

REGISTRATION REPORT

Part A

Risk Management

Product code: AG-S1-300 SC

Product name: DIODE

Active Substance:

Sulcotrione, 300 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ADAMA FRANCE SAS

Date: 12/04/2017

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PART A – Risk Management

The company ADAMA FRANCE SAS has requested marketing authorisation in France for the product DIODE (formulation codes: AG-S1-300 SC, sulcotrione 300 SC), containing 300 g/L sulcotrione, 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 DIODE (AG-S1-300 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DIODE (AG-S1-300 SC) have been made using endpoints agreed in the EU peer review of sulcotrione.

This document describes the specific conditions of use and labelling required for France for the registration of DIODE (AG-S1-300 SC).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA FRANCE SAS's application to market DIODE (AG-S1-300 SC) 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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Sulcotrione

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 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 sulcotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

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

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;

— the risk to insectivorous birds, aquatic and terrestrial non-target plants, and non-target arthropods.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of further information on the degradation in soil and

water of the cyclohexadione moiety and the long-term risk to insectivorous birds. They shall ensure that the notifier at whose request sulcotrione has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.

An EFSA conclusion is available (EFSA Scientific Report (2008); 150, 1-86).

A Review Report is available (SANCO/159/08 final, 6 January 2009 [inclusion]; SANCO/159/08 final rev 1, 11 July 2014 [confirmatory data]).

1.3 Regulatory Approach

The present application (2012-1140) was evaluated by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the voluntary zonal procedure for all Member States of the Southern zone taking into account the worst-case uses (“risk envelope approach”)². Where 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 in the decision letter.

The French Order of 12 September 2006³ 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 (dRR) based on Anses’ assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations, Commission Directive 2008/125/EC of 19 December 2008 and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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,

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 <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570>

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

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>

mainly based on the EU document on residue data extrapolation⁷ 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 DIODE (AG-S1-300 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not applicable: The applicant owns all the data submitted, and has submitted equivalent data to AII data still in protection.

However, generic field monitoring studies are used for the higher tier assessment of birds and mammals. The letters of Access for these studies are attached.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	DIODE (AG-S1-300 SC, sulcotrione 300 SC)
Authorisation number	2090024
Function	Herbicide
Applicant	ADAMA FRANCE SAS
Composition	Sulcotrione 300 g/L
Formulation type (code)	Suspension concentrate (SC)
Packaging	High density polyethylene (HDPE) bottle containing 1 L product HDPE container containing 5 L product

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

Physical hazards	-
Health hazards	Specific target organ toxicity — Repeated exposure, Hazard Category 2 Reproductive toxicity, Hazard Category 2

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

Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H361d	Suspected of damaging the unborn child
	H373	May cause damage to organs (kidney) through prolonged or repeated exposure
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains sulcotrione and 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

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: not authorisation renewal in France

2.2.4 Other phrases linked to the preparation

N/A: not authorisation renewal in France

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date : 12/04/2017

PPP (product name/code)
sulcotrione

DIODE/AG-S1-300 SC
Sulcotrione

Formulation type: SC
Conc. of a.s. 1: 300 g/L

Applicant:
Zone(s):

ADAMA FRANCE SAS
southern

professional use ☒
non-professional use ☐

Verified by MS: Yes

Crop and/or situation (a)	Product code	F,G Or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				Type (d-f)	Conc. of as (g/L) (i)	Method kind (f-h)	Growth stage & season (j)	No. max. (k)	Interval between applications (days)	g a.s./hL min.-max.	Water L/ha min.-max.	g a.s./ha min.-max.		
Maize	AG-S1-300 SC	F	<i>dicotyledonous and grass weeds</i>	SC	300	Foliar spray	BBCH <09	1	-	112.5-225	100-400	450	--	Not acceptable (operator exposure)
Maize	AG-S1-300 SC	F	<i>dicotyledonous and grass weeds</i>	SC	300	Foliar spray	BBCH 12 to 18	1 to 2	7 to 20	56.25-450	100-400	225 to 450	90	Cumulative rate 450 g a.s./ha split into 2 applications max. Not acceptable (operator exposure)
Sweet corn	AG-S1-300 SC	F	<i>dicotyledonous and grass weeds</i>	SC	300	Foliar spray	BBCH 12 to 18	1 to 2	7 to 20	37.5-300	100-400	150 to 300	42	Cumulative rate 300 g a.s./ha split into 2 applications max. Not acceptable (operator exposure)
Flax	AG-S1-300 SC	F	<i>dicotyledonous and grass weeds</i>	SC	300	Foliar spray	BBCH <09	1	-	75-600	100-400	600	F	Not acceptable (operator exposure)
Ryegrass	AG-S1-300 SC	F	<i>dicotyledonous and grass weeds</i>	SC	300	Foliar spray	BBCH 13 to 31	1 to 2	7 to 20	28.125 to 225	100 to 400	112.5 to 225	-	Cumulative rate 225 g a.s./ha split into 2 applications max. Not acceptable (operator exposure ; insufficient residue data).

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation DIODE (AG-S1-300 SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements. The appearance of the formulation is an off-white homogeneous suspension, with characteristic odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature > 400 °C and a flash point above 100 °C. In aqueous solution (1 %), its pH is 3.4 at 22 °C. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for an SC formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substance in the formulation are available and validated.

As relevant impurities (hydrogen cyanide and toluene) are by-products of the manufacturing process for sulcotrione and as such cannot be formed by storage of the formulation, an analytical method for the determination of relevant impurities in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph [draft assessment report] and in this dossier and validated for the determination of residues of sulcotrione in plants (high water content, high oil content and dry commodities), soil, water (surface and drinking) and air.

To update the dossier and to be in accordance with guide SANCO 825/00/rev8., the following methods are required:

- a validated analytical method for the determination of sulcotrione residue in fat,
- an ILV for the determination of sulcotrione residues in animal products.

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

DIODE (AG-S1-300 SC), containing 300 g/L sulcotrione, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

Considering the classification of the non-active ingredients, the active substances and the results of acute toxicity studies, the DIODE (AG-S1-300 SC) formulation requires the toxicological classification shown in Section 2.2.

3.1.3.2 Operator Exposure

Application volume: 400 L/ha

Operator exposure was assessed against the AOEL agreed in the EU review of sulcotrione. Data on dermal absorption of DIODE (AG-S1-300 SC) were provided and are considered acceptable.

Endpoint used in assessment for DIODE

Sulcotrione

Systemic AOEL :	0.0006 mg/kg bw/d
Dermal absorption of undiluted product:	0.3 %
Dermal absorption of diluted product:	20 %

Operator exposure was modelled using the German BBA model:

Parameters used in operator exposure assessment				
Crop	Equipment	Application rate L product/ha (g a.s./ha)		Model used
Open field				
Rye-grass	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Minimum application rate : 0.375 L/ha (112.5 g a.s./ha)		BBA

According to the model calculations, it can be concluded that the risk for the operator using DIODE (AG-S1-300 SC) on ryegrass **is unacceptable with the use of personal protective equipment and with a coverall (90 % protection factor) at the minimum application rate and with an application volume of 400 L/ha.**

Therefore the risk for the operator is also considered unacceptable for the higher application rates and with an application volume of 400 L/ha: flax, sweet corn, maize, millet, foxtail millet, *Miscanthus* and switchgrass.

Application volume: 100 L/ha

Operator exposure was assessed against the AOEL agreed in the EU review of sulcotrione. Data on dermal absorption of DIODE (AG-S1-300 SC) were provided and are considered acceptable.

Endpoint used in assessment for DIODE	
Sulcotrione	
Systemic AOEL :	0.0006 mg/kg bw/d
Dermal absorption of undiluted product:	0.3 %
Dermal absorption of diluted product:	5 %

Operator exposure was modelled using the German BBA model:

Parameters used in operator exposure assessment				
Crop	Equipment	Application rate L product/ha (g a.s./ha)		Model used
Open field				
Rye-grass	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Minimum application rate : 0.375 L/ha (112.5 g a.s./ha)		BBA

According to the model calculations, it can be concluded that the risk for the operator using DIODE on ryegrass is acceptable with the use of personal protective equipment and with a coverall (90 % protection factor) at the minimum application rate and with an application volume of 100 L/ha.

Operator exposure was modelled using the German BBA model:

Parameters used in operator exposure assessment				
Crop	Equipment	Application rate L product/ha (g a.s./ha)		Model used
Open field				
Sweet corn	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Minimum application rate : 0.5 L/ha (150 g a.s./ha)		BBA

According to the model calculations, it can be concluded that the risk for the operator using DIODE (AG-S1-300 SC) on sweet corn is **unacceptable with the use of personal protective equipment and with a coverall (90 % protection factor) with an application volume of 100 L/ha.**

Therefore the risk for the operator is also considered unacceptable for the higher application rates and with an application volume of 100 L/ha: flax, maize, millet, foxtail millet, *Miscanthus* and switchgrass.

The following personal protective equipment is recommended by the applicant and confirmed by Anses (France):

- **for mixing/loading**

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment and with hood;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above;
- Respiratory protection: disposable half-mask with a particle filter FFP3

- **for application _ Downward spraying**

If application with tractor with cab

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment and with hood;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab
- Respiratory protection: disposable half-mask with a particle filter FFP3
- Face shield certified according to EN 166-1F

If application with tractor without cab

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment and with hood;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment;
- Respiratory protection: disposable half-mask with a particle filter FFP3
- Face shield certified according to EN 166-1F

- **for equipment cleaning**

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment and with hood;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above;
- Respiratory protection: disposable half-mask with a particle filter FFP3.

3.1.3.3 Bystander Exposure

The exposure of bystanders present at the time of spraying was calculated using data presented in the report on EURO-POEM II⁸. It is concluded that there is no risk involved for the bystander after incidental short-term exposure to DIODE (AG-S1-300 SC) at an application rate of 1 L/ha and 400 L/ha spray volume. At higher application rates, bystander exposure is unacceptable. There is an acceptable risk for the bystander after incidental short-term exposure to DIODE (AG-S1-300 SC) at an application rate of 2 L/ha and 100 L/ha spray volume

3.1.3.4 Worker Exposure

DIODE (AG-S1-300 SC) 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.

Re-entry period: six hours⁹

The following personal protective equipment is proposed by Anses (France) for any workers who have to intervene on treated crops:

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment, and, if in contact with treated crops, nitrile gloves.

3.1.4 Residues and Consumer Exposure

Primary crop metabolisms were sufficiently investigated to define residue of sulcotrione for enforcement and risk assessment purposes in the crops under consideration.

3.1.4.1 Residues

Regarding the magnitude of residues in maize and millet, a sufficient number of residue trials is available to support the intended GAPs in France. These data allow it to be considered that no quantifiable residues of sulcotrione will be present in grains, and to confirm that no MRL exceedence will result from intended uses.

Regarding the magnitude of residues in sweet corn, a sufficient number of residue trials are available to support the intended GAPs in France. These data allow it to be considered that no quantifiable residues of sulcotrione will be present in grains, and to confirm that no MRL exceedence will result from intended uses.

As no data on CMBA residue levels was presented in ryegrass, residue trials are not considered acceptable.

No residue trials on Miscanthus and switchgrass have been assessed in the present evaluation since these crops are not intended to be used in human or animal diet.

As no residue trial was submitted for flax, seeds are not authorised to enter the human food or animal feed chains. Mitigation measures: Following treatment with DIODE (AG-S1-300 SC), by-products from flax grown for fibre must not be used as human food or animal feed.

As residues of sulcotrione do not exceed the trigger value of 0.1 mg/kg in all crops, there is no need to investigate the effect of industrial and/or household processing.

Succeeding crop studies were not needed for the approval of sulcotrione and it is very unlikely that residues of sulcotrione will be present in succeeding crops following use of DIODE (AG-S1-300 SC).

A theoretical CMBA residue level calculation in ryegrass shows that animal intake exceeds the highest level tested in the goat metabolism study. Therefore it is not possible to verify that animal MRLs will not be exceeded at the intended GAP. The intended use of DIODE (AG-S1-300 SC) on ryegrass cannot be considered acceptable.

⁸ EURO-POEM II - Bystander Working group Report.

⁹ The legal basis for this is Article 3 II of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

3.1.4.2 Consumer exposure

The toxicological profile of sulcotrione and CMBA were evaluated at EU level, which resulted in the proposal of ADIs (0.0004 mg/kg bw/d for sulcotrione and 0.2 mg/kg bw/d for CMBA) that were considered in the context of this evaluation. No ARfD has been defined for sulcotrione and CMBA.

Chronic consumer exposures resulting from the uses proposed in the framework of this application were calculated for sulcotrione and CMBA. Based on EFSA PRIMo (rev2), chronic exposures were considered acceptable for all groups of consumers.

For DIODE (AG-S1-300 SC), maximum groundwater concentrations of one metabolite of sulcotrione, CMBA, were shown to exceed the threshold of 0.75 µg/L. A refined risk assessment is thus needed.

	Metabolites	Maximum level in groundwater (µg/L)	Theoretical ingestion	
			µg/day	µg/kg bw/day
	Adult, 60 kg bw, 2 L/day water consumption:			
DIODE	CMBA	2.433	4.866	0.0811

To support the non-relevance of this metabolite, an ADI for CMBA is set from the one-generation rat study. The NOAEL is 2500 ppm, equivalent to 247.6 and 267 mg/kg bw/d in males and females, respectively. A safety factor of 1000 is applied, to set an ADI of 0.2 mg/kg bw/d.

The maximum theoretical ingestion of CMBA (0.0811 µg/kg bw/d) is much lower than this ADI. Therefore the metabolite is not expected to be a safety concern.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance sulcotrione and its metabolite CMBA 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 sulcotrione and its metabolite CMBA in soil, surface water and groundwater has 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 review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for sulcotrione and its metabolite CMBA are used for the ecoa toxicological risk assessment, and mitigation measures are proposed.

PECgw for sulcotrione do not exceed the trigger of 0.1 µg/L. PECgw for metabolite CMBA exceed the trigger of 0.1 µg/L but the metabolite is not considered of toxicological relevance in the calculated concentrations. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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.

Implications for labelling resulting from environmental fate assessment: None.

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 review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered

appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms and micro-organisms are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable when a buffer zone of 20 metres incorporating a permanent vegetative buffer zone of 20 metres is applied for use on maize and when a buffer zone of 5 metres is applied for use on flax and ryegrass.

A restriction for not using on artificially drained soils is required for use on flax and ryegrass.

For terrestrial non-target plants, the risks are acceptable when a buffer zone of 5 metres is applied.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- The efficacy of DIODE (AG-S1-300 SC) is considered satisfactory.
- The selectivity of DIODE (AG-S1-300 SC) is considered satisfactory on maize, sweet corn, flax and ryegrass only.
- The risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered acceptable, subject to certain labelling requirements.
- The risk of resistance developing or appearing is considered low.

Crops	Harmful organism	Method of application	Rate of use	Number of applications (per crop)	Conclusion of France for efficacy section	Remarks
Maize	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	1.5 L/ha	1*	Acceptable	-
Sweet corn	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	1 L/ha	1*	Acceptable	-
Flax grown for fibre	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	2.0 L/ha	1	Acceptable	-
Ryegrass	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	0.75 L/ha	1*	Acceptable	-
Millet	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	1.5 L/ha	1*	Acceptable but insufficient selectivity data	-
Foxtail (Hungarian) millet	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	1.5 L/ha	1*	Acceptable but insufficient selectivity data	-
<i>Miscanthus x giganteus</i>	<i>Annual weeds (dicotyledonous)</i>	Spraying	1.5 L/ha	1*	Acceptable but insufficient selectivity data	-

Crops	Harmful organism	Method of application	Rate of use	Number of applications (per crop)	Conclusion of France for efficacy section	Remarks
	<i>and grasses)</i>					
Switchgrass	<i>Annual weeds (dicotyledonous and grasses)</i>	Spraying	1.5 L/ha	1*	Acceptable but insufficient selectivity data	-

* Split application possible

3.2 Conclusions arising from French assessment

Use in maize pre-emergence:

- The operator exposure at rates equal to or greater than 0.375 L/ha with 400 L/ha spray volume is not acceptable.
- There is insufficient phytotoxicity data for millet, foxtail millet, *Miscanthus* and switchgrass.

Use in maize post-emergence:

- The operator exposure at rates equal to or greater than 0.5 L/ha with 100 L/ha spray volume is not acceptable.

Use in sweet corn:

- The operator exposure at rates equal to or greater than 0.5 L/ha with 100 L/ha spray volume is not acceptable.

Use in flax:

- The operator exposure at rates equal to or greater than 0.375 L/ha with 400 L/ha spray volume is not acceptable.

Use in ryegrass:

- The operator exposure, except for 0.375 L product/ha in 100 L spray mixture/ha is not acceptable.
- There is insufficient residue data (no residues trials measuring metabolite CMBA).

Taking into account the above, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

N/A: not authorisation renewal in France

3.4.3 Label amendments (see label in Appendix 2):

N/A: not authorisation renewal in France

Appendix 1 – Copy of the French decision



Décision relative à une demande de renouvellement de l'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 de renouvellement de l'autorisation de mise sur le marché du produit phytopharmaceutique **DIODE***

de la société ADAMA FRANCE SAS

enregistrée sous le n°2012-0892

Vu l'avis de l'Anses du 28 mai 2015,

Vu la notification de l'intention de retrait d'usages du 1^{er} juillet 2016,

Vu les observations transmises dans le cadre de la procédure contradictoire en date du 18 juillet 2016,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits réglementés de l'Anses concernant l'usage sorgho le 28 février 2017,

Considérant que les risques pour l'opérateur liés aux utilisations sur maïs, maïs doux, sorgho et lin sont inacceptables, et que les données disponibles sur graminées fourragères ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus en vigueur,

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

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est retirée** en France dans les conditions précisées dans la présente décision.



Informations générales sur le produit		
Noms du produit	DIODE KREATO SULCOGAN	
Type de produit	Générique	
Titulaire	ADAMA FRANCE SAS 6/8 avenue de la Cristallerie 92316 Sèvres CEDEX FRANCE	
Formulation Contenant	Suspension concentrée (SC)	
	300 g/L - sulcotrione	
Produit de référence	Nom commercial	MIKADO
	N° AMM	9100297
Numéro d'intrant	2070481	
Numéro d'AMM	2090024	
Fonction	Herbicide	
Gamme d'usages	Professionnel	

Date limite pour la vente et la distribution	3 mois à compter de la présente décision
Date limite pour le stockage et l'utilisation des stocks	9 mois à compter de la présente décision

A Maisons-Alfort, le 12 AVR. 2017

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)



ANNEXE I : Conditions de mise sur le marché demandées

Classification du produit	
Catégorie de danger	Mention de danger
Toxicité pour la reproduction, catégorie 2(d)	H361d : Susceptible de nuire au fœtus
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 aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH208 : Contient de la sulcotrione et de la 1,2-benzisothiazolin-3-one. Peut produire une réaction allergique	
Pour les phrases P se référer à la réglementation en vigueur.	




Liste des usages retirés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15305905 Graminées fourragères*Dés herbage	0,75 L/ha Motivation du retrait : L'usage est retiré en raison d'un manque de données démontrant que les usages en France sur ray-grass permettront de respecter les LMR en vigueur.	2/an	-
15505902 Lin*Dés herbage	2 L/ha Motivation du retrait : L'usage est retiré en raison de risques inacceptables pour les opérateurs.	1/an	-
16665901 Maïs doux*Dés herbage	1 L/ha Motivation du retrait : L'usage est retiré en raison de risques inacceptables pour les opérateurs.	2/an	42
15555901 Maïs*Dés herbage	1,5 L/ha Motivation du retrait : L'usage est retiré en raison de risques inacceptables pour les opérateurs.	2/an	90
15565901 Sorgho*Dés herbage	0,5 L/ha Motivation du retrait : L'usage est retiré en raison de risques inacceptables pour les opérateurs.	2/an	90

DIODE
AMM n°2090024

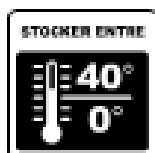
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Appendix 2 – Copy of the draft product label as proposed by the applicant



	<p>Diode® AMM N°2090024 SC – Suspension Concentrée Contient 300 g/L de sulcotrione (26,55 %)</p>
<p>N - Dangereux pour l'environnement</p>	
<p>R50/53 Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.</p>	
<p>Délai de ré-entrée des travailleurs sur la parcelle : 6h après traitement</p>	
<p>S29/35 Ne pas jeter les résidus à l'égout; ne se débarrasser de ce produit qu'en prenant toute précautions d'usage.</p>	
<p>S57 Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.</p>	
<p>S60 Eliminer le produit et son récipient comme un déchet dangereux.</p>	
<p>S 61 Eviter le rejet dans l'environnement. Consulter les instructions spéciales/ la fiche de données de sécurité.</p>	
<p>Lire les instructions ci-jointes avant emploi.</p>	
<p>Respecter les instructions d'utilisations pour éviter les risques pour l'homme et l'environnement :</p>	
<p>SP1 Ne pas polluer l'eau avec le produit ou son emballage.</p>	
<p>SPe 3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 m par rapport aux points d'eau et prévoir un dispositif végétalisé permanent non traité d'une largeur de 20 m, pour le maïs.</p>	
<p>Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau pour le lin et le ray-grass.</p>	
<p>SPe 3 Pour protéger les plantes non cibles, respecter une zone non traitée de 10 m pour le maïs et le ray-grass et de 15 m pour le lin, par rapport à la zone non cultivée adjacente.</p>	
<p>La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickdds.com ou à partir de www.ma-france.com ou en écrivant à lds@ma-france.com ou par courrier à l'adresse postale de MAKHTESHIM-AGAN France.</p>	

Produit fabriqué en Israël



Volume net : **5 L**

Distribué par :
MAKHTESHIM-AGAN France
2, rue Troyon
92316 Sèvres Cedex
Tél : 01 41 90 16 96
Fax : 01 46 42 71 17



MODE D'ACTION – PROPRIÉTÉS :

Diode® est herbicide à base de sulfonylurea, de la famille des triéthylamines. Diode® est un désherbant sélectif des cultures de maïs, millet, moha, maïs doux, miscanthus, panic, lin textile et ray-grass anglais, efficace sur un grand nombre de mauvaises herbes dicotylédones annuelles et également sur quelques graminées.

Diode® est absorbé par les mauvaises herbes principalement par voie foliaire mais également par les racines, particulièrement en conditions humides, si la dose appliquée est au moins égale à 1 L/ha. Grâce à cette action racinaire, Diode® assure le contrôle des relevés de certaines adventices pendant 2 à 3 semaines (chénopode blanc, morelle, digitale sanguine, renouée persicair).

Une fois traitées, les mauvaises herbes sensibles blanchissent dans les 3 à 4 jours après l'application puis disparaissent progressivement.

USAGES ET DOSES HOMOLOGUÉES :

Culture	Dose homologuée	Délai Avant Récolte	Nombre d'application max
Maïs	1,5 L/ha	30 jours	2 appl max/ha à dose fractionnée (post ou post-lévée)
Millet*	1,5 L/ha	30 jours	2 appl max/ha à dose fractionnée
Moha*	1,5 L/ha	30 jours	2 appl max/ha à dose fractionnée
Maïs doux	1 L/ha	42 jours	2 appl max/ha à dose fractionnée
Lin textile	2 L/ha	Non concerné	1 appl max/ha (prélevée uniquement)
Ray-grass	0,75 L/ha	Non concerné	2 appl max/ha à dose fractionnée
Miscanthus*	1,5 L/ha	Non concerné	2 appl max/ha à dose fractionnée
Panic ou Switchgrass*	1,5 L/ha	Non concerné	2 appl max/ha à dose fractionnée

* Selon l'Arrêté du 12 juin 2009 relatif aux modalités d'extension-extrapolation des autorisations de mise sur le marché de produits phytopharmaceutiques à certaines cultures présentant un caractère mineur.

Les Limites Maximales de Résidus sont consultables sur le site Internet de la Commission - Direction Générale Santé et protection du Consommateur à l'adresse suivante : http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm

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://le-phytoagriculture-pouch>

Délai de ré-entrée des travailleurs sur la parcelle : 6 h après traitement, conformément à l'arrêté du 12 septembre 2008 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L-253-1 du Code Rural.

MODE D'EMPLOI :

PRÉCONISATIONS D'EMPLOI :

Diode® s'utilise aux volumes/ha de bouillies habituellement employés en désherbage (100 à 400 L/ha) qui a disparu.

APPLICATION SUR MAÏS, MAÏS DOUX, MILLET, MOHA, MISCANTHUS, PANIC OU SWITCHGRASS

Diode® s'utilise sur maïs grain et maïs fourrage, soit en post-semis pré-lévée soit du stade 2 feuilles au stade 8 feuilles.

Sur maïs doux, Diode® s'utilise en post-lévée, du stade 2 feuilles au stade 8 feuilles.

En post-lévée, la culture doit être poussante et en bon état végétatif au moment de l'application. Ne pas traiter sur une culture mal implantée, en mauvais état sanitaire ou souffrant du froid, de l'excès d'eau, de la sécheresse. Éviter également de traiter une culture susceptible de subir de grands écarts thermiques.

Diode® est plus efficace sur mauvaises herbes jeunes. Avec les mauvaises herbes très sensibles à sensibles, traiter entre la levée et le stade 4 feuilles pour les dicotylédones et traiter entre la levée et le stade 3 feuilles pour les graminées. Pour les adventices moyennement sensibles, traiter entre la levée et le stade 2 feuilles. Dans tous les cas traiter sur des mauvaises herbes poussantes.

APPLICATION SUR LIN TEXTILE

Diode® s'utilise uniquement au printemps en post-semis pré-lévée de la culture. Il doit être appliqué sur sol propre sans grosses moles.

Diode® assure un désherbage de base précoce. Ce traitement devra éventuellement être complété par un traitement herbicide complémentaire.

APPLICATION SUR RAY-GRASS ANGLAIS

Diode® s'utilise uniquement au printemps en post-lévée entre le stade 3 feuilles et début tallage sur des mauvaises herbes jeunes et poussantes.

Il est possible d'associer Diode® avec d'autres herbicides complémentaires.

PRÉCAUTIONS D'EMPLOI :

- Appliquer Diode® sur des cultures poussantes en bon état végétatif.
- Éviter de traiter des cultures souffrant de froid, d'un excès d'eau, ou de la sécheresse.
- Température optimale: 15 à 25°C.
- Délai sans pluie ou sans irrigation après application : 4 heures.
- Il est recommandé de traiter avec une humidité relative est supérieure à 60%.

PROGRAMME DE TRAITEMENT ET STRATÉGIE DE DÉSHÉRBAGE :

Diode® peut s'intégrer plusieurs stratégies de désherbage :

- 1 - En post-semis pré-levée
- 2 - En ratissage après application d'un herbicide racinaire appliqué en post-semis prélevée ou en post-levée précoce du maïs.
- 3 - En post-levée précoce, associé à un herbicide résiduaire sélectif à ce stade.
- 4 - En programme de post-levée stricte. Un premier passage entre 2 et 4 feuilles du maïs qui peut être complet, en cas de besoin, par un second passage à 6-8 feuilles.

Diode® peut être utilement associé à des herbicides complémentaires.

CULTURES DE REMPLACEMENT :

Cultures suivantes dans la rotation : Dans le cas d'une rotation normale, après une application de Diode® les cultures possibles sont : blé tendre d'hiver et de printemps, blé dur, orge d'hiver et de printemps, ray-grass, lin, pomme de terre, scorsonère, sorgho, maïs.

En raison des phénomènes de blanchiment occasionnellement rencontrés sur certaines cultures suivantes, nous recommandons l'implantation des cultures telles qu'épinard, pois (notamment pois de conserve), haricots, trèfle violet, betteraves. Cette recommandation s'applique tout particulièrement dans des sols à faible activité microbienne, battants ou compactés.

Cultures de remplacement : En cas d'accident nécessitant le remplacement d'une culture désherbée avec Diode®, il est possible d'implanter maïs, sorgho, ray-grass. Nous recommandons alors l'implantation de cultures de soja, haricot, luzerne, trèfle violet, épinard, chou, colza.

CONDITIONS D'EMPLOI :

Agiter avant emploi. Verser la quantité nécessaire de Diode® dans la cuve du pulvérisateur remplie à moitié du volume d'eau nécessaire, le système d'agitation étant en marche, puis compléter avec la quantité d'eau nécessaire à l'application. Rincer trois fois les emballages et verser l'eau de rinçage dans la cuve du pulvérisateur.

Appliquer immédiatement la bouillie après sa préparation, et maintenir l'agitation pendant toutes les opérations de traitement.

Pulvériser les eaux de rinçage de la cuve sur la parcelle.

Bien nettoyer le pulvérisateur (cuve et circuits de pulvérisation) à l'aide d'un détergent et bien rincer pour éviter toute conséquence néfaste lors de l'utilisation de l'appareil sur d'autres cultures. L'emploi de Al Clear Extra (marque déposée Du Pont De Nemours) est recommandé pour ce nettoyage. Bien suivre les recommandations d'emploi de ce produit.

PRÉCAUTIONS GÉNÉRALES :

DANS LE CADRE DES BONNES PRATIQUES AGRICOLES :

Gestion du risque d'apparition de résistance :

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Conditions de stockage : Conserver le produit dans son emballage d'origine, dans un local réservé à cet usage à une température comprise entre 0° et 40°C.

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et éliminer via les collectes organisées par les distributeurs partenaires de la filière ADVALOR ou tout autre service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Éliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Éviter toute contamination des mares, puits, canaux, ruisseaux, eaux souterraines ou de distribution ou de tout autre point d'eau par le produit, la bouillie de pulvérisation et les eaux de rinçage des emballages et des équipements de traitement.

Mesures d'urgence : En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15. Présenter aux secours la fiche de données de sécurité. Puis signaler vos symptômes au réseau Phytitude : tél. 0 800 887 887 (numéro vert).

RECOMMANDATIONS : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage et qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conclure 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, telles que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte tenu des législations existantes, il appartient à l'utilisateur, dans le cas où les données issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Mehreshim Agri ne saurait être tenu en aucun cas pour responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

Appendix 3 – Letter(s) of Access

The letters of access are available and have been removed for confidentiality reasons.