

REGISTRATION REPORT

Part A

Risk Management

Product code: OXYFLUORFEN 24% EC

Product name(s): DIPIRIL

Active Substance(s):

Oxyfluorfen, 240 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: INDUSTRIAS AFRASA, S.A.

Date: 2020/12/28

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PART A – Risk Management

The company INDUSTRIAS AFRASA, S.A. has requested marketing authorisation in France for the product DIPIRIL (product code: OXYFLUORFEN 24% EC), containing 240 g/L oxyfluorfen 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 DIPIRIL (OXYFLUORFEN 24% EC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DIPIRIL (OXYFLUORFEN 24% EC) have been made using endpoints agreed in the EU peer review(s) of oxyfluorfen.

This document describes the specific conditions of use and labelling required for France for the registration of DIPIRIL (OXYFLUORFEN 24% EC).

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 INDUSTRIAS AFRASA, S.A.'s application to market DIPIRIL (OXYFLUORFEN 24% EC) 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

Oxyfluorfen

Commission Implementing Regulation (EU) N° 2017/359 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen

Specific provisions of Regulation (EU) No 2017/359 were as follows :

PART A

Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised, at a rate not exceeding 150 g active substance per hectare, per year.

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 oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed, shall be taken into account.

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

- operator safety and ensure that conditions of use impose the application of adequate personal protective equipment where appropriate,
- the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants.

Conditions of authorisation shall include risk mitigation measures such as no-spray buffer zones and drift reducing nozzles and shall provide for respective labelling of plant protection products. Those conditions shall include

further risk mitigation measures, where appropriate.’

An EFSA conclusion is available (EFSA Journal 2015;13(8):4205, 45 pp. doi:10.2903/j.efsa.2015.4205).

A Review Report is available (SANCO/11136/2011 rev 3, 24 January 2017).

1.3 Regulatory approach

The present application (2014-1194) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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”)¹ – 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 2017² 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 1107/2009³, 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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

¹ 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

² 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>

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

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

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁶ SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

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 DIPIRIL (OXYFLUORFEN 24% EC) , it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary.


2 DETAILS OF THE AUTHORISATION

2.1 Product identity

| | |
|--------------------------------|--|
| Product name (code) | DIPIRIL (OXYFLUORFEN 24% EC) |
| Authorisation number | N/A : no marketing authorisation granted |
| Function | herbicide |
| Applicant | INDUSTRIAS AFRASA, S.A. |
| Composition | 240 g/L oxyfluorfen |
| Formulation type (code) | Emulsifiable concentrate [Code: EC] |
| Packaging | N/A : no marketing authorisation granted |

2.2 Classification and labelling

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

| | | |
|------------------------------|--|--|
| Physical hazards | Flammable cat. 3 | |
| Health hazards | Aspiration hazard cat. 1 Skin sensitisation cat. 1B Eye irritation cat. 2 Acute toxicity (inhalation) cat. 4 Specific target organ toxicity – Single exposure cat. 3 – Respiratory tract irritation Carcinogenicity cat. 2 Specific target organ toxicity - Repeated exposure cat. 2 | |
| Environmental hazards | Hazardous to the aquatic environment, Acute Hazard, Cat 1 Hazardous to the aquatic environment, Chronic Hazard, Cat 1 | |
| Hazard pictograms |  | |
| Signal word | Warning | |
| Hazard statements | H226 | Flammable liquid and vapour |
| | H304 | May be fatal if swallowed and enters airways |
| | H317 | May cause an allergic skin reaction |

| | | |
|--|---|--|
| | H319 | Causes serious eye irritation |
| | H332 | Harmful if inhaled |
| | H335 | May cause respiratory irritation |
| | 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) | | |

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

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

N/A : no marketing authorisation granted

2.2.3 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, evaluated by France as zRMS.
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 2020/12/28

PPP (product name/code) **DIPIRIL (OXYFLUORFEN 24% EC)**
active substance 1 **oxyfluorfen**

Formulation type: **EC**
Conc. of as 1: **240 g/L**

Applicant: **INDUSTRIAS AFRASA, S.A.**
Zone(s): **southern**
Verified by MS: **yes**

professional use ☒
non professional use ☐

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|-----------|-----------------|---|-------------------------------|--|--|--|---|---|--|---|-------------------------|-------------------|---|
| Use-No. * | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, Fnp G, Gn, Gnp 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 a) per use b) per crop/season | Min. interval between applications (days) | kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season | g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | |
| 1 | SEU | Grapes | F | Annual grasses, broadleaves | Boom spraying Directed spray to ground ⁽¹⁾ | Dormant BBCH: 00 (Autumn – Early Spring) | a) 1 b) 1 | - | a) 0,6L/ha b) 0,6 L/ha | a) 0.144 as/ha b) 0,144 Kg as/ha | 400 | 180 | Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |
| 2 | SEU | Olive | F | Annual grasses, broadleaves | Boom spraying Directed spray to ground ⁽¹⁾ | BBCH: 80-90 (Autumn – Winter) | a)1 b) 1 | - | a) 0,6L/ha b) 0,6L/ha | a) 0.144kg as/ha b) 0.44 kg as/ha | 400- | 14 ⁽²⁾ | with presence of dropped olives on the ground Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |
| | | | | | | | | | | | 400 | 7 ⁽²⁾ | without presence of dropped olives on the ground Not acceptable because of the risk for |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|-----------|-----------------|---|-----------------------|--|--|--|---|---|--|---|-------------------------|------------|--|
| Use-No. * | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, G, Gn, 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, other dose rate expression, dose range (min-max) |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/season | Min. interval between applications (days) | kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season | g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min / max | | |
| | | | | | | | | | | | | | aquatic organisms, and the lack of data to demonstrate , efficacy |
| | | | | | | BBCH 00-49 (Winter-spring) | a) 1 b) 1 | – | a) 0,6L/ha b) 0,6 L/ha | a) 0.144kg as/ha b) 0.144 kg as/ha | 400 | NP | Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |
| 3 | SEU | Pome fruits | F | Annual grasses, broadleaves | Boom spraying Directed spray to ground ⁽¹⁾ | Dormant BBCH: 00 (Autumn – Early Spring) | a) 1 b) 1 | - | a) 0,6L/ha b) 0,6 L/ha | a) 0.144kg as/ha b) 0.144 kg as/ha | 400- | 180 | Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |
| 4 | SEU | Stone fruits | F | Annual grasses, broadleaves | Boom spraying Directed spray to ground ⁽¹⁾ | Dormant BBCH: 00 (Autumn – Early Spring) | a) 1 b) 1 | - | a) 0,6L/ha b) 0,6 L/ha | a) 0.144kg as/ha b) 0.144 kg as/ha | 400 | 180 | Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |
| 5 | SEU | Citrus | F | Annual grasses, broadleaves | Boom spraying Directed spray to ground ⁽¹⁾ | BBCH: 00 (Autumn – Early Spring) | a) 1 b) 1 | - | a) 0,6L/ha b) 0,6 L/ha | a) 0.144kg as/ha b) 0.44 kg as/ha | 400 | 21 | Not acceptable because of the risk for aquatic organisms, and the lack of data to demonstrate , efficacy |

(1) Applied as a banded application to the ground and along the crop row; the area between the rows is not treated

(2) PHI: 7 days if there is not presence of olives in the soil, PHI: 14 days if there is presence of olives in the soil

- 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

DIPIRIL (OXYFLUORFEN 24% EC) is a red, with aromatic solvent odour, emulsion, oil in water formulation, containing 240 g/l of oxyfluorfen. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product is flammable (flash point: 29°C). It has a self-ignition temperature of 359°C. The preparation contains more than 10% of H304 compounds and the kinematic viscosity at 40°C is below 20.5mm²/s. Therefore the preparation is classified H304 category 1 according to CLP criteria. In aqueous solution (1%), it has a pH value of 5.7 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/EVOH. Its technical characteristics are acceptable for an EC formulation. The formulation is classified H226 category 3 and H304 category 1.

3.1.2 Methods of analysis

Analytical method for the determination of the active substance in the formulation is available and validated. An analytical method for the determination of N,N-dimethylnitrosamine (relevant impurity from technical oxyfluorfen) in the preparation with a LOQ = 12 µg/kg is required.

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of residues of oxyfluorfen in plants (high water content, acidic and fatty crops), food of animal origin, soil, water (surface and drinking) and air.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

| Active Substance: Oxyfluorfen | | | |
|--------------------------------------|--|---|---|
| ADI | 0.003 mg kg bw/d | | Anses (GRED 2014) |
| ARfD | 0.3 mg/kg bw | | |
| AOEL | 0.013 mg/kg bw/d | | |
| Dermal absorption | Based default values according to guidance on dermal absorption (Efsa 2012): | | |
| | | Concentrate (used in formulation) 1.2 g/L | Spray dilution (used in formulation) 240 g/L |
| | Dermal absorption endpoints % | 25 | 60 (correction by oral absorption) |

3.1.3.1 Acute Toxicity

DIPIRIL (OXYFLUORFEN 24% EC) has a low toxicity in respect to acute oral, and dermal toxicity and is not irritating to the rabbit skin. DIPIRIL (OXYFLUORFEN 24% EC) has a low acute inhalation toxicity, is an eye irritant and is a skin sensitizer.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

| Crop | F/G ⁷ | Equipment | Application rate L product/ha | Spray dilution (L/ha) | Model |
|---|------------------|--|--|-----------------------------|-----------------|
| Risk envelop Grape/olive/pome and stone fruits/ citrus | F | Tractor mounted/trailed boom sprayer, Hydraulic nozzles | 0,6 L DIPIRIL/ha (144 g oxyfluorfen/ha) | 400 | German Model |

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

| Crop | Equipment | PPE and/or working coverall | % AOEL oxyfluorfen |
|---|---|---|-----------------------|
| Risk envelop Grape/olive/pome and stone fruits/ citrus | Tractor mounted/trailed boom sprayer, hydraulic nozzles | Working coverall and gloves during mixing/loading and application | 69 |

According to the model calculations, it can be concluded that the risk for the operator using DIPIRIL (OXYFLUORFEN 24% EC) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application for tractor mounted equipment.

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 4,8 % of the AOEL of oxyfluorfen.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to DIPIRIL (OXYFLUORFEN 24% EC).

3.1.3.4 Worker Exposure

DIPIRIL (OXYFLUORFEN 24% EC) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

3.1.3.5 Résident 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:

| | | % ADI | % AOEL |
|---|-------|-------|--------|
| Maximum daily measurement (0.5 ng/m ³) | Adult | < 0.1 | < 0.1 |
| | Child | < 0.1 | < 0.1 |
| Maximum weekly measurement (3.01 ng/m ³) | Adult | < 0.1 | < 0.1 |
| | Child | < 0.1 | < 0.1 |

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for oxyfluorfen as laid down in Reg. (EU) 396/2005 is not expected in grapes, olive, pome fruits, stone fruits and citrus.

The chronic and the short-term intakes of oxyfluorfen residues are unlikely to present a public health concern.

⁷ Open field or glasshouse

As far as consumer health protection is concerned, France agrees with the authorization of the proposed use(s).

Summary for oxyfluorfen

| Use- No. | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg 149/2008 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comments |
|-------------|-----------------|---------------------------------|----------------------------------|-----------------------------------|--|--------------------------------------|---|---|----------|
| 1 | Citrus | Yes | Yes | Yes | Yes | Yes | N | N | |
| 2 | Pome fruits | Yes | Yes | Yes | Yes | Yes | | | |
| 3 | Stone fruits | Yes | Yes | Yes | Yes | Yes | | | |
| 4 | Grapes | Yes | Yes | Yes | Yes | Yes | | | |
| 5 | Olives | Yes | Yes | Yes | Yes | Yes | | | |

Among the crops under consideration residue above 0,1 mg/kg are only expected in olives. Consequently standard hydrolysis study should be required in order to investigate the nature of residue in processed commodities. However as there is no step of pasteurisation, cooking-boiling or sterilisation in the process of olive oil or table olive such study is not considered to be required.

Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.

Since citrus, pome fruit, stone fruit, grapes and olives are perennial crops, the nature and magnitude of oxyfluorfen residues rotational crops was not further investigated under the current application.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for oxyfluorfen as laid down in Reg. (EU) 396/2005 is not expected in grapes, olive, pome fruits, stone fruits and citrus.

The chronic and the short-term intakes of oxyfluorfen residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the proposed use(s).

Summary for DIPIRIL

| Crop | PHI for OXYFLUORFEN 24% EC proposed by applicant | PHI/ Withholding period* sufficiently supported for oxyfluorfen | PHI for DIPIRIL proposed by zRMS | zRMS Comments (if different PHI proposed) |
|--------------|---|---|-------------------------------------|---|
| Citrus | 21 days | Yes | / | |
| Pome fruits | Application at BBCH00, PHI 180 days | Yes | / | |
| Stone fruits | Application at BBCH00, PHI 180 days | Yes | / | |
| Grapes | Application at BBCH00, PHI 180 days | Yes | / | |

| Crop | PHI for OXYFLUORFEN 24% EC proposed by applicant | PHI/ Withholding period* sufficiently supported for oxyfluorfen | PHI for DIPIRIL proposed by zRMS | zRMS Comments (if different PHI proposed) |
|--------|--|---|-------------------------------------|---|
| Olives | 14 days (1) | Yes | / | |
| | 7 days (1) | | / | |
| | N/A (2) | | / | |

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).

(1) Application late in the growing season: PHI: 7 days if there is not presence of olives on the soil, PHI: 14 days if there is presence of olives on the soil

(2) Application early in the growing season (absence of olives on trees and on the ground): PHI in days not applicable (application time primarily set by the growth stage during dormant period); PHI usually at least 180 days

3.1.5 Environmental fate and behaviour

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

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

PECgw for oxyfluorfen do not occur at levels exceeding those mentioned in regulation (EC) N° 1107/2009 and guidance document SANCO 221/2000⁸. 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.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

According to new requirements of Regulation (UE) N° 284/2013, data on chronic effects on adult bees and on development of bees should have been submitted by notifier as exposure of bees to the formulation cannot be excluded. Therefore, the risk to bees cannot be completely fulfilled. Thus, Member States may consider the risk for bees as not finalized, or required mitigation measures to avoid exposure of bees, and/or request chronic adults and

⁸ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

larvae toxicity studies at post-registration. At national level, zRMS will conclude that the risk for bees is not finalized.

The risks to aquatic organisms from exposure to the active substance oxyfluorfen were not acceptable using the peer reviewed RAC for aquatic organisms of 0.01 µg a.s./L (NOEC = 0.02 µg a.s./L, AS = 2). Therefore, zRMS concluded to a non-acceptable risk for aquatic organisms exposed to DIPIRIL (OXYFLUORFEN 24% EC).

3.1.7 Efficacy

Considering the data submitted:

- In the frame of the dose restriction to 150 g/ha of oxyfluorfen imposed by Regulation (EU) N° 2017/359, the applicant claims a dose of 144 g/ha of oxyfluorfen. The interest of the claimed dose of 144 g/ha of oxyfluorfen was not demonstrated. As a consequence, the provided data do not enable to finalize the evaluation.
- the selectivity level of DIPIRIL (OXYFLUORFEN 24% EC) is considered as satisfactory for all the claimed uses.
- the risks of negative impact on yield, quality, wine-making and cider-making, propagation, and adjacent crops are considered as acceptable. However, special attention should be paid to the conditions of application close to adjacent crops.
- the risk of resistance development or appearance to oxyfluorfen does not require a monitoring for the claimed uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **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

N/A : no marketing authorisation granted.

3.4.2 Post-authorisation data requirements

- N/A : no marketing authorisation granted

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2

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 du produit phytopharmaceutique **DIPIRIL***

de la société **INDUSTRIAS AFRASA, S.A.**

enregistrée sous le **n°2014-1194**

Vu les conclusions de l'évaluation de l'Anses du 19 mai 2020,

Considérant qu'un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation du produit, ne peut être exclu,

Considérant également que les données disponibles ne permettent pas de justifier la dose revendiquée,

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 | |
|---------------------------------------|--|
| Nom du produit | DIPIRIL |
| Type de produit | Produit de référence |
| Titulaire | INDUSTRIAS AFRASA S.A. Ciudad de Sevilla, 53 Pol. ind. Fuente del Jarro, 46988 Paterna - Valencia, Espagne |
| Formulation | Concentré émulsionnable (EC) |
| Contenant | 240 g/L - oxyfluorène |
| Numéro d'intrant | 9606-2014.01 |
| Numéro d'AMM | - |
| Fonction | Herbicide |
| Gamme d'usage | Professionnel |

A Maisons-Alfort, le

28 DEC. 2020

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle 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

| Liste des usages refusés | | | |
|---|---------------|-------------------------------|-----------------------------|
| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
| 12055911 Agrumes*Dés herbager*Cult. Installées | 0,6 L/ha | 1/an | 21 |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé car les données disponibles ne permettent pas de justifier la dose revendiquée. | | | |
| 12555902 Fruits à noyau*Dés herbager*Cult. Installées | 0,6 L/ha | 1/an | 180 |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé car les données disponibles ne permettent pas de justifier la dose revendiquée. | | | |
| 12505901 Olivier*Dés herbager*Cult. Installées | 0,6 L/ha | 1/an | 7 |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé car les données disponibles ne permettent pas de justifier la dose revendiquée. | | | |
| 12605905 Pommier*Dés herbager*Cult. Installées | 0,6 L/ha | 1/an | 180 |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé car les données disponibles ne permettent pas de justifier la dose revendiquée. | | | |
| 12705902 Vigne*Dés herbager*Cult. Installées | 0,6 L/ha | 1/an | 180 |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques. L'usage est également refusé car les données disponibles ne permettent pas de justifier la dose revendiquée. | | | |

DIPIRIL
AMM n°.

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

DIPIRIL

HERBICIDE DE PRÉLEVÉE

**Concentrée Émulsionnable (EC), contenant
240 g/L d'oxyfluorène.**

AMM n° 00000

Homologué et Distribué par :

INDUSTRIAS AFRASA, S.A.

Ciudad de Sevilla, 53
Pol. Ind. fuente del Jarro
46988 Paterna (Valencia)
Espagne
Tel. 96 132 17 00
Fax 96 132 17 16

Email: afrasa@afrasa.es

RÉSERVÉE AUX UTILISATEURS PROFESSIONNELS

Numéro du lot et date de fabrication, voir sur le bidon.

250 ml, 1, 5, 10 et 20 Litres

PRÉSENTATION DU PRODUIT

DIPIRIL est un désherbant de prélevée, à longue persistance d'action, pour le contrôle des mauvaises herbes graminées annuelles et les dicotylédones. DIPIRIL se positionne dans les premiers centimètres du sol et provoque la mort des plantules des mauvaises herbes au cours de leur élévation et aussi les très jeunes déjà sorties.

USAGES, DOSES, NOMBRE D'APPLICATIONS MAXIMUM ET DÉLAI AVANT RÉCOLTE (DAR)

| Culture | MMHH | Dose l/ha | Applications par culture / saison | DAR (jours) | ZNT |
|---|--|--------------|---|----------------|------|
| Vigne (raisin de table et à vin) cultures installées | Monocotylédones annuelles et Dicotylédones | 2.0-4.0 | 1 | 180 | 10 m |
| Olivier (olive de table et à huile) | | 1.0-4.0 | 1 | 7 /14 /NP | 10 m |
| Fruitiers à pépin (pommier, poirier, cognassier, nashi, etc) cultures installées | | 2.0-4.0 | 1 | 180 | 10 m |
| Fruitiers à noyau (pêcher/nectarine, abricotier, prunier, cerisier, etc) cultures installées | | 2.0-4.0 | 1 | 180 | 10 m |
| Agrumes (oranges, citrons, mandarines, etc), cultures installées | | 2.0-4.0 | 1 | 21 | 10 m |

Vigne (raisin de table et à vin): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Olivier (olive de table et à huile): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs).

Traitement avant et pendant la récolte (automne et hiver, BBCH 80-90):

- Avec présence d'olives tombées au sol au moment du traitement : 1.0 l/ha. Délai avant récolte: 14 jours
- Sans présence d'olives tombées au sol au moment du traitement : 2.0-4.0 l/ha. Délai avant récolte: 7 jours

Traitement après récolte jusqu'à avant floraison (hiver et printemps, BBCH 00-49): 2.0-4.0 l/ha. Délai avant récolte: non fixé.

Fruitiers à pépin (pommier, poirier, cognassier, nashi, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Fruitiers à noyau (pêcher/nectarine, abricotier, prunier, cerisier, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Agrumes (oranges, citrons, mandarines, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 21 jours.

RECOMMANDATIONS D'EMPLOI

- Soigner la pulvérisation par une application homogène, sur terre propre, en pré-émergence des mauvaises herbes.
- Éviter toute projection sur les arbres ou ceps à désherber
- Volume d'eau conseillé:
 - Application avec pulvérisateur suspendu au tracteur: 400 l/ha.

PRÉPARATION DE LA BOUILLIE

DIPIRIL s'utilise en pulvérisation après dilution dans l'eau. Remplir la cuve à 1/2 d'eau, mettre sous agitation, agiter le bidon et verser la quantité de DIPIRIL nécessaire puis compléter le remplissage. Maintenir l'agitation jusqu'à la fin de l'application.

PRECAUTIONS

- Pendant la préparation de la bouillie et au cours de l'application :
 - Porter un vêtement de protection et des gants appropriés.
 - Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie par temps calme, sans vent fort pour éviter, toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
 - Appliquer, après dilution, les fonds de cuve conformément à la législation en vigueur.
- Emballage : Réemploi de l'emballage interdit.
Éliminer les emballages vides via une collecte organisée par un 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.
- Stocker dans un local phytosanitaire conforme et fermé à clé. Conserver hors de porte des enfants, à l'écart des aliments et boissons y compris ceux pour animaux.
- Pour éviter le développement de résistances, ne pas appliquer ce produit ou tout autre contenant une substance active de la même famille chimique ou ayant le même mode d'action plus d'une application par année et culture.

Mélanges

Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de bonnes pratiques des officiels.

Consulter le site : <http://e-phy.agriculture.gouv.fr>

Important





Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées 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.

| |
|----------------|
| DIPIRIL |
|----------------|

| | |
|---|---|
| BIEN LIRE L'ÉTIQUETTE AVANT TOUTE UTILISATION | |
| <p>En cas d'urgence appeler le n° 15 ou le Centre Anti-poison de Paris 01 40 05 48 48. Signaler les symptômes au réseau Phyt'attitude, n° 0 800 887 887 (appel gratuit depuis un poste fixe) Fiche de Données de Sécurité: contacter XXXX - xxx@xxx.es - Tel.: +34 000 000 000</p> <p>Les limites maximales de résidus sont disponibles sur le site: http://ec.europa.eu/sanco_pesticides/public/index.cfm.</p> <p>240 g/l d'oxyfluorène - Concentré Émulsionnable (EC) Autorisation Mise Marché n° 000000</p> <p>Usages et doses autorisés: Vigne * Désherbage * Cultures installées, 2.0-4.0 l/ha; Olivier * Désherbage, 1.0-4.0 l/ha; Pommier * Désherbage * Cultures installées, 2.0-4.0 l/ha; Poirier - Cognassier - Nashi * Désherbage * Cultures installées, 2.0-4.0 l/ha; Pécher * Désherbage * Cultures installées, 2.0-4.0 l/ha; Abricotier * Désherbage * Culture installée, 2.0-4.0 l/ha; Cerisier * Désherbage * Cultures installées, 2.0-4.0 l/ha; Prunier * Désherbage * Cultures installées, 2.0-4.0 l/ha; Agrumes * Désherbage * Cultures installées 2.0-4.0 l/ha;</p> | |
|  <p>Xn - Nocif</p>  <p>N - Dangereux pour l'environnement</p> | <p>R10 : Inflammable R20 : Nocif par inhalation R36/38 : Irritant pour les yeux et la peau R43 : Peut entraîner une sensibilisation par contact avec la peau R50/53 : Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique</p> <p>S1 : Conserver sous clé S2 : Conserver hors de la portée des enfants S13 : Conserver à l'écart des aliments et boissons, y compris ceux pour animaux S24/25 : Éviter le contact avec la peau et les yeux S35 : Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage S36/37 : Porter un vêtement de protection et des gants appropriés S39 : Porter un appareil de protection des yeux/du visage S43 : En cas d'incendie, utiliser mousse. Ne jamais utiliser d'eau S46 : En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette S57 : Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant</p> <p>RESPECTER LES INSTRUCTIONS D'UTILISATION POUR ÉVITER LES RISQUES POUR L'HOMME ET L'ENVIRONNEMENT</p> |
| <p>Porter un vêtement de protection et des gants, pendant toutes les phases de mélange et de chargement. Consulter les instructions spéciales/la fiche de données de sécurité.</p> <p>Sp1 Ne pas polluer l'eau avec le produit ou son emballage.</p> <p>Spe3 Pour protéger les organismes aquatiques, respecter une bande tampon de végétation par rapport aux points d'eau de 10 mètres.</p> <p>Spe 3 Pour protéger les plantes non ciblées, respecter une zone-tampon non traitée de 10 mètres par rapport aux terres non agricoles.</p> <p>Délai rentrée: 6 heures.</p> | |
| <p>Contenu: 250 ml, 1, 5, 10, 20 Litres</p> |   <p>564131 002144</p> |


Bonnes pratiques phytopharmaceutiques

10 gestes responsables et professionnels

AVANT L'APPLICATION


- 1  **STOCKER** les produits phytopharmaceutiques dans un local spécifique, signalisé, fermé à clef et aéré/ventilé. Les classer et les identifier selon leur profil de risque.
- 2  **BIEN LIRE** l'étiquette avant toute utilisation : usages autorisés, précautions d'emploi (zone non traitée, délai de rentrée, délai avant récolte).
- 3  **CHOISIR** ses équipements de protection individuels (gants, lunettes, masque, bottes, tablier, combinaison) en tenant compte de chaque situation de travail (produit, exposition...).
- 4  **MAINTENIR** le bon état du matériel d'application : vérification à chaque utilisation, réglage régulier et contrôle tous les 5 ans par un organisme habilité.
- 5  **SÉCURISER** le remplissage : se placer à distance des points d'eau, avoir un dispositif anti-retour, surveiller en continu les opérations.
- 6  **RINCER** 3 fois les bidons au cours du remplissage et verser les eaux de rinçage dans la cuve du pulvérisateur. Égoutter complètement les emballages.

PENDANT L'APPLICATION

- 7  **ÉVITER** la dérive de pulvérisation : respect strict des zones non traitées en bord de cours d'eau, vent maximum de 3 Beaufort (19 km/h), buses à limitation de dérive et pulvérisateur bien réglé.

APRÈS L'APPLICATION

- 8  **DILUER** au champ le fond de cuve avec un volume d'eau claire équivalent à 5 fois le fond de cuve et l'appliquer sur la parcelle traitée. Renouveler 3 fois l'opération. Traiter les effluents résiduels par un dispositif reconnu par le Ministère de l'environnement.
- 9  **NETTOYER** les EPI en fin de traitement, se laver les mains et prendre une douche. Stocker les EPI usagés en vue de leur élimination.
- 10  **RECYCLER** les emballages vides égouttés, dans le cadre des campagnes de collecte Adivalor.

| Règlement CE 1272/2008 | | |
|---|---|---|
|  |  |  |
| ATTENTION | | |
| <p>H226 : Liquide et vapeurs inflammables H317 : Peut provoquer une allergie cutanée H319 : Provoque une sévère irritation des yeux H332 : Nocif par inhalation H410: Toxique pour les organismes aquatiques, entraîne des effets à long</p> <p>P102: Tenir hors de portée des enfants P210: Tenir à l'écart de la chaleur/des étincelles/des flammes nues/des surfaces chaudes. — Ne pas fumer. P273: Éviter le rejet dans l'environnement P280: Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage P303+P361+P353 : EN CAS DE CONTACT AVEC LA PEAU (ou les cheveux): Enlever immédiatement les vêtements contaminés. Rincer la peau à l'eau/se doucher P305+P351+P338 : EN CAS DE CONTACT AVEC LES YEUX: Rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer. P309+P310+P101: EN CAS d'exposition ou d'un malaise: Appeler immédiatement un CENTRE ANTIPOISON ou un médecin. En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette P391 : Recueillir le produit répandu P501 : Éliminer le contenu/récipient conformément à la réglementation nationale</p> <p>RESPECTER LES INSTRUCTIONS D'UTILISATION POUR ÉVITER LES RISQUES POUR L'HOMME ET L'ENVIRONNEMENT Porter un vêtement de protection et des gants, pendant toutes les phases de mélange et de chargement. Consulter les instructions spéciales/la fiche de données de sécurité. Sp1 Ne pas polluer l'eau avec le produit ou son emballage. Spe3 Pour protéger les organismes aquatiques, respecter une bande tampon de végétation par rapport aux points d'eau de 10 mètres. Spe 3 Pour protéger les plantes non ciblées, respecter une zone-tampon non traitée de 10 mètre par rapport aux terres non agricoles. Délai rentrée: 6 heures.</p> | | |

Appendix 3 – Letter(s) of Access

Not applicable.