

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: DIURON 80% SC**

**Product name: DIR 800 SC**

**Active substance:**

**diuron 800 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**New application**

**Applicant: ARYSTA LIFESCIENCE BENELUX SPRL**

**Date: 07/08/2018**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION .....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL .....	3
1.3	REGULATORY APPROACH .....	3
1.4	DATA PROTECTION CLAIMS .....	4
1.5	LETTER(S) OF ACCESS .....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION .....</b>	<b>6</b>
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>6</i>
2.3	PRODUCT USES .....	7
<b>3</b>	<b>RISK MANAGEMENT .....</b>	<b>9</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES .....	9
3.1.1	<i>Physical and chemical properties .....</i>	<i>9</i>
3.1.2	<i>Methods of analysis.....</i>	<i>9</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>9</i>
3.1.4	<i>Residues and Consumer Exposure .....</i>	<i>10</i>
3.1.5	<i>Environmental fate and behaviour .....</i>	<i>11</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>12</i>
3.1.7	<i>Efficacy.....</i>	<i>12</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....	13
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....	13
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 .....	13
3.4.1	<i>Post-authorisation monitoring .....</i>	<i>13</i>
3.4.2	<i>Post-authorisation data requirements .....</i>	<i>13</i>
3.4.3	<i>Label amendments.....</i>	<i>13</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>	<b>14</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>	<b>17</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS .....</b>	<b>21</b>

## PART A – Risk Management

The company ARYSTA LIFESCIENCE BENELUX SPRL has requested marketing authorisation in France for the product DIR 800 SC (formulation code: DIURON 80% SC), containing 800 g/L diuron, 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 DIR 800 SC (DIURON 80% SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DIR 800 SC (DIURON 80% SC) have been made using endpoints agreed in the EU peer review of diuron. This document describes the specific conditions of use and labelling required for France for the registration of DIR 800 SC (DIURON 80% 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 ARYSTA LIFESCIENCE BENELUX SPRL's application to market DIR 800 SC (DIURON 80% 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 first authorisation of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Diuron

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 at rates not exceeding 0,5 kg/ha (areic average) 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 diuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.

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

- The operator safety; conditions of use shall prescribe the use of personal protective equipment, if appropriate;
- The protection of aquatic organisms and non-target plants.

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

An EFSA conclusion is available (EFSA Scientific Report (2005) 25, 1-58, Conclusion on the peer review of diuron)

A Review Report is available (SANCO/2184/2008 rev 3, 10 July 2008).

### 1.3 Regulatory approach

The present application (2014-0134, 2016-4571) was evaluated in France by the French Agency for Food,

Environmental and Occupational Health & Safety (Anses)<sup>1</sup> in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)<sup>2</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017<sup>3</sup> 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 1107/2009<sup>4</sup>, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>6</sup> provides that:

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

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

<sup>1</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>2</sup> 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

<sup>3</sup> 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/AGRGI632554A/jo/texte>

<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

Where protection for data is being claimed for information supporting registration of DIR 800 SC (DIURON 80% 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**

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity


<b>Product name (code)</b>	DIR 800 SC (DIURON 80% SC)
<b>Authorisation number</b>	N/A : no marketing authorisation granted
<b>Function</b>	Herbicide
<b>Applicant</b>	ARYSTA LIFESCIENCE BENELUX SPRL
<b>Composition</b>	800 g/L diuron
<b>Formulation type (code)</b>	Suspension concentrate (SC)
<b>Packaging</b>	N/A : no marketing authorisation granted

### 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) No 1272/2008

<b>Physical hazards</b>	
<b>Health hazards</b>	Acute Toxicity (oral), Hazard Category 4 Carcinogenicity, Hazard Category 2 Specific target organ toxicity after repeated exposure, Hazard Category 2
<b>Environmental hazards</b>	Hazardous to the Aquatic environment, Chronic, Hazard Category 1 Hazardous to the Aquatic environment, Acute, Hazard Category 1
<b>Hazard pictograms</b>	
<b>Signal word</b>	Warning
<b>Hazard statements</b>	H302 Harmful if swallowed
	H351 Suspected of causing cancer
	H373 May cause damage to organs through prolonged or repeated exposure
	H400 Very toxic to aquatic life
	H410 Very toxic to aquatic life with long-lasting effects
<b>Precautionary statements</b> –	<i>For the P phrases, refer to the extant legislation</i>
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	Contains 1,2 benzisothiazol-3 (2H)-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

#### 2.2.4 N/A : no marketing authorisation granted Other phrases linked to the preparation

N/A : no marketing authorisation granted

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant.

When the conclusion is “not acceptable”, the intended use (and possible extrapolation according to French Order of 26 March 2014 (highlighted in green) is highlighted in grey and the main reason(s) reported in the remarks.

date: 07/08/2018

PPP (product name/code) **DIR 800 SC (DIURON 80% SC)**  
active substance 1 **diuron**

Formulation type: **SC**  
Conc. of a.s. 1: **800 g/L**

Applicant: **ARYSTA LIFESCIENCE BENELUX SPRL**  
Zone(s): **Southern EU**  
Verified by MS: **yes**

professional use ☒  
non- professional use ☐

Field of use: **herbicide**

Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)		Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha  a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha  a) max. rate per appl. b) max. total rate per crop/season	Water (L/ha)  min / max			
2	France	Vines (VITVI)	F	Mono and dicotyledonous weeds	tractor mounted sprayer manual knapsack sprayer	From 4 years after planting, application at weed stage BBCH 00	a) 1 b) 1	a) 1.88 <sup>2</sup> b) 0.625 <sup>2</sup>	a) 1.5 <sup>2</sup> b) 0.5 <sup>2</sup>	100-400	60	<b>Not acceptable for the risk for aquatic organisms and operator (manual knapsack sprayer application)</b>	Application must be directed and limited to ground in strip-band application under the rows avoiding drift by using low pressure and shields.  Application at the dose rate of 1.88 L/ha of formulated product equivalent to 1500 g a.s./ha and on <b>only 1/3 of the total field surface</b>
4	France	Pome Fruits	F	Mono and	tractor	From 4 years after	a) 1	a) 1.88 <sup>2</sup>	a) 1.5 <sup>2</sup>	100-400	60	<b>Not</b>	

Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)		Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha  a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha  a) max. rate per appl. b) max. total rate per crop/season	Water (L/ha)  min / max			
		(MABSD, PYUCO, CYDOB, PYUPC, MSPGE)		dicotyledonous weeds	mounted sprayer	planting application at weed stage BBCH 00	b) 1	b) 0.625 <sup>2</sup>	b) 0.5 <sup>2</sup>			acceptable for the risk for aquatic organisms	

(2) As the product is applied in strips, the application rate in the strip is 1.5 kg a.s./ha, as only one third of the area is treated in this way.

**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/ g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

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



### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

The formulation DIR 800 SC (DIURON 80% SC) is a suspension concentrate (SC) formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a homogeneous opaque white liquid, with a faint chemical odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 458 °C. In aqueous solution (1 %), it has a pH value of 7.8 at 21°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. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for an SC formulation. The test must be performed at the maximal concentration use (1.875 (v/v)).

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

The product must be shaken after storage and before use.

##### 3.1.2 Methods of analysis

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance diuron does not contain any relevant impurity, no pertinent analytical method is required.

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of diuron in plants (olives, vines, citrus and pome fruits), foodstuffs of animal origin, soil, water (surface and drinking) and air.

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

##### 3.1.3 Mammalian Toxicology

#### Endpoints used in risk assessment

Active substance: <b>diuron</b>			
ADI	0.007 mg/kg bw/d	EU	
ARfD	0.016 mg/kg bw		
AOEL	0.007 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human study performed on formulation		
		Concentrate (tested) 800 g/L	Diluted formulation (tested) 1.25 g/L
	In vitro (human) % %	0.1	18
		Concentrate (used in formulation) 800 g/L	Spray dilution (used in formulation) 1.25 g/L
	<b>Dermal absorption endpoints %</b>	<b>0.1</b>	<b>18</b>

##### 3.1.3.1 Acute Toxicity

DIR 800 SC (DIURON 80% SC) has a low inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser but is classified for acute oral toxicity (see Section 2.2).

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>8</sup>	Equipment	Application rate (g a.s./ha)	Spray dilution (L/ha)	Model
Fruit crops	F	Tractor-mounted boom sprayer	500 g a.s./ha	100-400	BBA
Grape	F	Hand-held sprayer (15L)	500 g a.s./ha	100-400	POEM

Considering proposed uses, operator systemic exposure was estimated using the German BBA model and UK-POEM model.

Crop	Equipment	PPE and/or working coverall	% AOEL diuron
Fruit crops, grapevines	Tractor- mounted boom sprayer	Working coverall and gloves during mixing/loading and application	99
Grapevines	Hand-held sprayer (15 L)	Working coverall and gloves during mixing/loading and application	1900

According to the model calculations, it may be concluded that the risk for the operator using DIR 800 SC (DIURON 80% SC) is acceptable for fruit crops and grape using a tractor-mounted boom sprayer and unacceptable for grape using a hand-held sprayer with a working coverall (90 % protection factor) and gloves during mixing/loading and application. For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

### 3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 15 % of the AOEL of diuron. It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to DIR 800 SC (DIURON 80% SC).

### 3.1.3.4 Worker Exposure

DIR 800 SC (DIURON 80% SC) is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. Evaluation of worker exposure is considered unnecessary. For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

### 3.1.3.5 Resident Exposure

Based on the currently available data in the report of the ORP (French pesticides residues observatory), it is concluded that there is no unacceptable risk to the resident exposed to DIR 800 EC.

### 3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. Any exceedence of the current MRLs for diuron as laid down in Reg. (EU) N° 396/2005 is not expected.

The chronic and short-term intakes of diuron residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorisation of the intended uses.

According to the available data, no specific mitigation measures should apply.

<sup>8</sup> Open field or glasshouse

### Summary for diuron

Use- No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 777/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
2	Vines Grape (table and wine grapes)	Yes	Yes	Yes	Yes	Yes	No	No	
4	Pome fruits	Yes	Yes	Yes	Yes	Yes		No	

As residues of diuron do not exceed the trigger values defined in Reg. (EU) No° 283/2013, there is no need to investigate the effect of industrial and/or household processing.

No crop rotations are expected in orchards and vineyards.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigations of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

### Summary for DIR 800 SC (DIURON 80% SC)

Crop	PHI for DIR 800 SC (DIURON 80% SC) requested by applicant	PHI/withholding period* sufficiently supported for	PHI for DIR 800 SC (DIURON 80% SC) proposed by zRMS	zRMS comments (if different PHI proposed)
		diuron		
Vines (table and wine grapes)	60 days	Yes	60 days	
Pome fruits	60 days	Yes	60 days	

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

### 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of diuron and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment. No refined PECsw values (Steps 3 and 4) have been validated since the incorporation method proposed (granular) was not considered representative and conservative.

PEC<sub>gw</sub> values for diuron and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on metabolites in groundwater.

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 DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.1.6 Ecotoxicology

#### 3.1.6.1 Birds

According to the results of the refined acute and long-term risk assessment for diuron, the TER<sub>A</sub> and TER<sub>LT</sub> are above the triggers of 10 and 5, respectively, showing no unacceptable potential acute and long-term risk for birds.

#### 3.1.6.2 Mammals

According to the results of the refined acute and long-term risk assessment for diuron, the TER<sub>A</sub> and TER<sub>LT</sub> are above the triggers of 10 and 5, respectively, showing no unacceptable potential acute and long-term risk for mammals.

#### 3.1.6.3 Aquatic organisms

According to the results of the acute and long-term assessment for diuron, aquatic organisms are considered to be at high risk from the intended uses of DIR 800 SC (DIURON 80% SC). Indeed, no FOCUS PEC steps 3 and 4 were considered valid by the zRMS (see details in section 3.1.5). **Therefore it was impossible to conclude on the risk assessment for these organisms.**

#### 3.1.6.4 Bees and Other Arthropod

All the hazard quotients are less than 50, indicating that the product poses an acceptable risk to bees.

The relevant values indicate that DIR 800 SC (DIURON 80% SC) poses an acceptable risk to in-field non-target arthropods following application according to the proposed use patterns. No off-field risk assessment is necessary.

#### 3.1.6.5 Soil microbial activity

DIR 800 SC (DIURON 80% SC) had no significant effect on soil micro-organisms at 3.14 mg product/kg dry weight (dw) soil and 15.7 mg/kg soil dw (equivalent to 2 and 10 mg a.s./kg soil dw, respectively). This is approximately four times higher than the maximum PEC<sub>soil</sub> of 2.369 mg/kg dw soil. This supports the conclusion that under field conditions, the use of DIR 800 SC (DIURON 80% SC) at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

#### 3.1.6.6 Effects on organic matter breakdown

The acute and long-term toxicity:exposure ratio (TER) values for earthworms are higher than the acute trigger values of 100 and 10, respectively. This indicates that DIR 800 SC (DIURON 80% SC), diuron and its metabolites pose no unacceptable acute and long-term risk to earthworms when applied according to the proposed uses.

#### 3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

The potential effect of DIR 800 SC (DIURON 80% SC) has been tested in vegetative vigour and seedling emergence tests on 10 non-target terrestrial plants. All TER values were above the trigger value of 5 at a drift rate of 0.0277 % for field areas when nozzles with 50 % drift reduction were used. Without drift-reduction nozzles, all TER values were above the trigger value of 5 with the implementation of a 5 five-metre unsprayed buffer zone. No further risk mitigation measures have to be applied.

### 3.1.7 Efficacy

Considering the data submitted:

The efficacy of DIR 800 SC (DIURON 80% SC) is considered as satisfactory.

The selectivity of DIR 800 SC (DIURON 80% SC) is considered as satisfactory.

The risk of negative impact (on yield, quality, transformation processes, propagation and succeeding crops) is considered acceptable.

Concerning adjacent crops, the absence of trials means it is essential to avoid the drift of the preparation DIR 800 SC (DIURON 80% SC) on to monocotyledonous or vegetable crops, as well as to avoid the drift on to the green parts of adjacent crops. Considering the absence of reported cases of resistance to diuron, the risk of the appearance and development of resistance does not require a monitoring for the requested uses.

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, **an authorisation cannot be granted** because the risk to aquatic organisms cannot be finalised for grape and pome fruit; the operator exposure for hand-held equipment on grape is also unacceptable. 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**

N/A : not authorised.

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

#### **3.4.1 Post-authorisation monitoring**

N/A : not authorised.

#### **3.4.2 Post-authorisation data requirements**

N/A : not authorised.

#### **3.4.3 Label amendments**

N/A : not authorised.

## Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché, la demande de changement de composition et les demandes associées du produit phytopharmaceutique **DIR 800 SC***

*de la société* ARYSTA LIFESCIENCE BENELUX SPRL

*enregistrées sous le* n°2014-0134, 2014-0681, 2016-1859, 2016-3003,  
2016-4571, 2016-3867, 2017-1936

*Vu les conclusions de l'évaluation de l'Anses du 28 mars 2018 relatives à la demande d'autorisation de mise sur le marché,*

*Vu les conclusions de l'évaluation de l'Anses du 28 juillet 2017 relatives à la demande de changement de composition,*

*Considérant que l'estimation des expositions, liées à l'utilisation du produit sur vigne pour des applications manuelles est supérieure à la valeur limite acceptable du diuron pour les opérateurs,*

*Considérant également, qu'en l'absence de données suffisantes, l'absence de risque d'effet nocif pour les organismes aquatiques ne peut être démontrée,*

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

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



Informations générales sur le produit	
Noms du produit	DIR 800 SC TEMPRA NG DIRECTOR
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE BENELUX SPRL Rue de Renory 26/1, B-4102 Ougrée, Belgique
Formulation	Suspension concentrée (SC)
Contenant	800 g/L - diuron
Numéro d'intrant	9656-2014.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le

07 AOUT 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)

DIR 800 SC  
AMM n°-

Page 2 sur 3



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>12605905</b> Pommier*Désherbage*Cult. Installées	1,875 L/ha	1/an	60
<b>Motivation du refus :</b> L'usage en application sous le rang sur 1/3 de la surface totale, est refusé au motif que les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les organismes aquatiques.			
<b>12705902</b> Vigne*Désherbage*Cult. Installées	1,875 L/ha	1/an	60
<b>Motivation du refus :</b> L'usage en application sous le rang sur 1/3 de la surface totale, est refusé au motif qu'il existe un risque d'effet nocif pour l'opérateur lors des applications manuelles et que les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les organismes aquatiques.			



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

# DIR 800 SC®

*HERBICIDE*

**Suspension concentrée  
800 g/L ou 62.5 % (w/w) diuron**

**UTILISATION LIMITÉE AUX AGRICULTEURS ET AUX  
APPLICATEURS PROFESSIONNELS**

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

**LIRE L'ÉTIQUETTE AVANT UTILISATION**

Autorisation de Mise sur le Marché n°

**Poids Net:**

**Date de fabrication :**

**N° de lot :** voir sur emballage

Détenteur:

Agriphar S.A.

Rue de Renory, 26/1

B- 4102 Ougrée (Belgique)

**CULTURES, USAGES ET DOSES D'EMPLOI AUTORISÉES**

DIR 800 SC est un herbicide qui agit en prélevée des adventices type graminées et dicotylédones annuelles et pluriannuelles en cultures de fruits à pépins, vignes, agrumes et olives et en surfaces non cultivées.

DIR 800 SC est appliqué sur sol propre avant l'émergence des adventices pour contrôler les jeunes adventices sensibles pendant une période prolongée.

DIR 800 SC s'utilise à la dose de 1.5 Kg/ha dans une bouillie de 400 L d'eau/ha maximum.

DIR 800 SC s'applique en dirigé, à faible pression (1 à 2 bars) directement sous le rang. La dose par hectare doit être maintenue sur la surface réellement traitée (1/3 de la surface traitée)

DIR 800 SC s'applique dans des cultures âgées de plus de 4 ans.

## **MAUVAISES HERBES SENSIBLES:**

### **Très sensibles:**

*Abutilon theophrasti, Achillea millefolium, Amaranthus lividus, Amaranthus retroflexus, Ammi majus, Anacyclus clavatus, Anagallis arvensis, Anthyllis sp., Arrhenatherum elatius, Asparagus sp., Bromus rigidus, Bromus sp., Bromus sterilis, Calendula officinalis, Cardamine hirsuta, Chamamelum fuscum, Chenopodium hybridum, Chenopodium polyspermum, Conyza canadiensis, Crepis vesicaria, Cynodon dactylon, Digitaria sanguinalis, Diplotaxis catholica, Diplotaxis eruroides, Elytrigia repens, Epilobium sp., Epilophila verna, Erodium malacoides, Erodium cicutum, Erodium moschatum, Fumaria officinalis, Galium aparine, Geranium dissectum, Hordeum murinum, Inula viscosa, Lactuca serriola, Lamium album, Lamium amplexicaule, Lamium purpureum, Lamium sp., Lolium perenne, Malva sp., Malva sylvestris, Medicago lupulina, Medicago polymorpha, Medicago sativa, Mentha sp., Papaver rhoeas, Parietaria judaica, Phacelia tanacetifolia, Plantago lanceolata, Rumex bucephalophorus, Rumex obtusifolius, Scorpiurus muricatus, Setaria pumila, Setaria verticillata, Setaria viridis, Sherardia arvensis, Solanum dulcamara, Sonchus asper, Sonchus sp., Sonchus tenerrimus, Sorghum halepense, Spergula arvensis, Stellaria media, Thlaspi arvense, Trifolium repens, Trifolium sp., Urtica dioica, Veronica hederifolia and Vicia sativa.*

### **Sensibles:**

*Amaranthus graecizans, Anthemis arvensis, Bromus hordaceus, Bromus squarrosus, Capsella bursa-pastoris, Chamaesyce prostrata, Chenopodium album, Chenopodium vulvaria, Cirsium arvense, Convolvulus arvensis, Convolvulus althaeoides, Conyza bonariensis, Datura stramonium, Epilobium adnatum, Euphorbia falcata, Euphorbia supina, Geranium sp., Heracleum sphondylium, Holcus lanatus, Kochia scoparia, Lactuca serriola, Lolium rigidum, Lolium sp., Phalaris minor, Picris echinoides, Poa annua, Portulaca oleracea, Sisymbrium irio, Solanum nigrum, Sonchus oleraceus, Urtica urens, Veronica officinalis and Vicia sepium.*

### **Modérément sensibles:**

*Anagallis arvensis, Anchusa azurea, Avena fatua, Calendula arvensis, Cichorium intibis, Convolvulus althaeoides, Echinochloa crus-galli, Equisetum arvense, Geranium molle, Geranium pusillum, Geranium rotundifolium, Inula viscosa, Lavatera trimestris, Lolium multiflorum, Mercurialis annua, Persicaria lapathifolia, Phalaris sp., Plantago sp., Polygonum aviculare, Senecio vulgaris, Setaria sp., Sorghum halepense, Taraxacum officinale, Veronica hederifolia and Veronica persica.*

## **MÉLANGE ET PULVÉRISATION**

DIR 800 SC se mélange aisément avec de l'eau et peut être dilué dans un volume de bouillie de pulvérisation de 100-400 litres/ha. Il est recommandé de traiter en dirigé à faible pression à l'aide d'un pulvérisateur à dos ou d'un tracteur équipé d'une rampe de pulvérisation sur lesquels des écrans de protection sont adaptés.

Calibrer correctement les pulvérisateurs selon les conditions d'utilisation.

En raison de l'efficacité élevée de DIR 800 SC et des méthodes d'application, il est recommandé de suivre les instructions suivantes afin d'éviter tout problème de dérive :

- Traiter par temps calme en l'absence du vent.
- Utilisation de buses anti-dérive.
- Pulvérisation à faible pression.
- Utilisation d'écran de protection

### **DÉLAI AVANT RÉCOLTE:**

Fruits à pépins et vignes : 60 jours

Olives et agrumes : 21 jours

### **STRATÉGIE DE RÉSISTANCE DES MAUVAISES HERBES**

Quand des herbicides du même mode d'action sont utilisés plusieurs années consécutives sur les mêmes parcelles, la sélection des biotypes résistants peut avoir lieu. Ceux-ci peuvent se propager et devenir dominants. Une espèce d'adventice est considérée résistante si elle survit à une application correctement effectuée à la dose recommandée. Afin de minimiser et contrôler l'apparition de résistance, une stratégie de gestion appropriée doit être adoptée. Celle-ci doit combiner l'utilisation de plusieurs herbicides à modes d'action différents dans un programme cultural. Des documents de guidance ont été produits par le « Groupe D' Action De Résistance De Mauvaises Herbes » (HRAC) et sont disponibles auprès de votre distributeur ou fabricant.

En cas de suspicion de résistance des mauvaises herbes, contactez votre distributeur ou le fabricant.

### **REMARQUES**

Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage, qui ont été déterminés en fonction des caractéristiques et des applications pour lesquelles le produit 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 ces produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture.

La société ne sera pas responsable des pertes ou des dégâts occasionnés par une utilisation non conforme à ses recommandations. L'utilisateur assume tous les risques associés à un tel usage, non conforme à ces recommandations.



## ATTENTION

- H302 Nocif en cas d'ingestion.  
H351 Susceptible de provoquer le cancer.  
H373 Risque présumé d'effets graves pour les organes à la suite d'une exposition prolongée.  
H410 Très toxique pour les organismes aquatiques, entraîne des effets à long terme.

- P102 Tenir hors de portée des enfants.  
P202 Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité.  
P260 Ne pas respirer les aérosols.  
P264 Se laver les mains soigneusement après manipulation.  
P270 Ne pas manger, boire ou fumer en manipulant ce produit.  
P273 Éviter le rejet dans l'environnement.  
P280 Porter des gants de protection/des vêtements de protection/du visage.  
P391 Recueillir le produit répandu.

P301+P312 EN CAS D'INGESTION: appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.

P501 Éliminer le contenu/emballages conformément à la réglementation en vigueur.

## N° d'appel centre anti poison : 01 40 05 48 48

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 des systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).

SPe3 Pour protéger les organismes aquatiques respecter une zone non traitée de 20 mètres par rapport aux points d'eau.

SPe3 Pour protéger les plantes non cibles respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Élimination du produit et de l'emballage : Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

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### **Appendix 3 – Letter(s) of Access**

Not necessary