

REGISTRATION REPORT

Part A

Risk Management

Product code: AG-MD1-312.5 SC

Product name: TAVAS

Active substances:

metribuzin, 250 g/L

diflufenican, 62.5 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(marketing authorisation and label extension)

Applicant: ADAMA France S.A.S.

Date: 23/08/2017

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PART A – Risk Management

The company ADAMA France S.A.S. has requested marketing authorisation in France for the product TAVAS (formulation code: AG-MD1-312.5 SC), containing 250 g/L metribuzin and 62.5 g/L diflufenican 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 TAVAS (AG-MD1-312.5 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TAVAS (AG-MD1-312.5 SC) have been made using endpoints agreed in the EU peer review of both metribuzin and diflufenican.

This document describes the specific conditions of use and labelling required for France for the registration of TAVAS (AG-MD1-312.5 SC).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application to market TAVAS (AG-MD1-312.5 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

Metribuzin

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

In assessing applications to authorise plant protection products containing metribuzin for uses other than in post-emergence selective herbicide in potatoes Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

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 metribuzin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment Member States:

- must pay particular attention to the protection of algae, aquatic plants, non-target plants outside the treated field and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.
- must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment.

The Member States concerned shall request the submission of further data to confirm the risk assessment for groundwater. They shall ensure that the notifiers at whose request metribuzin has been included in this Annex provide such studies to the Commission within two years from the approval.

An EFSA conclusion is available (EFSA Scientific Report (2006) 88, 1-74).

A Review Report is available (SANCO/10051/2006 final rev. 1, 21 November 2011).

Diflufenican

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 diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account.

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

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,
- the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate.

An EFSA conclusion is available (EFSA Scientific Report (2007) 122, 1-84).

A Review Report is available (SANCO/3782/08 – rev. 1, 14 March 2008).

1.3 Regulatory approach

The present applications (2014-0849 [marketing authorisation] and 2015-6482 [extension of use]) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

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

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, 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 TAVAS (AG-MD1-312.5 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. A copy of the letter(s) of access for metribuzin and its metabolites is reproduced in Part A, Appendix 3.

A letter is not necessary for diflufenican: the applicant has provided equivalent studies to the original applicant's

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/AGRGI632554A/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/AGRGI407093A/jo>

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

Annex II dossier.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

| | |
|--------------------------------|--|
| Product name (code) | TAVAS (AG-MD1-312.5 SC) |
| Authorisation number | 2170691 |
| Function | Herbicide |
| Applicant | ADAMA France S.A.S. |
| Composition | 250 g/L metribuzin 62.5 g/L diflufenican |
| Formulation type (code) | Suspension concentrate (SC) |
| Packaging | High-density polyethylene bottles or containers holding 1, 5, 10 or 20 L product |

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

| | | |
|--|--|--|
| Physical hazards | - | |
| Health hazards | - | |
| 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 | 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. 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

The authorisation of the preparation is linked for professional uses only to the following conditions:

| | |
|-------|--|
| SP 1 | Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads. |
| SPe 1 | To protect groundwater, following use on pome fruits or stone fruits, do not apply this or any other product containing metribuzin more than every other year. |
| SPe 2 | To protect aquatic organisms, do not apply to artificially drained soil for uses on pome fruits and stone fruits. |
| SPe 2 | To protect groundwater, do not apply this product to more than 50 % of the plot surface for the uses on grapes, pome fruits and stone fruits, when using the 2 L/ha rate. |
| SPe 3 | To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres ⁸ with an unsprayed vegetated buffer zone of 5 metres to surface water bodies for the uses on potato |
| SPe 3 | To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies for the uses on grapes, pome fruits and stone fruits. |
| SPe 3 | To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land. |

2.2.4 Other phrases linked to the preparation

| | | |
|---|-----------------------|---|
| Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details | | |
| Re-entry period ¹⁰ : Six hours | | |
| Pre-harvest interval ¹¹ : | Pome fruits | 14 days |
| | Table and wine grapes | F - Application must be made at growth stage BBCH 59 at the latest. |
| | stone fruits | F - Application must be made at growth stage BBCH 59 at the latest |
| | Potato | F - Application must be made at growth stage BBCH 09 at the latest |
| Other mitigation measures: | | |
| - Do not harvest fruit which have been in direct contact with the soil, for application after growth stage BBCH 59. | | |
| The label must include the following recommendations: “EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.” | | |
| The label must reflect the conditions of authorisation. | | |

⁸ The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹⁰ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹¹ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

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

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

| | | | |
|--------------------------------|-------------------------|-----------------------------|-------------------------------------|
| PPP (product name/code) | TAVAS/(AG-MD1-312.5 SC) | Formulation type: | GAP, date: 2017-08-23 |
| active substance 1 | metribuzin | Conc. of a.s. 1: | suspension concentrate (SC) |
| active substance 2 | diflufenican | Conc. of a.s. 2: | 250 g/L |
| Applicant: | ADAMA France S.A.S. | professional use | <input checked="" type="checkbox"/> |
| Zone(s): | southern EU | non-professional use | <input type="checkbox"/> |
| Verified by MS: | yes | | |
| Field of use: | herbicide | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|--------------------------------|--------------------|--|-------------------|---|---|---|---|--|--|-----------------------------|---------------|--|
| 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: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number (min. interval between appl.) a) per use b) per crop/ season | 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 | | |
| Marketing authorisation | | | | | | | | | | | | |
| 4 | FR | Wine and table grapes | F | Weeds | soil spraying broadcast tractor- mounted sprayer | BBCH 00- 59 Feb-Jun | a) 1 b) 1 | a) 1 b) 1 | a) 62.5/250 b) 62.5/250 | 80-400 | F | Acceptable |
| 5 | FR | Wine and table grapes | F | Weeds | soil spraying on rows tractor- mounted sprayer | BBCH 00- 59 Feb-Jun | a) 1 b) 1 | a) 2 b) 2 | a) 125/500 b) 125/500 | 80-400 | F | Acceptable For application on rows only. Do not apply on more than 50 % of plot surface. |
| 6 | FR | pome fruits | F | Weeds | soil spraying on rows tractor- mounted sprayer | BBCH 00-85 Feb-Aug | a) 1 b) 1 | a) 1 b) 1 | a) 62.5/250 b) 62.5/250 | 80-400 | 14 | Acceptable Do not apply to artificially drained soil Do not harvest fruit which have been in direct contact with the soil, for application after growth stage BBCH 59. Do not apply this or any other product containing metribuzin more than every other year |
| 7 | FR | pome fruits | F | Weeds | soil spraying on rows tractor- | BBCH 00-85 Feb-Aug | a) 1 b) 2 | a) 2 b) 2 | a) 125/500 b) 125/500 | 80-400 | 14 | Acceptable For application on rows only. |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
|-------------------------|--------------------|--|-------------------|---|-------------------------|---|---|--|--|-----------------------------|---------------|---|
| 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 appl.) a) per use b) per crop/ season | 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 | | |
| | | | | | mounted sprayer | | | | | | | <p>e.g. safener/synergist per ha</p> <p>e.g. recommended or mandatory tank mixtures</p> |
| | | | | | | | | | | | | <p>Do not apply on more than 50 % of plot surface.</p> <p>Do not apply to artificially drained soil</p> <p>Do not harvest fruit which have been in direct contact with the soil, for application after growth stage BBCH 59.</p> <p>Do not apply this or any other product containing metribuzin more than every other year</p> |
| 8 | FR | stone fruits | F | Weeds | Broadcast soil spraying | BBCH 00-59 Feb-April | a) 1 b) 1 | a) 1 b) 1 | a) 62.5/250 b) 62.5/250 | 80-400 | F | <p>Do not apply to artificially drained soil</p> <p>Do not apply this or any other product containing metribuzin more than every other year</p> |
| 9 | FR | stone fruits | F | Weeds | soil spraying on rows | BBCH 00-59 Feb-April | a) 1 b) 1 | a) 2 b) 2 | a) 125/500 b) 125/500 | 80-400 | F | <p>Acceptable</p> <p>For application on rows only.</p> <p>Do not apply on more than 50 % of plot surface.</p> <p>Do not apply to artificially drained soil</p> <p>Do not apply this or any other product containing metribuzin more than every other year</p> |
| Extension of use | | | | | | | | | | | | |
| 1 | FR | Potato | F | Weeds | Broadcast soil spraying | BBCH 00-09 | a) 1 b) 1 | a) 1.2 b) 1.2 | a) 75/300 b) 75/300 | 100-400 | F | Acceptable |
| | | | | | | | | | | | | |

| | | |
|-------------------------------|--|---|
| Remarks table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) | (d) Select relevant |
| | (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 | (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 |
| | (c) g/kg or g/l | (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 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. | 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 TAVAS (AG-MD1-312.5 SC) is a suspension concentrate. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of an off-white liquid, with a characteristic odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 600 °C. In aqueous solution (1 %), it has a pH value of 7.0 at 21 °C. There are no effects 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 substances' 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 packaging. Its technical characteristics are acceptable for a suspension concentrate 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 in the formulation are available and validated. As the active substances diflufenican and metribuzin do not contain relevant impurities, no pertinent analytical method is required.

3.1.2.2 Analytical methods for residues

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

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

| Active substance: diflufenican | | | |
|---------------------------------------|---|--|---|
| ADI | 0.2 mg kg bw/d | EU | |
| ARfD | Not relevant | | |
| AOEL | 0.11 mg/kg bw/d | | |
| Dermal absorption | Based on default values according to guidance on dermal absorption (Efsa 2012): | | |
| | | Concentrate (tested) 600 g/L | Diluted formulation (tested) 1.5 g/L |
| | <i>In vitro</i> (human) % | 0.15 | 5 |
| | | Concentrate (used in formulation) 64.4 g/L | Spray dilution (used in formulation) 0.16 g/L |
| | Dermal absorption endpoints % | 25 | 75 |

| Active substance: metribuzin | | | |
|-------------------------------------|--------------------------------------|---|---|
| ADI | 0.013 mg kg bw/d | EU | |
| ARfD | 0.02 mg/kg bw/d | | |
| AOEL | 0.02 mg/kg bw/d | | |
| Dermal absorption | Based on “triple pack” approach: | | |
| | | Concentrate (tested) 264.6 g/L | Diluted formulation (tested) 0.44 g/L |
| | <i>In vitro</i> (human) % | 1 | 58 |
| | <i>In vitro</i> (rat) % | 29 | 56 |
| | <i>In vivo</i> (rat) % | 1 | 30 |
| | | Concentrate (used in formulation) 268.8 g/L | Spray dilution (used in formulation) 0.67 g/L |
| | Dermal absorption endpoints % | 0.03 | 31 |

3.1.3.1 Acute Toxicity

TAVAS (AG-MD1-312.5 SC), containing 62.5 g/L pure diflufenican and 250 g/L pure metribuzin has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed is as shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

| Crop | F/G ¹² | Equipment | Application rate 2 L product/ha (g a.s./ha) | Spray dilution (L/ha) | Model |
|------------------------------------|-------------------|---|---|--------------------------|-------|
| Wine and table grapes, fruit trees | F | Tractor-mounted boom sprayer, hydraulic nozzles | 129 g diflufenican 538 g metribuzin | 80-400 | BBA |

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

| Crop | Equipment | PPE and/or working coverall | % AOEL diflufenican | % AOEL metribuzin |
|------------------------------------|---|---|---------------------|-------------------|
| Wine and table grapes, fruit trees | Tractor-mounted boom sprayer, hydraulic nozzles | Working coverall and gloves during mixing/loading and application | 9 | 63 |

¹² Open field or glasshouse

According to the model calculations, it may be concluded that the risk for the operator using TAVAS (AG-MD1-312.5 SC) is acceptable for application on all crops, with a working overall (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 1 % of the AOEL of diflufenican and 8.5 % of the AOEL of metribuzin.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to TAVAS (AG-MD1-312.5 SC).

3.1.3.4 Worker Exposure

TAVAS (AG-MD1-312.5 SC) is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. Worker exposure is considered to be not relevant.

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

3.1.3.5 Relevance of metabolites

For metribuzin, three metabolites were identified:

- DK (0.264 µg/L) is not relevant.
- DADK (4.492 µg/L) and-methyl-DADK (10.164 µg/L) are not relevant but a consumer risk assessment via drinking water was essential. For these two metabolites, consumer exposure was below the ADI of metribuzin (1 % of ADI for DADK and 2 % for 4-methyl-DADK).

The metabolite 4-methyl-DADK is present at a concentration greater than 10 µg/L for the arboriculture use. Thus these crops cannot be authorised in France unless measures such as lower overall doses (one application every two years) are in place

3.1.4 Residues and Consumer Exposure

Overall conclusion

The available data are considered to be sufficient for risk assessment purposes. Any exceedence of the current MRLs of 0.1* mg/kg for metribuzin and of 0.01* mg/kg for diflufenican in fruits (pome fruits, stone fruits and grapes) and potato as laid down in Reg. (EU) 396/2005 is not expected.

The available data are considered sufficient for risk assessment purposes.

The chronic and short-term intakes of metribuzin residues and chronic intake of diflufenican 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.

Data gaps

None.

Data required post-authorisation

None.

3.1.4.1 Residues

Information on TAVAS (AG-MD1-312.5 SC)

| Crop | PHI for TAVAS (AG-MD1-312.5 SC) proposed by applicant | PHI/withholding period* sufficiently supported for | | PHI for TAVAS (AG-MD1-312.5 SC) proposed by zRMS | zRMS Comments (if different PHI proposed) |
|--------------------------------|---|--|--------------|--|---|
| | | metribuzin | diflufenican | | |
| Pome fruits | PHI 14 (BBCH 00-85) | Yes | Yes | PHI 14 (BBCH 00-85) | No-residue situation expected |
| Stone fruits | F** (BBCH 00-59 or on soil at post-harvest) | Yes | Yes | F** (BBCH 00-59) | No-residue situation expected |
| Grapes (wine and table grapes) | F** (BBCH 00-59) | Yes | Yes | F** (BBCH 00-59) | No-residue situation expected |
| Potato | F** (BBCH 00-09) | Yes | Yes | F** (BBCH 00-09) | No-residue situation expected |

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).

Waiting periods before planting succeeding crops

Not relevant.

3.1.4.2 Consumer exposure

The preparation AG-MD1-312.5 SC contains diflufenican and metribuzin.

Summary for diflufenican

| | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg. 603/2015 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comments |
|---|--------------------------------|---------------------------|----------------------------|-----------------------------|---|------------------------------|--|--------------------------------------|--|
| / | Pome fruits | Yes | Yes | Yes | Yes | Yes | No | No | For pome fruits: do not harvest fruits touching the ground. No-residue situation expected. |
| / | Stone fruits | Yes | Yes | Yes | Yes | Yes | | No | |
| / | Grapes (wine and table grapes) | Yes | Yes | Yes | Yes | Yes | | No | |

| | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg. 603/2015 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comments |
|---|--------|---------------------------|----------------------------|-----------------------------|---|------------------------------|--|--------------------------------------|----------|
| / | Potato | Yes | Yes | Yes | Yes | Yes | | No | |

Summary for metribuzin

| Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance Reg. 1146/2014 | Chronic risk for consumers identified? | Acute risk for consumers identified? | Comments |
|----------|--------------------------------|---------------------------|----------------------------|-----------------------------|---|-------------------------------|--|--------------------------------------|--|
| / | Pome fruits | Yes | Yes | Yes | Yes | Yes | No | No | For pome fruits: do not harvest fruits touching the ground. No-residue situation expected. |
| / | Stone fruits | Yes | Yes | Yes | Yes | Yes | | No | |
| / | Grapes (wine and table grapes) | Yes | Yes | Yes | Yes | Yes | | No | |
| / | Potato | Yes | Yes | Yes | Yes | Yes | | No | |

As residues of the two a.s.s do not exceed the trigger values defined in Reg. (EU) No 603/2015, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

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 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 PEC values of diflufenican, metribuzin and their 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 values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for diflufenican, metribuzin 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, for applications made every other year on apples and stone fruits, and for annual applications on grapes and potato. Therefore no unacceptable risk of groundwater contamination is expected from the intended uses under these conditions.

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 Terrestrial Vertebrates

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 diflufenican and metribuzin. 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 mammals¹³ is acceptable following use of TAVAS (AG-MD1-312.5 SC) according to the proposed patterns.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms was carried out according to the EFSA Guidance Document on Aquatic Ecotoxicology (2013) and considering the EU agreed endpoints of diflufenican and metribuzin, their metabolites and data on the formulation TAVAS (AG-MD1-312.5 SC).

Proposed risk mitigation measures for GAP-use of AG-MD1-312.5 SC

| Crop | Timing of Application | Proposed risk mitigation measures |
|------------------------|-----------------------|--|
| Grapes | February - June | - Spray drift buffer zone of 5 m |
| Pome fruit/stone fruit | February - August | - Spray drift buffer zone of 5 m - Drainage restriction |
| Potato | | - vegetated buffer zone of 10m |

3.1.6.3 Effects on Bees and Other Arthropod Species

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 diflufenican, metribuzin and the formulation AG-MD1-312.5 SC. All hazard quotients for TAVAS (AG-MD1-312.5 SC), diflufenican and metribuzin were less than 50, indicating that the risk to bees is acceptable following use of TAVAS (AG-MD1-312.5 SC) according to the proposed patterns.

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 TAVAS (AG-MD1-312.5 SC).

The in-field and off-crop hazard quotient (HQ) values were below the trigger value, indicating that the risk to in-field and off-crop non-target arthropods is acceptable following use of TAVAS (AG-MD1-312.5 SC) according to the proposed patterns.

¹³ from direct dietary exposure, drinking water and secondary poisoning.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment was carried out according to the Guidance Document on Terrestrial Ecotoxicology (*op. cit.*) and considering the EU agreed endpoints of diflufenican, metribuzin, their metabolites and the formulation AG-MD1-312.5 SC. The acute and chronic TER values for TAVAS (AG-MD1-312.5 SC), diflufenican, metribuzin and their metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of TAVAS (AG-MD1-312.5 SC) according to the proposed patterns.

3.1.6.5 Effects on Soil Non-target Micro-organisms

The risk of AG-MD1-312.5 SC to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECS. The no effect levels exceed the relevant PECS values, indicating that the risk to soil micro-organisms is acceptable following use of AG-MD1-312.5 SC according to the proposed pattern.

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

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 AG-MD1-312.5 SC. The risk to non-target plants is acceptable following use of AG-MD1-312.5 SC according to the proposed patterns, with a 5 m buffer zone.

3.1.7 Efficacy

Considering the data provided:

- The level of efficacy provided by TAVAS (AG-MD1-312.5 SC) is considered satisfactory.
- The level of selectivity provided by TAVAS (AG-MD1-312.5 SC) is considered satisfactory.
- The risks of negative impacts on yield, quality, wine-making and cider-making are considered negligible. Concerning adjacent crops, some management measures are proposed in order to make this risk acceptable.
- The risk of resistance appearing or developing is considered to be low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed 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.

4 CONCLUSION OF THE NATIONAL COMPARATIVE ASSESSMENT (Art. 50 of Regulation (EC) No 1107/2009)

The product TAVAS (AG-MD1-312.5 SC) contains diflufenican and metribuzin which are approved as candidate for substitution as two of PBT criteria are fulfilled;

The extension of use on potatoes was submitted after 1st August 2015, and then comparative assessment was necessary for this use only.

As a conclusion of the comparative assessment use on potato is not suitable for substitution because:

Step 1:

- Taking into account resistance control strategies (preventive effect for resistance emergence in *Chenopodium album*, *Polygonum aviculare*, *Sinapsis arvensis*, *Solanum nigrum*) :
 - The number of modes of action available on four weeds on potatoe is not sufficient
 - The candidate substance is a significant component of the resistances management strategy, the substitution of the product on the concerned use is not retained.

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 et les demandes associées du produit phytopharmaceutique **TAVAS***

de la société ADAMA FRANCE SAS

enregistrées sous les n°2014-0849, 2014-0851, 2014-0854, 2015-0342 et 2015-6482

Vu les conclusions de l'évaluation de l'Anses du 28 juillet 2017,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



| Informations générales sur le produit | |
|---------------------------------------|---|
| Noms du produit | TAVAS ELYSIUM BRETTEUR PLUS |
| Type de produit | Produit de référence |
| Titulaire | ADAMA FRANCE SAS 6/8 avenue de la Cristallerie 92316 Sèvres CEDEX FRANCE |
| Formulation | Suspension concentrée (SC) |
| Contenant | 250 g/L - métribuzine 62,5 g/L - diflufénicanil |
| Numéro d'intrant | 686-2014.01 |
| Numéro d'AMM | 2170691 |
| Fonction | Herbicide |
| Gamme d'usages | Professionnel |

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 juillet 2019.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 23 AOUT 2017

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)



ANNEXE I : Modalités d'autorisation du produit

| Vente et distribution | |
|--|-------------------|
| Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages : | |
| Emballage | Contenance |
| Bouteilles en polyéthylène haute densité | 1 L |
| Bidons en polyéthylène haute densité | 5 L ; 10 L ; 20 L |

| Classification du produit | |
|---|---|
| La classification retenue est la suivante : | |
| Catégorie de danger | Mention de danger |
| Dangers pour le milieu aquatique - Danger aigu, catégorie 1 | H400 : Très toxique pour les organismes aquatiques |
| Dangers pour le milieu aquatique - Danger chronique, catégorie 1 | H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme |
| EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique. | |
| Pour les phrases P se référer à la réglementation en vigueur. | |
| Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions. | |



Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

| Usages | Dose maximale d'emploi | Nombre maximum d'applications | Stade d'application BBCH | Délai avant récolte (jours) | Zone Non Traitée aquatique (mètres) | Zone Non Traitée arthropodes non cibles (mètres) | Zone Non Traitée plantes non cibles (mètres) | Mention abeilles |
|--|--|-------------------------------|-------------------------------------|-----------------------------|-------------------------------------|--|--|------------------|
| 12555902 Fruits à noyau*Désherbage*Cult. Installées | 2 L/ha | 1/an | entre les stades BBCH 00 et BBCH 59 | F (BBCH 59) | 5 | - | 5 | - |
| | Application sur le rang. Ne pas appliquer sur plus de 50 % de la surface de la parcelle. 1 application maximum par an et par parcelle. Non autorisé sur sols artificiellement drainés. Ne pas appliquer ce produit ou tout autre produit contenant de la métribuzine plus d'une année sur deux. | | | | | | | |
| 15655901 Pomme de terre*Désherbage | 1 L/ha | 1/an | entre les stades BBCH 00 et BBCH 59 | F (BBCH 59) | 5 | - | 5 | - |
| | 1 application maximum par an et par parcelle. Non autorisé sur sols artificiellement drainés. Ne pas appliquer ce produit ou tout autre produit contenant de la métribuzine plus d'une année sur deux. | | | | | | | |
| 12605905 Pommier*Désherbage*Cult. Installées | 1,2 L/ha | 1/an | entre les stades BBCH 00 et BBCH 09 | F (BBCH 09) | 5 (dont DVP 5) | - | 5 | - |
| | 2 L/ha | 1/an | entre les stades BBCH 00 et BBCH 85 | 14 | 5 | - | 5 | - |
| Application sur le rang. Ne pas appliquer sur plus de 50 % de la surface de la parcelle. 1 application maximum par an et par parcelle. Non autorisé sur sols artificiellement drainés. Ne pas appliquer ce produit ou tout autre produit contenant de la métribuzine plus d'une année sur deux. Si l'application est effectuée après le stade BBCH 59, ne pas récolter les fruits en contact direct avec le sol. | | | | | | | | |
| | 1 L/ha | 1/an | entre les stades BBCH 00 et BBCH | 14 | 5 | - | 5 | - |

TAVAS
AMM n°2170691



| Liste des usages autorisés En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ. En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage. | | | | | | | | | |
|--|--|--|-------------------------------------|-----------------------------|-------------------------------------|--|--|------------------|--|
| Usages | Dose maximale d'emploi | Nombre maximum d'applications | Stade d'application BBCH | Délai avant récolte (jours) | Zone Non Traitée aquatique (mètres) | Zone Non Traitée arthropodes non cibles (mètres) | Zone Non Traitée plantes non cibles (mètres) | Mention abeilles | |
| | | | 85 | | | | | | |
| | | 1 application maximum par an et par parcelle. Non autorisé sur sols artificiellement drainés. Ne pas appliquer ce produit ou tout autre produit contenant de la métribuzine plus d'une année sur deux. Si l'application est effectuée après le stade BBCH 59, ne pas récolter les fruits en contact direct avec le sol. | | | | | | | |
| | 2 L/ha | 1/an | entre les stades BBCH 00 et BBCH 59 | F (BBCH 59) | 5 | - | 5 | - | |
| | Application sur le rang. Ne pas appliquer sur plus de 50 % de la surface de la parcelle. | | | | | | | | |
| | 1 L/ha | 1/an | entre les stades BBCH 00 et BBCH 59 | F (BBCH 59) | 5 | - | 5 | - | |
| | 1 application maximum par an et par parcelle. | | | | | | | | |

DVP : Dispositif Végétalisé Permanent.

TAVAS
AMM n°2170691



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application avec pulvérisateur à rampe :

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

• pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation.

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, amené à entrer dans la culture après traitement, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures



Respect des limites maximales de résidus (LMR)

Sur « pommier », ne pas récolter les fruits en contact direct avec le sol si l'application est effectuée après le stade BBCH 59.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SPe 1 : Pour protéger les eaux souterraines, suite à une utilisation sur « pommier » et « fruits à noyaux », ne pas appliquer ce produit ou tout autre produit contenant de la métribuzine plus d'une année sur deux.
- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit sur plus de 50 % de la surface pour les usages sur "vigne", "pommier" et "fruits à noyaux" à la dose de 2 L/ha.
- SP 1 : 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.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour l'usage sur "pomme de terre".
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur "vigne", "pommier" et "fruits à noyaux".
- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés pour les usages sur "pommier" et "fruits à noyaux".

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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

TAVAS®

Cultures
Vigne, arboriculture et pomme de terre

La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou en écrivant à fds@adama.com ou par courrier à l'adresse postale d'ADAMA s.a.s ou en scannant le flashcode avec votre téléphone mobile.

Matières actives : Métribuzine 250 g/L + diflufenicanil 62,5 g/L
Formulation : SC - Suspension concentrée
AMM N°xxxxxxx

Titulaire de l'AMM :
ADAMA France s.a.s
6/8, avenue de la Cristallerie
92316 Sèvres Cedex
Tél. : 01 41 90 16 96
Fax : 01 46 42 71 17
® Marque enregistrée par une société du groupe ADAMA

HERBICIDE
Polyvalent

ADAMA

5 Litres

MODE D'ACTION – PROPRIÉTÉS

Tavas[®] contient de la métribuzine, matière active de la famille des triazinones et du diflufenicanil, de la famille des pyridine-carboxamides :

- la métribuzine est un herbicide à large spectre. Absorbé par le système racinaire, elle inhibe certaines étapes du processus de la photosynthèse. La destruction des adventices en cours de levée jusqu'au stade plantule est rapide et complète, qui montre également une bonne efficacité au niveau foliaire lorsqu'elle est appliquée en post-levée précoce des mauvaises herbes.
- le diflufenicanil qui agit en post-lévée et pré-levée des mauvaises herbes soit par absorption au niveau des jeunes tissus (principalement par la tigelle et les racines superficielles des adventices) soit par contact, est actif sur de nombreuses dicotylédones.

A pleine dose, **Tavas[®]** est efficace sur de nombreuses graminées et dicotylédones annuelles.

MODE D'EMPLOI

Usages et doses homologués :

| Libellé de l'usage | Cultures associées pour le produit | Dose | Nombre d'application | Délai avant récolte (DAR) |
|--|------------------------------------|---|----------------------|---------------------------|
| Vigne*Désherbage*Cult. Installées | Vigne ⁽¹⁾ | 1 L/ha en plein, 2L/ha sur le rang | 1 appl. max/an | - |
| Pommier*Désherbage*Cult. Installées | Pommier ⁽¹⁾ | 1 L/ha en plein, 2L/ha sur le rang sans dépasser 1 L/ha planté | 1 appl. max/an | 14 jours |
| | Poirier ⁽¹⁾ | | | |
| | Cognassier ⁽¹⁾ | | | |
| | Nashi ⁽¹⁾ | | | |
| Fruits à noyau*Désherbage*Cult. Installées | Pêcher ⁽¹⁾ | 1 L/ha en plein, 2L/ha sur le rang | 1 appl. max/an | BBCH 59 max |
| | Abricotier ⁽¹⁾ | | | |
| | Prunier ⁽¹⁾ | | | |
| | Cerisier ⁽¹⁾ | | | |
| Pomme de terre*désherbage | Pomme de terre | 1,2 L/ha | 1 appl. max/an | Pré levée (BBCH 00-09) |

⁽¹⁾ Ne pas utiliser sur jeune plant.

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement, conformément à l'arrêté du 12 juin 2015 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L-253-1 du Code Rural.

Conditions d'emploi :

- Sur vigne et fruits à noyaux, **Tavas**® peut être utilisé jusqu'à BBCH 59 (avant floraison).
- Sur fruits à pépins, **Tavas**® peut être utilisé jusqu'à 14 jours avant récolte.
- Respecter une zone non traitée de 5 mètres par rapport aux parcelles adjacentes de betteraves.

Préparation de la bouillie :

Agiter énergiquement le bidon avant usage. Verser directement la quantité requise de **Tavas**® dans le réservoir en cours de remplissage, l'agitation étant en mouvement.

Le port par l'opérateur et le travailleur d'un vêtement de protection approprié pendant le mélange/chargement et l'application du produit est obligatoire. Le port de gants est recommandé.

PRÉCAUTIONS GÉNÉRALES

Gestion du risque d'apparition de résistance :

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

Dans le cadre des Bonnes Pratiques Agricoles :

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Éliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique.

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

Equipements de protection individuels (EPI) :

Pour protéger l'opérateur, porter :

Pendant le mélange/chargement :

- Combinaison de travail 65 % polyester/35 % coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant,
- EPI de type tablier ou blouse à manches longues certifiés de catégorie III et de type (PB3) à porter par-dessus la combinaison précitée,
- Gants certifiés en nitrile tels qu'ils sont recommandés par Schwope et al.[1] conformes à la norme EN 374-3.

Pendant l'application :

- Combinaison de travail 65 % polyester/35 % coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant,
- Gants en nitrile à usage unique tels que recommandés par Schwope et al. conformes à la norme EN 374-3 (dans le cas d'utilisation d'un tracteur à cabine, le port de gants pendant l'application n'est nécessaire que lors d'interventions sur le matériel de pulvérisation et les gants doivent être stockés à l'extérieur de la cabine). Gants réutilisables si application avec lance ou pulvérisateur à dos,
- Bottes montantes conformes à la norme EN 13 832-3 pour la culture de pomme de terre.

Pendant le nettoyage du matériel de pulvérisation :

- Combinaison de travail 65 % polyester/35 % coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant,
- EPI de type tablier ou blouse à manches longues certifiés de catégorie III et de type (PB3) à porter par-dessus la combinaison précitée,
- Gants certifiés en nitrile tels que recommandés par Shwope et al. conformes à la norme EN 374-3.
- Bottes montantes conformes à la norme EN 13 832-3 pour la culture de pomme de terre.

Conditions de stockage :

Conserver le produit dans son emballage d'origine, stocker dans un local réservé à cet usage, dans un endroit frais sec et bien ventilé à l'abri de la chaleur (T<40°C) et de l'humidité.

Premiers secours :

Inhalation : Eloigner la victime de la zone dangereuse. Transporter la victime à l'air frais et selon les symptômes, consulter le médecin.

Contact cutané : Enlever immédiatement les vêtements sales et imbibés, les laver en profondeur à grande eau et avec du savon, en cas d'irritation de la peau (rougeurs, etc.), consulter un médecin.

Contact avec les yeux : Oter les verres de contact. Rincer abondamment à l'eau pendant plusieurs minutes. Si nécessaire, consulter le médecin.

Ingestion : Rincer soigneusement la bouche avec de l'eau. Faire boire abondamment de l'eau, consulter le médecin. Avoir la fiche de données sur soi.

Mesures d'urgence :

En cas d'urgence, appeler le 15 ou le centre antipoison le plus proche de votre domicile.

Présenter aux secours l'étiquette et la Fiche de Données de Sécurité.

N° vert de PHYT'ATTITUDE (réseau de toxicovigilance agricole de la MSA) : Tél. 0 800 887 887.

IMPORTANT : Respecter 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, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.



TAVAS®

AMM N°xxxxxxx
SC - Suspension concentrée
Métribuzine 250 g/L (41,7%)
+ diflufénicanil 62,5 g/L (16,7%)

Attention

H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 : Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement.

P102 : Tenir hors de portée des enfants.

P501 : N'éliminer le contenu qu'en prenant toutes les précautions d'usage.

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

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.

Spe 2 : Pour protéger les organismes aquatiques, ne pas appliquer sur sols artificiellement drainés pour l'application précoce en arboriculture.

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé de 5 mètres par rapport aux points d'eau pour la culture de pomme de terre.

SPe3 : Pour protéger les plantes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour la culture de la pomme de terre.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.

Lire les instructions ci-jointes avant emploi.

Titulaire de l'AMM : ADAMA France s.a.s
6/8, avenue de la Cristallerie
92316 Sèvres Cedex
Tél. : 01 41 90 16 96 - Fax : 01 46 42 71 17

Produit fabriqué en Israël

| | |
|---------------------|---------------------------------|
| N° de lot | VOIR SUR L'EMBALLAGE |
| Date de fabrication | |

Appendix 3 – Letter(s) of Access

Bayer CropScience



ANSES
Direction des Produits Réglementés
UGAmm
253, avenue du Général Leclerc
94701 MAISONS ALFORT Cedex
France

LETTER OF ACCESS to Annex II Data for Metribuzin According to Directive 91/414/EEC

Anne Helgers
BCS-Global Regulatory Affairs

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2014-01-21

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Board of Management
Liam Condon,
Chairman
Bernd Naaf
Michael A. Schulz

Chairman of the
Supervisory Board:
Werner Baumann

Registered Office:
Monheim am Rhein
Local Court of Düsseldorf,
HRB 46985

Dear Sir/Madam,

As mentioned in the Review Report document SANCO/10051/2006_rev. 1 dated 1st November 2006, Bayer CropScience (BCS) owns a complete set of data, including the protected data resulting in the listing of Metribuzin onto Annex I of directive 91/414/EEC (Inclusion directive 2007/25/EC dated 23 April 2007) with effect from 01 October 2007.

In accordance with a Data Access Agreement signed between Bayer CropScience AG (BCS) and Feinchemie Schwebda GmbH (FCS) (Member of the Makhteshim Agan Group) (hereafter referred to as The Data Access Agreement), BCS hereby authorizes the Authorities in **France** to access the Annex II protected data held on the active ingredient Metribuzin listed below in order to register the following products:

| | |
|-----------|--|
| Applicant | Makhteshim-Agan France |
| Product | AG-MD1-312.5 SC Registration number.: not yet allocated |

Bayer CropScience



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List of studies continued: _____

Bayer CropScience



3/4

In addition to the studies addressed in the Data Access Agreement BCS grants access to the following studies:

1. The right of referral is expressly limited to the studies mentioned above. No access to any further studies is granted by this letter of access.
2. The right of referral to the Dossier is only valid in support of the above named. The use of the registration obtained thanks to this letter is limited to Agricultural Uses. Any subsequent applications concerning the above-mentioned product require an additional letter of access.
3. The right of referral to the Dossier is not transferable to any further companies or other legal or natural entities or its employees, advisors or customers, except for Affiliates of FCS.
4. FCS or any of other affiliates of FCS, its employees, its advisors or its customers is not authorized to receive any copies of the Dossier nor is it authorized to inspect or view Dossier or any specific document in whole or in part, provided this is consistent with the laws of the territory concerned.

Yours sincerely

Bayer CropScience AG



Anne Helgers
Global Regulatory Manager

Not applicable for diflufenican.