèfle ou d'autres légumineuses en toute sécurité.

Bonnes pratiques phytosanitaires :
Les dommages sur les cultures dus aux chevauchements de rampe lors de la pulvérisation sont en général transitoires. Éviter toutefois les chevauchements de rampe et les surdosages, cela pouvant entraîner des dégâts sur la culture et affecter les rendements.
Éviter la dérive de pulvérisation sur les cultures adjacentes, en particulier pour l'avoine et autres cultures de graminées, levées ou sur le point de lever, car elles sont particulièrement sensibles.

Nettoyage du pulvérisateur :
Après chaque traitement avec AVADEX FACTOR, nettoyer soigneusement l'extérieur du pulvérisateur. Rincer soigneusement la cuve du pulvérisateur à l'eau claire conformément à la législation en vigueur. Il est conseillé d'effectuer 3 rinçages, le dernier rinçage s'effectuant avec de l'eau additionnée d'un nettoyant (recommandé pour le nettoyage des pulvérisateurs).

Élimination du produit et de l'emballage :
- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Éliminer les emballages vides *via* les collectes organisées par des distributeurs partenaires de la filière ADIVALOR.
- Éliminer les fonds de cuve conformément à la réglementation en vigueur.

IMPORTANT: Respectez 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. Conduisez 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 vente du Ministère de l'Agriculture.

Appendix 3 – Letter(s) of Access

Not applicable.