

REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 0900 C

Product name(s): BENI

Chemical active substance(s):

Bentazone, 870 g/kg

SOUTHERN ZONE

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Sharda Cropchem España

Date: 11/04/2022

Table of Contents

| | | |
|----------|--|-----------|
| 1 | Details of the application | 4 |
| 1.1 | Application background | 4 |
| 1.2 | Letters of Access | 5 |
| 1.3 | Justification for submission of tests and studies | 5 |
| 1.4 | Data protection claims | 5 |
| 2 | Details of the authorisation decision | 5 |
| 2.1 | Product identity | 5 |
| 2.2 | Conclusion | 6 |
| 2.3 | Substances of concern for national monitoring | 6 |
| 2.4 | Classification and labelling | 6 |
| 2.4.1 | Classification and labelling under Regulation (EC) No 1272/2008 | 6 |
| 2.4.2 | Standard phrases under Regulation (EU) No 547/2011 | 6 |
| 2.4.3 | Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) | 6 |
| 2.5 | Risk management | 6 |
| 2.5.1 | Restrictions linked to the PPP | 7 |
| 2.5.2 | Specific restrictions linked to the intended uses | 7 |
| 2.6 | Intended uses (only NATIONAL GAP) | 8 |
| 3 | Background of authorisation decision and risk management | 11 |
| 3.1 | Physical and chemical properties (Part B, Section 2) | 11 |
| 3.2 | Efficacy (Part B, Section 3) | 11 |
| 3.3 | Methods of analysis (Part B, Section 5) | 11 |
| 3.4 | Mammalian toxicology (Part B, Section 6) | 12 |
| 3.4.1 | Acute toxicity | 12 |
| 3.4.2 | Operator exposure | 12 |
| 3.4.3 | Worker exposure | 13 |
| 3.4.4 | Bystander and resident exposure | 13 |
| 3.5 | Residues and consumer exposure (Part B, Section 7) | 14 |
| 3.5.1.1 | Summary for BENI (BENTAZONE 87% SG) | 15 |
| 3.6 | Environmental fate and behaviour (Part B, Section 8) | 15 |
| 3.7 | Ecotoxicology (Part B, Section 9) | 16 |
| 3.8 | Relevance of metabolites (Part B, Section 10) | 16 |
| 4 | Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) | 16 |
| 5 | Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation | 16 |
| 5.1.1 | Post-authorisation monitoring | 17 |

| | | |
|-------------------|--|-----------|
| 5.1.2 | Post-authorisation data requirements | 17 |
| Appendix 1 | Copy of the product authorisation | 18 |
| Appendix 2 | Copy of the product label | 22 |
| Appendix 3 | Letter of Access | 24 |

PART A

RISK MANAGEMENT

1 Details of the application

The company SHARDA CROP CHEM ESPAÑA has requested a marketing authorisation in France for the product BENI (synonym: BENTAZONE 87% SG; formulation code: SHA 0900 C), containing 870 g/kg bentazone, as a herbicide for professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report (RR), Part B Sections 1-10 and Part C, and where appropriate the addendum for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to BENI (SHA 0900 C) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of BENI (SHA 0900 C) have been made using endpoints agreed in the EU peer reviews of bentazone.

This document describes the specific conditions of use and labelling required for France for the registration of BENI (SHA 0900 C).

Appendix 1 of this document provides a copy of the product authorisation.

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of SHARDA CROP CHEM ESPAÑA's application to market BENI (SHA 0900 C) 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.

The present application (2016-1972) 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 applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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 on the acceptability of risk are based on the criteria provided in Regulation (EU)

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 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

No 546/2011³, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

Not relevant. A data matching table has been provided and was partially acceptable.

1.3 Justification for submission of tests and studies

According to the applicant: *“This dossier relies on test and studies providing data and information specific to the formulation BENTAZONE 87% SG as required by the EU regulation”*.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BENI (SHA 0900 C) it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7

2 Details of the authorisation decision

2.1 Product identity

| | |
|--|--|
| Product code | SHA 0900 C. |
| Product name in MS | BENI |
| Authorisation number | N/A : no marketing authorisation granted |
| Low risk (article 47) | No. |
| Function | Herbicide. |
| Applicant | SHARDA CROPChem ESPAÑA. |
| Active substance(s) (incl. content) | Bentazone, 870 g/kg. |
| Formulation type | Water-soluble granule (SG). |
| Packaging | N/A : no marketing authorisation granted |
| Coformulants of concern for national authorisations | - |
| Restrictions related to identity | - |
| Mandatory tank mixtures | None. |
| Recommended tank mixtures | None. |

³ 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

2.2 Conclusion

The evaluation of the application for BENI resulted in the decision to refuse the authorisation.



2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

| | |
|-------------------------------|--|
| Hazard class(es), categories: | Acute toxicity, hazard category 4 (oral) Eye Irritation, hazard category 2 Hazardous to the aquatic environment, chronic, category 2 |
| Hazard pictograms: |   SGH07 SGH09 |
| Signal word: | Warning |
| Hazard statement(s): | H302: Harmful if swallowed. H319: Causes serious eye irritation. H411: Toxic to aquatic life with long lasting effects. |
| Precautionary statement(s): | <i>For the P phrases, refer to the existing legislation</i> |
| Additional labelling phrases: | To avoid risks to man and the environment, comply with the instructions for use [EUH401] |
| | Contains bentazone. May produce an allergic reaction [EUH208] |

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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

The French Order of 4 May 2017⁴ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021⁵ 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” 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 applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

⁴ 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/AGRG1632554A/jo/texte>

⁵ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

SHA 0900 C / BENI
Part A - National Assessment
FRANCE DEPR version

2.6 Intended uses (only NATIONAL GAP)

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.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2022-04-11

PPP (product name/code): BENI/SHA 0900 C
Active substance 1: bentazone
Safener: -
Synergist: -
Applicant: SHARDA CROPChem ESPAÑA
Zone(s): Southern Zone ^(d)
Verified by MS: Yes
Field of use: Herbicide

Formulation type: Water-soluble granules (SG)^(a, b)
Conc. of a.s. 1: 870 g/kg ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☒
Non-professional use: ☐

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|--|--------------------|---|--|---|-----------------------|--|---|--|--|---|----------------------------------|---------------|--|
| Use- No. ^(e) | Member state(s) | Crop and/ or situation (crop destination/purpose of crop) | F, Fn, G, Gn, Gpn or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾ |
| | | | | | Method/Ki nd | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg 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 | | |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | |
| 1 | FR | Maize | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a) 1 b) 1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (earthworms) |
| 2 | FR | Sweet maize | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a) 1 b) 1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (earthworms, selectivity) |

SHA 0900 C / BENI
Part A - National Assessment
FRANCE DEPR version

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|--|--------------------|---|---|---|-----------------------|--|---|--|--|---|----------------------------------|---------------|--|
| Use- No. ^(e) | Member state(s) | Crop and/ or situation (crop destination/purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/synergist per ha ^(f) |
| | | | | | Method/Ki nd | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg 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 | | |
| 3 | FR | Forage maize | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a) 1 b) 1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (earthworms) |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | |
| 4 | FR | Flax | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a)1 b)1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (earthworms, selectivity) |
| 5 | FR | Forage grasses | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a)1 b)1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (MRL, earthworms, selectivity) |
| 6 | FR | Forage legumes | F | Broadleaved weeds | Foliar application | BBCH 10-19 | a)1 b)1 | NA | (a) 1.0 (b) 1.0 | (a) 870 (b) 870 | 150- 400 | | Not acceptable (MRL, earthworms, selectivity) |

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
 (c) g/kg or g/l

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

SHA 0900 C / BENI
 Part A - National Assessment
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| | | | | |
|-------------------------|---|--|----|--|
| Remarks columns: | 1 | Numeration necessary to allow references | 7 | Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application |
| | 2 | Use official codes/nomenclatures of EU Member States | 8 | The maximum number of application possible under practical conditions of use must be provided. |
| | 3 | For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) | 9 | Minimum interval (in days) between applications of the same product |
| | 4 | F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application | 10 | For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. |
| | 5 | Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. | 11 | The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha). |
| | 6 | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench | 12 | If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". |
| | | Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. | 13 | PHI - minimum pre-harvest interval |
| | | | 14 | Remarks may include: Extent of use/economic importance/restrictions |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

BENI is a water-soluble granule (SG) formulation. 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 faint yellow granules, with characteristic odour. It is not explosive, has no oxidising properties and is not highly flammable. In 1 % aqueous solution, it has a pH value of 7.2 at 20 °C. There is no effect of high temperatures on the stability of the formulation, since after 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE.

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

3.2 Efficacy (Part B, Section 3)

Considering the data provided:

- BENI's efficacy level is considered acceptable for all intended uses.
- BENI's selectivity level is considered acceptable on maize and forage maize. **However, no data have been provided regarding its selectivity on sweet maize, flax, forage leguminous crops and forage grasses. Therefore it is not considered possible to reach a conclusion about these crops.**
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered acceptable.
- The risk of resistance developing or appearing to bentazone does not require monitoring for the intended uses.

3.3 Methods of analysis (Part B, Section 5)

Analytical methodology for the determination of the active substance in the formulation is available and validated.

Analytical methodology for the determination of the relevant impurity 1,2-dichloroethane in the formulation is not available. As 1,2-dichloroethane cannot be formed during formulation and storage, an analytical method for its determination must be provided post-authorisation.

Analytical methods are available in the Review Assessment Report (RAR) and in this dossier and validated for the determination of residues of bentazone in plants (high-water-content, high-protein-content and high-oil-content), foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

| | | | |
|------------------------------------|--|---|--|
| Active substance: bentazone | | | |
| ADI | 0.09 mg/kg bw/d | | EU (2018) |
| ARfD | 1 mg/kg bw | | |
| AOEL | 0.13 mg/kg bw/d | | |
| (AAOEL) | - | | |
| Dermal absorption | Based on an default values according to guidance on dermal absorption (Efsa 2012): | | |
| | | Concentrate (used in formula- tion) 87 g/L | Spray dilution (used in formulation) 2.175 g/L |
| | Dermal absorption endpoints % | 25 | 75 |
| Oral absorp- tion | 100 % | | |

3.4.1 Acute toxicity

BENI, containing 870 g/kg bentazone, has a low toxicity in respect to acute inhalation and dermal toxicity; it is irritating to the rabbit eye but is not irritating to the rabbit skin, nor a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

| Crop type | F/G ⁷ | Equipment <i>Application method</i> | Maximum application rate kg as/ha | Minimum volume water (L/ha) |
|---------------|------------------|---|--------------------------------------|-----------------------------------|
| Risk envelope | F | Vehicle-mounted <i>Downward spraying</i> | 0.87 | 150 |

Considering proposed uses, operator systemic exposure was estimated using the EFSA model⁸:

| Crop | Equipment | PPE and/or working coverall | % AOEL bentazone |
|------|-----------|-----------------------------|---------------------|
|------|-----------|-----------------------------|---------------------|

⁷ Open field or glasshouse

⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

| | | | |
|-----------------------|---|---|-------|
| Risk envelope cereals | Vehicle-mounted <i>Downward spraying</i> | Working coverall and gloves during mixing/loading and application | 10.52 |
|-----------------------|---|---|-------|

According to the model calculations, it may be concluded that the risk for the operator using BENI is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore estimation of worker exposure was calculated according to the AOEM model. Exposure is estimated to be 70 % of the AOEL of bentazone with PPE.

It may be concluded that there is no unacceptable risk anticipated for the worker.

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

3.4.4 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set⁹.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and/or child) when drift-reduction technology is used to reduce the resident exposure:

| Model (AOEM) - All pathways (mean) | % AOEL bentazone |
|------------------------------------|------------------|
| Resident (children) | 95.96 |
| Resident (adults) | 4.05 |

⁹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

3.5 Residues and consumer exposure (Part B, Section 7)

Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation BENI are presented in **Erreur ! Source du renvoi introuvable.** They have been selected from the individual GAPs in the southern zone for maize, sweet maize, forage maize and minor uses for flax, forage grasses and forage legumes. A list of all intended uses within the southern zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL for bentazone as laid down in Reg. (EU) 396/2005 is not expected, **except for forage grasses and forage legumes.**

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

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

Data gaps

Noticed data gaps reported in the EU peer review are:

- Characterisation and identification of the fraction M3 in wheat straw based on all analytical evidence available in the raw data from the wheat metabolism study and considering also the potential uptake by the plants of soil metabolites;
- Additional residue trials are required to complete the residue data set for the following crops : sweet corn, forage grasses and forage legumes;
- A ruminant feeding study dosing a representative mixture of bentazone and 6-hydroxy-bentazone with the determination of the residues of bentazone, 6-hydroxy-bentazone and their conjugates separately in all animal commodities;
- A storage stability study in products of animal origin is also required.

Summary of the evaluation

The active substance bentazone was reapproved in June 2018. The corresponding review report SANTE/12012/2015 Rev 8 stated that the most important endpoint including residue definitions have to be considered from the peer review conclusions of EFSA.

However, the extant MRL legislation (i.e., Regulation n° 1146/2014) was established with the former residue definitions. Consequently, the following considerations were taken into account in the framework of this application:

- MRL compliance was performed using the previous monitoring residue definition (sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated));
- Consumer risk assessment was also carried on with the previous residue definition (sum of bentazone and the conjugates of the metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone).

It should be highlighted that the old endpoints are more critical than the new residue definition proposals. Indeed, some metabolites (like 8-hydroxy-bentazone and/or conjugates of bentazone) were included for old plant and animal residue definitions and are not considered any more in current residue definitions. Therefore the approach adopted can be considered a worst case.

New studies in forage grasses and forage legumes are being conducted by the applicant (ongoing).

3.5.1.1 Summary for BENI (BENTAZONE 87% SG)

Table 3.5-1: Information on BENI (BENTAZONE 87% SG) (KCA 6.8)

| Crop | PHI for BENI requested by applicant | PHI/withholding period* sufficiently supported for bentazone | PHI for BENI proposed by zRMS | zRMS Comments (if different PHI proposed) |
|--------------------------|-------------------------------------|--|-------------------------------|---|
| Maize | N.A – BBCH 10-19 | Yes | F – BBCH 10 18 | |
| Sweet maize | N.A – BBCH 10-19 | Yes | F – BBCH 10 16 | |
| Linseed (including flax) | N.A – BBCH 10-19 | Yes | F – BBCH 10 18 | |
| Forage maize | N.A – BBCH 10-19 | Yes | F – BBCH 10 18 | |

NR: not relevant

* Purpose of withholding period to be specified

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

3.6 Environmental fate and behaviour (Part B, Section 8)

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

The PEC values of bentazone 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.

PEC soil and PEC_{sw} values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for bentazone and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000¹⁰ (if product is used only every other year for uses on maize and flax). Available calculations do not cover applications on winter forage grasses and winter forage legumes.

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.

3.7 Ecotoxicology (Part B, Section 9)

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 and its 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, aquatic organisms, and other non-target arthropods, soil macro- and micro-organisms are acceptable for the intended uses. **Since the TERIt value for earthworms is lower than the trigger of 5 and no additional data to refine the risk has been submitted by the notifier, the risk is considered “non-finalised” for an application of BENI according to the GAP.**

According to new requirements of the Commission Regulation (EU) No. 284/2013 of 1 March 2013, data on chronic effects on adult bees and on development of bees should have been submitted by the applicant, as exposure of bees to the formulation cannot be excluded. Therefore the risk evaluation for bees cannot be completely fulfilled. Member States may thus consider the risk for bees as “not finalised”, or require mitigation measures to avoid exposure of bees, and/or request chronic adult and larvae toxicity studies, post-authorisation. At national level, France as zRMS will conclude that the risk for bees is not finalised.

No risk to non-target terrestrial plants is expected after the application of BENI according to the GAP when risk mitigation measures are specified.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance bentazone is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point

¹⁰ 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.

3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted

Appendix 1 Copy of the product authorisation

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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 **BENI***

de la société SHARDA CROP-CHEM ESPAÑA S.L.

enregistrée sous le n°2016-1972

Vu les conclusions de l'évaluation de l'Anses du 10 mars 2020,

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

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.

SHA 0900 C / BENI
Part A - National Assessment
FRANCE DEPR version

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| Informations générales sur le produit | |
|---------------------------------------|--|
| Nom du produit | BENI |
| Type de produit | Produit de référence |
| Titulaire | SHARDA CROPCHAM ESPAÑA S.L. Carril Condomina nº3 30006 MURCIA Espagne |
| Formulation | Granulé soluble dans l'eau (SG) |
| Contenant | 870 g/kg - bentazone |
| Numéro d'intrant | 560-2016.01 |
| Numéro d'AMM | - |
| Fonction | Herbicide |
| Gamme d'usage | Professionnel |

A Maisons-Alfort, le 11/04/2022

DocuSigned by:

 AE281A955A42454...
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

BENI
AMM n° -

Page 2 sur 3

SHA 0900 C / BENI
Part A - National Assessment
FRANCE DEPR version

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ANNEXE : Conditions de mise sur le marché demandées


| Liste des usages refusés | | | |
|--|---------------|-------------------------------|-----------------------------|
| Usages | Dose d'emploi | Nombre maximum d'applications | Délai avant récolte (jours) |
| 15305905 Graminées fourragères*Désherbage | 1 kg/ha | 1/an | - |
| Motivation du refus : L'usage est refusé car le nombre d'essais résidus disponibles est insuffisant pour vérifier le respect des limites maximales de résidus et au motif que les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de démontrer la sélectivité du produit. | | | |
| 15455911 Légumineuses fourragères*Désherbage | 1 kg/ha | 1/an | - |
| Motivation du refus : L'usage est refusé car le nombre d'essais résidus disponibles est insuffisant pour vérifier le respect des limites maximales de résidus et au motif que les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de démontrer la sélectivité du produit. | | | |
| 15505902 Lin*Désherbage | 1 kg/ha | 1/an | - |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de démontrer la sélectivité du produit. | | | |
| 16665901 Maïs doux*Désherbage | 1 kg/ha | 1/an | - |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre ni de démontrer la sélectivité du produit. | | | |
| 15555901 Maïs*Désherbage | 1 kg/ha | 1/an | - |
| Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les vers de terre. | | | |

BENI
AMM n°-

Page 3 sur 3

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



SGH07

Mentions de danger:

H302: Nocif en cas d'ingestion

H319: Provoque une sévère irritation des yeux

H412: Nocif pour les organismes aquatiques, entraîne des effets néfastes à long terme

Conseils de prudence :

P264 : Se laver les mains soigneusement après manipulation

P270 : Ne pas manger, boire ou fumer en manipulant ce produit

P280 : Porter un équipement de protection des yeux, des vêtements de protection, des gants de protection

P303+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

P337+P313 : Si l'irritation oculaire persiste: consulter un médecin

P501 : Éliminer le contenu/réceptacle dans un centre de collecte de déchets dangereux ou spéciaux, conformément à la réglementation locale, régionale, nationale et/ou internationale

EUH208 : Contient benzazone (25057-89-0). Peut produire une réaction allergique

EUH 401 : Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement

ÉQUIPEMENT DE PROTECTION:

1. Mélanges/chargement:

Les caractéristiques du vêtement de travail et de l'EPI pour la phase de mélange/chargement du produit BENI, sont les suivantes : Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement **déperlant**; Gants en nitrile certifiés EN 374-3; Lunettes norme EN 166 (CE, sigle 3)

2. Application du produit:

Les caractéristiques du vêtement de travail et de l'EPI pour la phase d'application du produit BENI, sont les suivantes : Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement **déperlant**.

Sur application avec tracteur sans cabine: Gants en nitrile certifiés EN 374-3; Lunettes norme EN 166 (CE, sigle 3).

3. Nettoyage du matériel de pulvérisation:

Les caractéristiques du vêtement de travail et de l'EPI pour la phase de nettoyage du matériel de pulvérisation utilisé pour l'application du produit BENI, sont les suivantes : Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement **déperlant**; Gants en nitrile certifiés EN 374-3; Lunettes norme EN 166 (CE, sigle 3).

Granulés solubles dans l'eau (SG) contenant 870 g/kg de benzazone

AMM n° XXXXXXXXXX délivrée le XXXXXXXXXX par le Ministère de l'Agriculture, de l'agro-alimentaire et de la forêt

HERBICIDE / MAÏS, LIN, LÉGumineuses FOURRAGÈRES, GRaminées FOURRAGÈRES

BENI est un herbicide à usage agricole et professionnel uniquement, pouvant être utilisé sur le maïs, lin, légumineuses fourragères, graminées fourragères

BENI se présente sous la forme de granulés solubles dans l'eau (SG) contenant 870 g/kg de benzazone.

Poids net: XXXX

Date de fabrication: XXXXXXXX

Lot N°: XXXXX

Date d'expiration: XXXXXXXX

Détenteur d'homologation: Shaoda Conchem España S.L.

Edificio Alabaxa Business Center, Carril Condominia, nº 3, 12th Floor, 30006 Murcia, Spain

Distribué par: XXXXX

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "PhytoAlerte" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

NOTICE D'EMPLOI

IMPORTANT: Ces informations sont parties de l'étiquette du produit BENI. Toutes les instructions de cette étiquette doivent être lues attentivement avant l'emploi.

RECAUTIONS:

Pour l'utilisateur: Éviter le contact du produit avec les yeux, la peau et les voies respiratoires. En cas d'incident en cours d'application, arrêter le pulvérisateur en zone non contaminée autant que possible, ne pas porter les mains ou les gants souillés à la bouche, ne pas déboucher une buse en soufflant. Après l'application, rincer les équipements de protection, se laver les gants puis les mains, prendre une douche. Ne pas réutiliser l'emballage du produit.

Pour le distributeur: Conserver le produit dans son emballage d'origine fermé de manière étanche, dans un endroit bien ventilé et sous clef, hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

APRÈS UTILISATION: Éliminer les emballages vides des collectes organisées par les distributeurs partenaires de la filière AQUIVALOR (08 10 12 18 85, numéro vert, prix d'un appel local), en accord avec la réglementation en vigueur.

REPARATION DE LA BOUILLE:

Si le bouchon agit comme un obstacle, remplir la cuve à moitié d'eau, bien agiter l'agitateur en marche. Ajouter BENI, compléter en eau pour remplir la cuve. Remettre l'agitateur en marche. Maintenir l'agitation.

MELANGE:

Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site : <http://e-phy.agriculture.gouv.fr>

NOTES GÉNÉRALES:

Consulter les procédures de nettoyage des appareils sur les étiquettes de tous produits associés et être sûr d'utiliser le procédé le plus rigoureux et recommandé. Respecter les bonnes pratiques agricoles.

CONDITIONS DE VENTE:

Tous nos produits sont de haute qualité et sont appropriés aux usages recommandés. Toutefois nous ne pouvons contrôler les conditions dans lesquelles ils seront stockés, manipulés, mélangés ou utilisés ni contrôler les conditions climatiques dans lesquelles ils seront employés. Ces différents paramètres précités peuvent affecter la performance du produit. C'est pourquoi, notre société et nos revendeurs déclinent toute responsabilité quant à la qualité des produits qui sont affectés par de mauvaises conditions de stockage, de manipulation ou d'application par l'utilisateur.

USAGES ET DOSES AUTORISÉES:

BENI est un herbicide pouvant être utilisé sur les cultures et aux doses d'application suivantes:

| Cultures | Cibles | dose d'emploi | volume de dilution | Stade d'application | nombre d'application | Délai avant récolte |
|--------------------------|----------------------|---------------|--------------------|---------------------|----------------------|---------------------|
| Maïs | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |
| Maïs doux | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |
| Maïs fourrage | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |
| Lin | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |
| Légumineuses fourragères | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |
| Sarrasin | d'hybrides adhésives | 1 kg/ha | 150-450 l/ha | BCH 10-19 | 1 | Non applicable |

Appendix 3 Letter of Access

Not applicable.