

REGISTRATION REPORT

Part A

Risk Management

Product code: EF-1176

Product name: WINCH EV

Active substances:

isoxaben, 107 g/L

oryzalin, 429 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal of marketing authorisation)

Applicant: DOW AGROSCIENCES S.A.S.

Date: 2018-05-02

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH	4
1.4	DATA PROTECTION CLAIMS	5
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION	6
2.1	PRODUCT IDENTITY	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	<i>6</i>
2.2.4	<i>Other phrases linked to the preparation</i>	<i>7</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT.....	10
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties</i>	<i>10</i>
3.1.2	<i>Methods of analysis</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>12</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>13</i>
3.1.7	<i>Efficacy</i>	<i>14</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	15
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	15
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	15
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>15</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>15</i>
3.4.3	<i>Label amendments</i>	<i>15</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	16
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	19
	APPENDIX 3 – LETTER(S) OF ACCESS	24

PART A – Risk Management

The company DOW AGROSCIENCES S.A.S. has requested renewal of the marketing authorisation in France for the product WINCH EV (formulation code: EF-1176, marketing authorisation n° 2010143), containing 107 g/L isoxaben and 429 g/L oryzalin 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 WINCH EV (EF-1176) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of WINCH EV (EF-1176) have been made using endpoints agreed in the EU peer reviews of both isoxaben and oryzalin.

This document describes the specific conditions of use and labelling required for France for the registration of WINCH EV (EF-1176).

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 DOW AGROSCIENCES S.A.S.'s application to market WINCH EV (EF-1176) 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

Isoxaben

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 isoxaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, the risk to non-target terrestrial plants and the potential leaching of metabolites to groundwater.

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

The Member States concerned shall request the submission of confirmatory information as regards:

- (a) the specification of the technical material, as commercially manufactured,
- (b) the relevance of the impurities;
- (c) the residues in rotational crops;
- (d) the potential risk to aquatic organisms.

The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a) and (b) by 30 November 2011 and the information set out in points (c) and (d) by 31 May 2013.

An EFSA conclusion is available (EFSA Journal 2010;8(9):1714).

A Review Report is available (SANCO/12826/2010 final 28 January 2011).

Oryzalin

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 oryzalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.

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

- the operator safety and ensure that conditions of use include the application of adequate personal protective equipment;
- the protection of aquatic organisms and non target plants;
- the protection of groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the risk to herbivorous birds and mammals;
- the risk to bees, in the flowering season.

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

The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolites OR13 (2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide) and OR15 (2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide) in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards:

- (1) the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12;
- (2) the relevance of the test material used in the toxicity dossiers in view of the specification of the technical material;
- (3) the risk assessment for aquatic organisms;
- (4) the relevance of the metabolites OR13 and OR15, and the corresponding groundwater risk assessment, if oryzalin is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’.

The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 30 November 2011 and the information set out in point (3) by 31 May 2013. The information set out in point (4) shall be submitted within six month of notification of a decision classifying oryzalin.

EFSA conclusions are available (EFSA Journal 2010; 8(9):1707 [approval] and EFSA Journal 2013;11(8):3351 [confirmatory data]).

A Review Report is available (SANCO/12665/2010 Final, 28 January 2011 [approval] and 20 March 2014 [confirmatory data]).

1.3 Regulatory approach

The present application (2014-0262) 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. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 1107/2009⁴, implementing regulations, Regulation (EU) no 540/2011 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, 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 WINCH EV (EF-1176), 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: the applicant has provided sufficient data to show that access is not required.

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/AGR1632554A/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

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/AGR1407093A/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 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	WINCH EV (EF-1176)
Authorisation number	2010143 – authorization withdrawn
Function	Herbicide
Applicant	DOW AGROSCIENCES S.A.S.
Composition	107 g/L isoxaben 429 g/L oryzalin
Formulation type (code)	Suspension concentrate (SC)
Packaging	Polyethylene terephthalate (PET) or high-density polyethylene (HDPE) (0.25 L, 0.5 L, 1 L, 2 L, 3 L, 5 L, 10 L, 15 L or 20 L)

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	Carcinogenicity, Hazard Category 2	
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	H351	Suspected of causing cancer
	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)	EUH 208	Contains 1,2-benzisothiazol-3(2H)-one and oryzalin. 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 authorisation withdrawn:

2.2.4 Other phrases linked to the preparation

N/A authorisation withdrawn:

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” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

PPP (product name/code): **WINCH EV (EF-1176)** Formulation type: **SC** ^(a, b)
Active substance 1: isoaben Conc. of a.s. 1: **107 g/L** ^(c)
Active substance 2: oryzalin Conc. of a.s. 2: **429 g/L** ^(c)
Applicant: **DOW AGROSCIENCES S.A.S.** Professional use: ☒
Zone(s): Southern ^(d) 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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Park footpaths, walkways, cemeteries	F	Annual grasses and broadleaf weeds	Spot application Backpack sprayer with hand-held lance and boom	Not applicable Spring / Summer	a) 1 b) 1	-	5	a) Isoxaben 535 Oryzalin 2145 b) Isoxaben 535 Oryzalin 2145	400 / 800	n/a	Not acceptable (operator exposure)

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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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

WINCH EV (EF-1176) is an SC formulation. All studies have been performed in accordance with the current requirements. The appearance of the formulation is that of an orange, opaque, viscous water-based liquid. It is not explosive and has no oxidising properties. The product has a flash point of 97.7 C. It has a self-ignition temperature of 290 C. In aqueous solution (1 % dilution), its pH is 6.3 at 23 C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 C and 14 days at 54 C, neither the active substance content nor the technical properties were changed. Stability data indicate a shelf life of at least two years at ambient temperature (PET or 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 substances and relevant impurities (toluene [methylbenzene] and N-nitrosodi-N-propylamine in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of isoxaben and oryzalin in plants (high-water-content, acidic, fatty), foodstuffs of animal origin, soil, water (surface and drinking) and air. Analytical methods for the determination of residues of oryzalin in foodstuffs of animal origin are not necessary.

The active substances are 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

Endpoints used in risk assessment

Active substance: isoxaben			
ADI	0.05 mg kg bw/d		EU (2011)
ARfD	not applicable		
AOEL	0.25 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation:		
		Concentrate (tested) 520 g/L	Diluted formulation (tested) 0.25 g/L
	<i>In vitro</i> (human) %	6.6%	16.7%
		Concentrate (used in formulation) 107 g/L	Spray dilution (used in formulation) 0.67-5.35 g/L
	Dermal absorption endpoints %	17%	17%
Active substance: oryzalin			
ADI	0.05 mg kg bw/d		EU (2011)
ARfD	Not applicable		
AOEL	0.05 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate	Spray dilution

		(used in formulation) 429 g/L	(used in formulation) 2.68-21.45 g/L
	Dermal absorption endpoints %	25%	75%

3.1.3.1 Acute Toxicity

EF-1176 containing 107 g/L isoxaben and 429 g/L oryzalin has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Non-crop (footpaths and alleys)	F	Lance	5 L/ha (isoxaben: 590 g/ha oryzalin: 2235 g/ha)	400-800	MODOP ZNA

Considering the proposed non-crop uses, operator systemic exposure was estimated using a French (UPJ⁸) study from 2009-2010⁹ dedicated to non-agricultural use:

Crop	Equipment	PPE and/or working coverall	% AOEL isoxaben (AOEL = 0.25 mg/kg bw/d)	% AOEL oryzalin (AOEL = 0.05 mg/kg bw/d)
Non-crop (footpaths and alleys)	Lance	Working coverall and gloves during mixing/loading and application	5.8 %	452 %

According to the model calculations, it can be concluded that **the risk for the operator using EF-1176 is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.**

In order to refine operator exposure when applying EF-1176 using a lance in non-crop situations, the applicant provided an operator exposure study. This study was used to determine the dermal and inhalational exposure of the operator during mix/loading and application of the preparation GARLON L 60, containing clopyralid and triclopyr, with a lance connected to a mix-tank in amenity grassland.

This study was not taken into account in this zRMS risk assessment because GARLON L 60 does not contain oryzalin. Moreover, only three operators out of seven were measured for glove and hand-wash exposure and none of the seven operators was measured for body exposure. Exposure during mix/loading was therefore underestimated in that study.

(The study and applicant's assessment is presented in Appendix 4 of the dRR part B section 3).

3.1.3.3 Bystander Exposure

⁸ UPJ: the French trade association for garden/amenity pesticide manufacturers

⁹ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group «produits phytosanitaires : substances et préparations chimiques» Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

For the use for which application is made using a lance, drift is considered to be controlled by the operator. An estimate of the exposure of people present near the spray zones was therefore not undertaken; it is considered to be negligible.

3.1.3.4 Worker Exposure

EF-1176 is intended to be used on non-agricultural areas, not requiring the intervention of workers after treatment; estimating worker exposure is therefore considered to be unnecessary.

3.1.3.5 Resident Exposure

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure of people living near sprayed areas was estimated to be as follows:

		% ADI		% AOEL	
		isoxaben	oryzalin	isoxaben	oryzalin
Maximum daily measurement (isoxaben: 2.84 ng/m ³ oryzalin: 0.7 ng/m ³)	Adult	0.002	0.001	0.0005	0.001
	Child	0.003	0.001	0.001	0.001
Maximum weekly measurement (isoxaben: 0.83 ng/m ³)	Adult	0.001	-	0.0001	-
	Child	0.001	-	0.0002	-

3.1.3.6 Relevance of metabolites

The isoxaben metabolites hydroxyl-isoxaben and 2,6-dimethoxy benzamide are non-genotoxic (EFSA Journal 2010;8(9):1714).

According to SANCO/221/2000 rev. 10 a consumer exposure assessment needs to be provided for metabolites, which have passed the evaluation in step 3. The consumer exposure assessment can be performed by using the threshold of toxicological concern (TTC) approach, if the estimated groundwater concentration of the metabolite(s) is equal to or below 0.75 µg/L.

With EF-1176, the predicted concentration of the metabolite hydroxyl-isoxaben is 7.891 µg/L in groundwater. The ADI used for this metabolite is 0.05 mg/kg bw/d (ADI of isoxaben). The predicted concentration of the metabolite 2,6-dimethoxy benzamide is 1.488 µg/L in groundwater. The ADI used for this metabolite is 0.0015 mg/kg bw/d (TTC threshold).

Considering a body weight of 60 kg and a water consumption of 2 L/d, consumer exposure represents 0.53 % of the ADI of hydroxyl-isoxaben and 3.3 % of the ADI of 2,6-dimethoxy benzamide.

Metabolite	PECgw (µg/L)	Ingestion		ADI (mg/kg bw/d)	% ADI
		µg/d	µg/kg bw/d		
Adult, 60 kg bw, 2L water/d:					
Hydroxyl-isoxaben	7.891	15.782	0.2630	0.05	0.53%
2,6-dimethoxy benzamide	1.488	2.976	0.0496	0.0015	3.3%

The consumer risk via drinking water is therefore acceptable.

3.1.4 Residues and Consumer Exposure

WINCH EV (EF-1176) is a herbicide for non-crop uses, therefore no risk for the consumer is expected.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU reviews were used to calculate predicted

environmental concentrations (PECs) 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 PECs of isoxaben, oryzalin and their metabolites in soil, groundwater and surface water 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 peer reviews or agreed in the assessment based on new data provided.

The results for PEC_{soil} and PEC_{sw} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment and mitigation measures are proposed.

PEC_{gw} values for isoxaben, oryzalin and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses, in the conditions specified below.

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

3.1.6 Ecotoxicology

3.1.6.1 Effects on birds and mammals

The risk assessment for birds and mammals was carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and considering the EU agreed endpoints of isoxaben and oryzalin.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals¹⁰ is acceptable following use of EF-1176 according to the proposed pattern.

3.1.6.2 Effects on aquatic species

The risk assessment for aquatic organisms is carried out according to the EFSA Guidance Document on Aquatic Ecotoxicology and considering the EU agreed endpoints of isoxaben, oryzalin, their metabolites and data on the formulation EF-1176.

The TER values using worst-case PEC_{sw} values for isoxaben, oryzalin and their metabolites exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of EF-1176 according to the proposed pattern, with the following risk mitigation measures:

Crop:	Drainage scenarios which fail:
5 m spray drift zone buffer	
Permeable non-crop uses	/

It should be noted that the proposed impermeable non-crop uses are not acceptable following the use of EF-1176 according to the proposed use patterns.

3.1.6.3 Effects on bees

The risk assessment for bees was carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of isoxaben, oryzalin and the formulation EF-1176.

¹⁰ from direct dietary exposure, drinking water and secondary poisoning.

All hazard quotients for EF-1176 are less than 50, indicating that the risk to bees is acceptable following its use according to the proposed pattern.

3.1.6.4 Effects on other non-target arthropods

The risk assessment for non-target arthropods was carried out according to the Guidance Document ESCORT 2 and considering the EU agreed endpoints of the formulation EF-1176.

The in-field hazard quotient (HQ) and off-crop HQ values are below the trigger value, indicating that the risk to in-field and off-crop non-target arthropods is acceptable following use of EF-1176 according to the proposed pattern.

3.1.6.5 Effects on earthworms

The risk assessment for earthworms was carried out according to the Guidance Document on Terrestrial Ecotoxicology (*op. cit.*) and considering the EU agreed endpoints of isoxaben, oryzalin their metabolites and the formulation EF-1176.

The acute and chronic TER values for isoxaben, oryzalin and their metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of EF-1176 according to the proposed pattern.

3.1.6.6 Effects on Soil Non-target Micro-organisms

The risk of EF-1176 to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with the PEC_s.

The no effect levels exceed the relevant PEC_s values, indicating that the risk to soil micro-organisms is acceptable following use of EF-1176 according to the proposed use pattern.

3.1.6.7 Assessment of Potential for Effects on Non-target plants

The risk assessment for non-target plants was carried out according to the Guidance Document on Terrestrial Ecotoxicology (*op. cit.*) and considering the EU agreed endpoints of the formulation EF-1176. To protect non-target terrestrial plants, a 5 m buffer zone is required for use of EF-1176 according to the proposed pattern.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- The efficacy of WINCH EV (EF-1176) is considered satisfactory
- The risk of negative impact on non-target organisms, is considered acceptable.
- The risk of resistance developing or appearing is considered to be low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted, due to unacceptable risk to the operator**. 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

No further information is required.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

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
WINCH EV

de la société DOW AGROSCIENCES SAS

enregistrée sous le n°2014-0262

Vu les conclusions de l'évaluation de l'Anses du 15 décembre 2017,

Vu le courrier d'intention de retrait de l'Anses du 5 mars 2018,

Considérant que l'utilisation du produit entraîne un risque d'effet nocif pour les opérateurs,

Considérant que les exigences visées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc plus respectées,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.



Informations générales sur le produit	
Noms du produit	WINCH EV WINCH PJT
Type de produit	Produit de référence
Titulaire	DOW AGROSCIENCES SAS 371, rue Ludwig Van Beethoven 06560 VALBONNE FRANCE
Formulation	Suspension concentrée (SC)
Contenant	107 g/L – isoxabène 429 g/L – oryzalin
Numéro d'intrant	2010143
Numéro d'AMM	2010143
Fonction	Herbicide
Gamme d'usages	Professionnel

Conditions générales de retrait : sans délais de grâce

A Maisons-Alfort, le 02 MAI 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)

WINCH EV
AMM n°2010143

Page 2 sur 3



ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages retirés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015904 Usages non agricoles* Désherb. total	5 L/ha	1/an	Non applicable
	Motivation du retrait : L'usage est retiré en raison d'un risque pour les opérateurs.		
11015903 Usages non agricoles* Désherbage* All. PJT, Cimet., Voies	5 L/ha	1/an	Non applicable
	Motivation du retrait : L'usage est retiré en raison d'un risque pour les opérateurs.		

WINCH EV
AMM n°2010143

Page 3 sur 3

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

	WINCH EV (Contient de l'isoxaben et de l'oryzalin) l'oryzalin peut provoquer une réaction R50/53 Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.
N – Dangereux pour l'environnement	
Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement.	
S24	Éviter le contact avec la peau.
S35	Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes les précautions d'usage.
S37	Porter des gants appropriés.
S57	Utiliser un moyen de confinement approprié pour éviter toute contamination du milieu environnant.
Spe3	Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres par rapport aux points d'eau. Pour protéger les arthropodes et les plantes non-cibles, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.
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).
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.	
Dow AgroSciences Distribution S.A.S. Marco Polo - bâtiment B ZAC du Font de l'Orme 1 BP 1220 – 790 Avenue du Docteur Donat 06254 MOUGINS Cedex Tél. : 0800 47 08 10	

Fiche de données de sécurité disponible sur notre site Internet : www.dowagro.fr

En cas d'urgence appelez le 15 ou le centre anti-poison puis signalez vos symptômes au réseau "Phyt'attitude", numéro vert 0 800 887 887 (appel gratuit depuis un poste fixe).

**Add logo Adivalor
version**

EMB. 67106

Add barcode same as previous

MAIN PANEL

Logo DAS

WINCH EV *

HERBICIDE DE PRELEVÉE DES ZONES NON AGRICOLES

- DESHERBAGE TOTAL
- DESHERBAGE DES ALLEES DE PARCS, JARDINS , TROTTOIRS, CIMETIERE ET VOIE DE COMMUNICATION

IM n° 2010143, délivrée le 6 avril 2001- Dow AgroSciences S.A.S. **

Marco Polo - bâtiment B

* Marque Dow AgroSciences.

ZAC du Font de l'Orme 1

(2) En respectant les préconisations mentionnées dans le chapitre

3P 1220 – 790 Avenue du Docteur Donat

"recommandations importantes".

16254 MOUGINS Cedex

Tél. : 0800 47 08 10

X litres e

Right Panel

COMPOSITION :

Suspension concentrée (SC)
isoxaben ⁽¹⁾ 107 g/L (9,05 % p/p)
oryzalin ⁽¹⁾ : 429 g/L (36,29 % p/p)

⁽¹⁾ Substance actives brevetées et fabriquées par Dow AgroSciences.

USAGES ET DOSES AUTORISÉS :

Culture	Usage	Dose	Nombre d'application	Délai avant récolte en jours (DAR)	Largeur de la zone non traitée (ZNT)
Usage non agricole	Désherbage Total	5 L/ha	1 appl. par an	N/A	Eau : 10 m
	Désherbage Total* Sites Industriels				
	Désherbage Allées de de Parcs, Jardins, Trottoirs, Cimetières, Voies de communication				

Point de gel : -5°C.

Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Conserver uniquement dans l'emballage d'origine.

Porter un vêtement de protection approprié (catégorie III type 5/6), des gants en nitrile et un appareil de protection des yeux et du visage pendant toutes les phases d'utilisation du produit.

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.

Lors de l'application, prendre toutes les mesures nécessaires pour éviter tout transfert de produit en dehors de la zone traitée, notamment sur les étangs, cours d'eau et fossés.

Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseaux, étangs, mares

...

Aussitôt après la fin des traitements nettoyer et rincer soigneusement le pulvérisateur à l'eau claire.

Pour les effluents (fonds de cuve, eaux de rinçage), respecter la réglementation en vigueur concernant l'utilisation des produits phytopharmaceutiques.

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

Emballages vides : rendre inutilisable, puis éliminer via une collecte organisée par un service de collecte spécifique.

PREMIERS SOINS

- Retirer immédiatement les vêtements contaminés par le produit.
- Après inhalation : repos, air frais, secours médical.
- Après contact avec la peau : se laver immédiatement et longuement à l'eau courante.
- Après contact avec les yeux : rincer aussitôt à l'eau courante pendant au moins 15 minutes en maintenant les paupières écartées. Consulter un ophtalmologue.
- Après ingestion : ne pas faire vomir, ne pas faire boire. Consulter immédiatement un médecin.

INNER PAGES

PRÉSENTATION DU PRODUIT

Mode d'action :

WINCH EV est un herbicide de prélevée qui empêche la germination des graminées et des dicotylédones annuelles.

Il est composé d'un mélange d'isoxaben et d'oryzalin qui ont tous deux une activité de prélevée des adventices mais selon deux modes d'actions différents.

L'isoxaben appartient à la famille des benzamides (groupe L HRAC). Il est absorbé par les racines des graines en cours de germination. Il bloque la croissance des méristèmes ce qui provoque la mort rapide des plantules et empêche leur levée.

L'oryzalin appartient à la famille des dinitroanilines ou DNA (groupe K1 HRAC). Il agit essentiellement en bloquant la multiplication cellulaire des graines en germination, empêchant la levée des adventices.

Mode d'emploi :

WINCH EV est destiné à être appliqué en pulvérisation après dilution dans l'eau :

- Bien agiter le bidon de WINCH EV
- Remplir à moitié la cuve du pulvérisateur avec de l'eau.
- Mettre en route l'agitation et verser dans la cuve la dose de produit nécessaire.
- Dans le cas d'un mélange avec un produit foliaire, verser en premier WINCH EV dans la cuve partiellement remplie d'eau puis le produit foliaire.
- Terminer le remplissage de la cuve et maintenir l'agitation jusqu'à la fin de l'application.
- Utiliser la bouillie immédiatement après sa préparation.

Ne préparer que le volume de bouillie nécessaire au traitement.

Aussitôt après la fin de l'application, nettoyer et rincer très soigneusement le pulvérisateur à l'eau claire.

Pour assurer une pulvérisation optimale, entretenir régulièrement votre pulvérisateur. WINCH EV est compatible avec les pompes doseuses herbicides.

Conditions d'application :

- Traiter sur sol propre, débarrassé de sa végétation et des feuilles mortes qui peuvent faire obstacle au bon positionnement de l'herbicide. En présence d'herbes levées, le produit peut être associé à un herbicide foliaire.
- Traiter de préférence sur sol légèrement humide pour un bon positionnement du produit dans la couche superficielle du sol.

Dose d'application :

WINCH s'utilise à la dose de 5L/ha .

Efficacité :

WINCH EV doit être appliqué avant la levée des adventices pour être efficace, il est sans effet sur les adventices déjà levées au moment du traitement et sur les plantes vivaces. En présence de mauvaises herbes déjà levées (même au stade plantules), raisonner l'emploi de WINCH EV avec un herbicide foliaire autorisé, à sa dose normale d'emploi.

Dicotylédones très sensibles et sensibles : amarantes, chénopodes, céraistes, érigeron du Canada, mercuriales, géranium, Renouée persicaire, Renouée des oiseaux, pourpier, stellaire, véronique

Graminées très sensibles et sensibles : brome stérile, pâturin annuel, digitale sanguine , sétaire

Sélectivité :

WINCH EV peut s'employer en toute sécurité à proximité d'un grand nombre d'espèces d'arbres et d'arbustes d'ornement. WINCH EV ne présente pas de risque pour les gazons en bordure d'allées.

Période d'utilisation :

WINCH EV peut s'employer toute l'année. L'efficacité sera optimisée si le traitement est effectué sur sol humide. Éviter les longues périodes de sécheresse.

Recommandations particulières :

- La couleur orange du produit permet de bien visualiser le traitement. Sur certains matériaux clairs et poreux, la couleur peut persister quelques jours.
- Traiter seulement par temps calme, sans vent et à une température comprise entre 5°C et 25°C à l'ombre.
- Réserver de préférence un appareil uniquement pour les traitements de désherbage.

Lutte contre la 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 des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents.

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 facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

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

Appendix 3 – Letter(s) of Access

Not applicable.