REGISTRATION REPORT
Part A

Risk Management

Product code: BELTANOL-L

Active Substance: 500 g/L 8-hydroxyquinoline neutral sulphate

COUNTRY: FRANCE

European Union

Interzonal Rapporteur Member State: FRANCE

NATIONAL ASSESSMENT

(Indoor uses)

Applicant: PROBELTE, S.A.

Date:08/03/2016

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PART A – Risk Management

The company PROBELTE S.A. has requested marketing authorisation in France for the product BELTANOL-L, a soluble concentrate (SL) containing 500 g/L of 8-hydroxyquinoline sulfate for use as a fungicide- bactericide in drip irrigation water.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to BELTANOL-L where that data has not been considered in the EU review process. Otherwise assessments for the safe use of BELTANOL-L have been made using endpoints agreed in the EU review of 8-hydroxyquinoline.

This document describes the specific conditions of use and labelling required for France for the registration of BELTANOL-L.

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 PROBELTE's application to market BELTANOL-L in France as a fungicide - bactericide in *solanacea*, cucurbits (edible and inedible peel) and strawberry in greenhouse (product uses described under point 2.3).

France acted as an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

1.2. Active substance approval

Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011
Specific provisions of regulation were as follows : **PART A** Only uses as fungicide and bactericide in greenhouses 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 8-hydroxyquinoline, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate.

The applicant shall submit confirmatory information on 8-hydroxyquinoline and its salts as regards:

(1) the method of analysis for air,

(2) a new storage stability covering the storage time periods of samples from both the metabolism study and from the supervised residue trials.

The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.

An EFSA conclusion is available (EFSA Journal 2011;9(1):1964).

A Review Report is available (SANCO/11636/2011 rev 3, 15 July 2011).

1.3. Regulatory Approach

The present application (n°2012-2284) was 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 European Union, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the European Union. 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 in the decision letter.

The French Order of 12 September 2006[3] provides that:

- unless formally stated in the product authorisation, the PHI is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum reentry 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

[1] French Food Safety Agency

[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

[3] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570

The current document (RR) based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], 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) No546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Last, the French Order of 26 March 2014[6] provides that:

- an authorization 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 this French order.

Then, at FR level, possible extrapolation of submitted data and corresponding assessment from "reference" crops to linked ones are assessed even if not clearly intended by applicant in the dRR, and a conclusion is reached on acceptability of intended uses on those linked crops. The aim of this order, mainly based on EU document on residue data extrapolation [7] is to supply minor crops with registered PPP.

Then, GAPs table (§2.3.) and decision may include uses on crops not clearly intended by applicant.

The decision, as duplicated 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 BELTANOL-L, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. It is claimed data protection for all these studies for ten years; all of them are property of PROBELTE S.A.

1.5. Letters of Access

BELTANOL-L is a product based on 8-hydroxyquinoline. This active substance has been included in the Annex I of Directive 91/414/EEC. PROBELTE S.A. is the applicant for this active substance and therefore is the owner of the full Annex II dossier. PROBELTE S.A. is also the owner of the Annex III studies containing in this dossier. Therefore, no letter of access is considered necessary since PROBELTE

[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/AGRG1407093A/jo

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

S.A. is the applicant for this submission and also the owner of the full Annex II dossier of the active ingredient.

2. DETAILS OF THE AUTHORISATION

2.1. Product Identity

Product Name	BELTANOL-L
Authorization Number (for re-registration)	2150931
Function	Fungicide/Bactericide
Applicant	PROBELTE, S.A.
Composition	500 g/L of 8-hydroxyquinoline neutral sulphate
Formulation type	Soluble Concentrate [Code: SL]
Packaging	PE/EVOH (100 mL, 250 mL, 500 mL, 1 L, 5 L) PE/PA (10 L)

2.2. Classification and Labelling

2.2.1. Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2. Classification and labelling in accordance with Regulation (EC) No 1272/2008

According to the regulation UE 1272/2008 and from the RAC opinion (05/06/2015) [8] (The classification of the active substance "reproductive toxicity category 1B, H360D" is not yet harmonized. The RAC opinion has been considered for the classification of the preparation).

[8] RAC Opinion proposing harmonised classification and labelling at EU level of Quinolin-8-ol; 8-hydroxyquinoline (CLH-O-0000001412-86-60/F). http://echa.europa.eu/documents/10162/8180ee20-05ee-462c-937b-0bcd43cc921f

Classification	Acute Toxicity category 3 Skin corrosion category 1A Skin sensitisation category 1 Reproductive toxicity category 1B Aquatic Chronic category 1
Hazard pictograms	
Signal word	Danger
Hazard statements	H301 Toxic if swallowed. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H360D May damage the unborn child. H410 Toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	***Refer to the label***

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).

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: not applicable for drip irrigation
Pre-harvest intervals: - Strawberry, Cucurbits with edible peel: F (last application 30 days after transplanting and before flowering) - Tomatoe, Cucurbits with inedible peel: 70 days

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

2.3. Product uses (Authorised GAP and uses in France)

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 izRMS. 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 an 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. 3, date: 2016-03-08

PPP (product name/code)	**BELTANOL-L**	**Formulation type:**	**SL**
active substance 1	**8-Hydroxyquinoline**	**Conc. of as 1:**	**500 g/L expressed as 8-hydroxyquinoline sulphate**
safener n.a.		**Conc. of safener:**	**n.a.**
synergist	**n.a.**	**Conc. of synergist:**	**n.a.**
Applicant:	**PROBELTE S.A.**	**professional use**	**X**
Zone:	**European Union**	**non professional use**	☐
Verified by MS: yes	**France**		

1	2	3	4	5	6	7	8	10	11	12	13	14
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 **
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use	L product / ha a) max. rate per appl.	kg as/ha a) max. rate per appl.	Water L/ha max		
1	EU, all zones	Fruiting vegetables, *Solanacea*	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Pseudomonas,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application	2 (14)	4.0	2.0***	7500	NA	Covered by vegetative period (required by the applicant)
1	EU, all zones	Fruiting vegetables *Solanacea* **(Eggplant, Peppers, Other minor *Solanacae* crops)**	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Pseudomonas,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application **and before flowering**	2 (14)	4.0	2.0***	**5000-20000**	**70**	**Potential MRL exceedance for eggplants,peppers and minor solanacea crops**
1	EU, all zones	Fruiting vegetables *Solanacea* **(Only Tomatoes)**	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Pseudomonas,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application **and before flowering**	2 (14)	4.0	2.0***	**5000-20000**	**70**	**PHI proposed according to available data** **Efficacy demonstrated on *Pythium, Phytophthora, Clavibacter michiganensis* and *Pseudomonas spp***

1	2	3	4	5	6	7	8	10	11	12	13	14
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 **
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use	L product / ha a) max. rate per appl.	kg as/ha a) max. rate per appl.	Water L/ha max		
2	EU, all zones	Cucurbits-edible peel	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application	2 (14)	4.0	2.0***	7500	NA	Covered by vegetative period (required by the applicant)
2	EU, all zones	Cucurbits with-edible peel (cucumber, zucchini, gherkins, other minor cucurbits with edible peel)	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application **and before flowering**	2 (14)	4.0	2.0***	**5000-20000**	**F**	**F (last application 30 days after transplanting and before flowering)** **Efficacy demonstrated on *Pythium*, *Phytophthora.* and *Pseudomonas spp***
3	EU, all zones	Cucurbits-inedible peel	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application	2 (14)	4.0	2.0***	7500	NA	Covered by vegetative period (required by the applicant)
3	EU, all zones	Cucurbits-inedible peel (melon, pumpkin, watermelon and, other minor cucurbits with inedible peel)	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application **and before flowering**	2 (14)	4.0	2.0***	**5000-20000**	**70**	**PHI proposed according to available data** **Efficacy demonstrated on *Pythium*, *Phytophthora.* and *Pseudomonas spp***
4	EU, all zones	Vegetable crops Strawberry	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Xanthomonas,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application	2 (14)	4.0	2.0***	7500	NA	Covered by vegetative period (required by the applicant)
4	EU, all zones	Strawberry	I	Soil fungi and bacteria *(Pythium, Rhizoctonia, Phytophthora, Fusarium, Xanthomonas,etc…)*	Drip irrigation	1º: 5-15 days after transplanting 2º: 14 days after 1st application **and before flowering**	2 (14)	4.0	2.0***	**5000-20000**	**F**	**F (last application 30 days after transplanting and before flowering)** **Efficacy demonstrated on *Pythium*, *Phytophthora.* and *Pseudomonas spp***

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** 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.
*** Application rate of **8-hydroxyquinoline-sulphate** is 2.0 kg/ha, corresponding to 1.496 kg/ha **8-hydroxyquinoline**
NA: Not applicable

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(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,
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The minimum and maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

3. RISK MANAGEMENT

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

3.1.1. Physical and chemical properties (Part B, Section 1, Points 2 and 4)

The product BELTANOL-L is a soluble concentrate formulation. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of yellow liquid, with slight saffron odour. It is not auto flammable nor explosive, has no oxidising properties. In aqueous solution, it has a pH value around 2. The stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a soluble concentrate formulation.

Nevertheless, the stability of the solution after storage at 54°C for 14 days should be investigated.

The applicant indicated that the formulation was corrosive (R35). No physical and chemical study is performed to justify this classification.

3.1.2. Methods of analysis (Part B, Section 2)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

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

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Analytical methods are available in the monograph and in this dossier and validated for the determination of residues of 8-hydroxyquinoline in plants (acidic matrices and matrices with high water content), soil, water (surface and drinking) and air.

To update the dossier : **an analytical method and its ILV should be available for the determination of residues in foodstuff of animal origin as well as confirmatory methods for the determination of residues in soil and water (drinking and surface).**

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

3.1.3. Mammalian toxicology (Part B, Section 3,)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

BELTANOL-L was a representative formulation in the EU review of 8-hydroxyquinoline.

Acute toxicity tests with BELTANOL-L (pH of BELTANOL-L less than 2.5) were not performed since according to current OECD guidelines testing of substances known to cause marked pain and distress due to corrosive or irritating properties need not to be carried out.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

BELTANOL-L is a soluble concentrate formulation containing 500 g 8-hydroxyquinoline sulfate/L, that corresponds to 374 g/L 8-hydroxyquinoline (8-HQ).

BELTANOL-L is recommended as fungicide and bactericide for the application in tomato in glasshouse by drip irrigation. It is intended for use in two applications per crops with an interval of 14 days using 4L product/ha diluted in a volume of 5000L to 20000 L of water. Application rate of 8-HQ sulphate is 2 kg/ha, corresponding to 1.496 kg/ha 8-HQ.

It has been considered that, due to drip irrigation, exposure of the operator will only occur during mixing/loading of BELTANOL-L and not during the application

Estimations of potential operator exposure have been undertaken for 8-hydroxyquinoline using the BBA model. According to the model calculations, it can be concluded that the risk for the operator using BELTANOL-L on cucurbits, *solanacea* and strawberry by drip irrigation is acceptable with the use of personal protective equipment (gloves during mixing and loading).

Given the corrosive potential of BELTANOL-L, impermeable gloves, protecting clothes and eye/face protection should be worn when handling the concentrate.

The following personal protective equipment is recommended by applicant:

During mixing/loading

- Gloves (nitrile, EN 374-3) ;
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment;
- Long-sleeved aprons of Category III Type 3;
- Glasses or face shield (CE, EN 166 “sigle 3”).

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

BELTANOL-L is proposed to be applied by drip irrigation indoor. It is reasonable to assume that the risk for a bystander is negligible considering the way BELTANOL-L is applied.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

BELTANOL-L is applied by downward drip irrigation on soil at an early stage of the development of the vegetation (5 to 30 day after transplanting) at an application rate of 4L/ha diluted in 5000 L to 20000 L water.

Due to the active substance properties (vapour pressure, adsorption to soil) and the method of application any dermal (handling treated compost or irrigating system) or inhalation exposure for workers entering a treated area can be considered as very low.

By recommending the use of gloves, the worker exposure can be considered as acceptable.

3.1.4. Residues and consumer exposure (Part B, Section 4)

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation BELTANOL-L are presented in paragraph IIIA 8.3. They have been selected from the individual GAPs in the Southern Europe for *Solanacea*, cucurbits with edible peel, cucurbits with inedible peel and strawberries. A list of all intended uses within the Southern Europe is given in Appendix 2 (Part B, section 4).

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg in tomatoes for 8-hydroxyquinoline as laid down in Reg. (EC) N°396/2005 is not expected. However, it is not possible to know if the current MRL of 0.01 mg/kg would be exceeded or not for other *Solanacea*.

No exceedance of the current MRL of 0.01 mg/kg in cucurbits with edible peel, cucurbits with inedible peel and strawberries for 8-hydroxyquinoline as laid down in Reg. (EC) N°396/2005 are expected.

The chronic and the short-term intakes of 8-hydroxyquinoline residues are unlikely to present a public health concern.

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

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

Data gaps

Noticed data gaps are:

- 2 additional indoor trials on cucurbits with edible peel
- 2 additional indoor trials on cucurbits with inedible peel
- 2 additional indoor trials on strawberries

These data are required to confirm an expected “no residue situation”.

Summary of the assessment

The preparation BELTANOL-L is composed of 8-hydroxyquinoline.

Summary for 8-hydroxyquinoline

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EC) N° 1004/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	*Solanacea*	Yes	Yes	Yes	Yes	**Yes for tomato only**	No	No	Proposed modification of GAPs
2	Cucurbits-edible peel	Yes	Yes (2 indoor)	Yes	Yes	Yes		No	
3	Cucurbits-inedible peel	Yes	Yes (2 indoor)	Yes	Yes	Yes		No	Proposed modification of GAPs
4	Strawberry	Yes	Yes (2 indoor + 2 SEU outdoor)	Yes	Yes	Yes			

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

For cucurbits-edible peel, cucurbits-with inedible peel and strawberries, additional data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application.

For eggplants and other *Solanacea*, intended uses are not supported, and change of the in force MRLs and additional trials should be submitted.

As residues of 8-hydroxyquinoline do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

As 8-hydroxyquinoline has a half-life of less than 1 day in soil and as no relevant metabolites occur. It is therefore not expected that residues in the soil will be taken up by succeeding plants and therefore metabolism study and field trials in succeeding crops are not required.

As no significant residue levels of 8-hydroxyquinoline were found in harvested plant material it is not expected that crops under consideration are fed to livestock in relevant amounts. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for BELTANOL-L

Information on BELTANOL-L (KCA 6.8)

Crop	PHI for BELTANOL-L proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for BELTANOL-L proposed by zRMS	zRMS Comments (if different PHI proposed)
		8-hydroxyquinoline		
Solanacea		No (except tomato)	70 days for tomato	PHI proposed, linked to available data
Cucurbits with edible peel	1º: 5-15 days after transplanting 2º: 14 days after 1st application and before flowering	Yes		
Cucurbits with edible peel	1º: 5-15 days after transplanting 2º: 14 days after 1st application and before flowering	No	70 days	PHI proposed, linked to available data
Strawberries	1º: 5-15 days after transplanting 2º: 14 days after 1st application and before flowering	Yes		

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

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for BELTANOL-L
Crop group	Led by 8-hydroxyquinoline	
All groups	NR	NR

NR: not relevant

3.1.5. Environmental fate and behaviour (Part B, Section 5)

The fate and behaviour in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) N°1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance and its metabolite for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of 8-hydroxyquinoline sulfate in soil, surface water and groundwater has 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 review or agreed in the assessment based on new data provided.

The results for PECsoil and PECsw for the active substance are used for the eco-toxicological risk assessment.

PECgw for 8-hydroxyquinoline sulfate do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

3.1.6. Ecotoxicology (Part B, Section 6)

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Due to the lack of exposure, no risk assessment is deemed to be necessary for birds and mammals and the risk to birds and mammals from the use of BELTANOL-L, according to the intended uses, can be considered acceptable.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Data on toxicity of BELTANOL-L are available. All acute TER values for 8-hydroxyquinoline exceed the required trigger values, indicating that 8-hydroquyquinoline poses an acceptable acute risk to aquatic organisms following the proposed use of BELTANOL-L.

No long tests were necessary to be submitted during EU revision for 8-hydroxyquinoline. Neither these studies are considered necessary to be submitted within this dossier considering the intended uses for BELTANOL-L in greenhouses and the unlikelihood for the product/active ingredient to reach surface water.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

All hazard quotients (HQ) were found to be less than 50, indicating that the active substance pose an acceptable risk to bees. Therefore an acceptable risk to bees is expected from the application of BELTANOL-L.

Other non-target arthropods

The in-field HQ values indicate that BELTANOL-L poses an acceptable risk to non-target arthropods with the intended uses.

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

The TER values for acute risk are greater than the trigger of 10, indicating an acceptable acute risk to earthworms from BELTANOL-L at the proposed label rates.

In glasshouse, earthworms are marginally exposed, therefore the long term risk is considered acceptable.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

No further testing is regarded to be necessary.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

No effect on ground micro-organisms is expected after the treatments with BELTANOL-L according to the GAPs.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

According to the GAP for BELTANOL-L, it is intended to be applied by drip irrigation without pressure. This application technique precludes exposure of terrestrial non target plants.

3.1.7. Efficacy (Part B, Section 7)

The efficacy of the product BELTANOL-L, applied per drip irrigation at 4 L/ha, has been demonstrated against several soil fungi (*Pythium spp, Phytophothora spp,)* in *Solanacea*, cucurbits and strawberry crops. The product was also efficient against the bacterials *Pseudomonas spp.* and *Clavibacter michiganensis.* No adverse effects are expected on treated crops.

The active substance has not been classified in any FRAC group. The risk of resistance related to the active substance is unknown. However, the risk of resistance has been qualified to be low, considering the targeted diseases and the number of applications (maximum 2 per crop).

Target group diseases	Applic. method	Crops	Application rate	Water volume	Nber of application	Timing / Growth stage of crop	Anses - Section 7 opinion
Soil fungi (damping-off diseases)	Drip irrigation	<u>Cucurbits</u> <u>*Solanacea*</u> (tomato, aubergine, pepper,) <u>Strawberry</u>	4,0 L/ha (2000 g a.s./ha)	5 000 – 20 000 L/ha	1-2 (min 14 days between applic.)	1º: 5-15 days after transplanting 2º: from 14 days after 1st application to start of flowering.	**Possible use against all soil diseases and bacterials.** (Efficacy shown on soil fungi *Pythium spp, Phytophothora spp,* and on the bacteria *Pseudomonas spp.* and *Clavibacter michiganensis*). <u>Post-registration data asked</u>: Provide new efficacy trials on the bacterials *Xanthomonas spp, Erwinia spp*. and on the soil fungi *Fusarium spp* (delay: 3 years).
Bacterials							

3.2. Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product decision.

3.3. Substances of concern for national monitoring

No information stated.

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

3.4.1. Post-authorisation monitoring

No further information is required.

3.4.2. Post-authorisation data requirements

The French decision requests the submission of post-authorisation confirmatory pieces of information within 2 years regarding:

- The stability of the solution after storage at 54°C for 14 days.
- An analytical method and its ILV should be available for the determination of residues in foodstuff of animal origin.
- Confirmatory methods for the determination of residues in soil and water (drinking and surface).
- 2 additional residue indoor trials on cucurbits with edible peel.
- 2 additional residue indoor trials on cucurbits with inedible peel.
- 2 additional residue indoor trials on strawberries.
- The stability of storage on acid matrix during a minimal period of three months.

The French decision requests the submission of post-authorisation confirmatory pieces of information within 3 years regarding:

- New efficacy trials on the bacterials *Xanthomonas spp, Erwinia spp*. and on the soil fungi *Fusarium spp***.**

3.4.3. Label amendments (see label in Appendix 2)

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.
The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French decision

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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 règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***BELTANOL-L***

de la société	*PROBELTE S.A.*
enregistrée sous le	*n°2012-2284*

Vu les conclusions de l'évaluation du 16 février 2016,

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.

BELTANOL-L
AMM n°2150931

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Informations générales sur le produit	
Nom du produit	BELTANOL-L
Type de produit	Produit de référence
Titulaire	PROBELTE S.A. Carretera Madrid km 384.6 P.I. El Tiro 30100 Espinardo Murcia ESPAGNE
Formulation	Concentré soluble (SL)
Contenant	500 g/L - sulfate de 8-hydroxyquinoline
Numéro d'intrant	999-2012.01
Numéro d'AMM	2150931
Fonction	Fongicide et bactéricide
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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2022.

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 08 MARS 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation ne peut mettre sur le marché le produit que dans les emballages suivants:	
Emballage	**Contenance**
Bouteille en Polyéthylène/Ethylène vinyl alcool	100 mL
Bouteille en Polyéthylène/Ethylène vinyl alcool	250 mL
Bouteille en Polyéthylène/Ethylène vinyl alcool	500 mL
Bouteille en Polyéthylène/Ethylène vinyl alcool	1 L
Bidon en Polyéthylène/Ethylène vinyl alcool	5 L
Bidon en Polyéthylène/ Polyamide	10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie	**Code H**
Toxicité aiguë (par voie orale) orale, catégorie 3	H301 : Toxique en cas d'ingestion
Corrosion/irritation cutanée, catégorie 1A	H314 : Provoque des brûlures de la peau et des lésions oculaires graves
Sensibilisation cutanée, catégorie 1	H317 : Peut provoquer une allergie cutanée
Toxicité pour la reproduction, catégorie 1B	H360D : Peut nuire au fœtus
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraine des effets néfastes à long terme
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.	

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Liste des usages autorisés

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jour(s))	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
01101022 Cultures légumières*Désinfection* Eaux Irrig. Sol. Nut.	**4 L/ha**	**2 /an**	-	F	-	-	-	-
	Autorisé uniquement sous abri, sur cucurbitacées à peau comestible et fraisier DAR F au plus tard 30 jours après transplantation et avant floraison							
	4 L/ha	**2 /an**	-	70	-	-	-	-
	Autorisé uniquement sous abri, sur tomate et cucurbitacées à peau non comestible							

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Liste des usages refusés

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jour(s))
01101022 Cultures légumières*Désinfection* Eaux Irrig. Sol. Nut.	**4 L/ha**	**2 /an**	-	-
	Non autorisé sur les autres cultures revendiquées (aubergine, poivron, piment et autres solanacées mineures) en raison d'un risque de dépassement des LMR			

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, 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

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m^2 ou plus avec traitement déperlant ;
- Equipement de Protection Individuelle (EPI) partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Gants en nitrile certifiés pour les risques chimiques conformes à la norme EN 374-3 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

Pour le travailleur, porter

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m^2 ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-3, en cas de contact avec le matériel d'irrigation.

Délai de rentrée

Non applicable.

Respect des limites maximales de résidus (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

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

Protection de l'eau

- 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).

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Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir des essais d'efficacité supplémentaires sur les bactérioses de type, *Xanthomonas spp.* et *Erwinia spp.* et les champignons de type *Fusarium spp.*	36	-
Fournir une étude de stabilité de la solution après stockage à 54°C pendant 14 jours.	24	-
Fournir une méthode d'analyse et son ILV pour la détermination des résidus de 8-hydroxyquinoline dans les matrices d'origine animale.	24	-
Fournir des méthodes de confirmation pour la détermination des résidus de 8-hydroxyquinoline dans le sol et l'eau (de surface et de boisson).	24	-
Fournir 2 essais sur concombre sous abri, 2 essais sur melon ou autre cucurbitacée à peau non comestible sous abri DAR de 70 jours, 2 essais sur fraise sous abri afin de confirmer l'absence de résidu quantifiable.	24	-
Fournir une étude de stabilité au stockage sur matrice acide couvrant une durée minimale de 3 mois.	24	-

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

(*Page principale*)

Concentré soluble (SL)

BELTANOL-L®

FONGICIDE-BACTERICIDE systémique polyvalent des fraisiers et cultures légumières

Volume net
1 L , 5 L

COMPOSITION
sulphate de 8-hydroxyquinoline…….50%p/v (500 g/l)

Lot et date de production: imprimé sur le bidon.

AMM No. XXXXXX

Lire attentivement l'étiquette avant emploi

PRODUIT POUR LES PROFESSIONNELS.

Homologué et fabriqué par:
PROBELTE, S.A.
CTRA. MADRID, KM 384,6
30100 ESPINARDO-MURCIA-ESPAÑA
PHONE.: 00+34+968 30 72 50, FAX.: 00+34+968 30 54 32
Email: probelte@probelte.es.

(*Partie gauche*)

BELTANOL-L®
Concentré soluble contenant 500 g/l de sulfate de 8-hydroxyquinoline
AMM n° XXXXXX

C – Corrosif **N – Dangereux pour l'environnement**

R22 : Nocif en cas d'ingestion.
R35 : Provoque de graves brûlures.
R41 : Risque de lésions oculaires graves.
R43 : Peut entraîner une sensibilisation par contact avec la peau
R51/53 : Toxique pour les organismes aquatiques, peut entrainer des effets néfastes à long terme pour l'environnement aquatique.

S1/2 : Conserver sous clé et hors de portée des enfants.
S13 : Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S23 : Ne pas respirer les vapeurs.
S26 : En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S36/37/39 : Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux/du visage
S45 : En cas d'accident ou de malaise, consulter immédiatement un médecin (si possible lui montrer l'étiquette).

Conditions d'emploi
-Délai de rentrée : 48 heures
-SP1- Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. / Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]

Eviter le rejet dans l'environnement. Consulter la Fiche de Données de Sécurité. Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

La fiche de données de sécurité est disponible sur le site : www.probelte.es
En cas d'urgence **appeler le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48) puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Les limites maximales de résidus sont disponibles sur le site :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.
Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.
Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

PRECAUTIONS

- Pendant la préparation de la bouillie, porter des gants imperméables et un appareil de protection des yeux/du visage.
- Au cours de l'application :
    - Porter un vêtement de protection et des gants appropriés.
    - Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort pour éviter, toute dérive de pulvérisation vers les fossés, cours d'eau.
    - Appliquer, après dilution, les fonds de cuve conformément à la législation en vigueur.
- Emballage : Réemploi de l'emballage interdit ; rincer soigneusement le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.
  Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique (ex : Adivalor).
  Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Stocker dans un local phytosanitaire conforme et fermé à clé. Conserver hors de porte des enfants, à l'écart des aliments et boissons y compris ceux pour animaux.

Mélanges

Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de bonnes pratiques des officiels.
Consulter le site : http://e-phy.agriculture.gouv.fr

(Partie droite)

PRESENTATION

BELTANOL-L est un fongicide et bactéricide systémique utilisé de manière préventive et curative dans l'eau d'irrigation contre de nombreuses maladies et bactérioses du sol.
Il s'utilise sur fraisier et de nombreuses cultures maraîchères sous abri.

USAGES ET DOSES AUTORISEES

Traitements généraux * traitement dans l'eau d'irrigation * désinfection

Cultures (plein champ et sous abri)	**Ravageurs**	**Doses L/ha**	**Applications par culture**	**DAR**
Tomate, aubergine, poivron, piment,	Champigons et bactéries du sol (*Pythium, Rhizoctonia, Phytophthora, Fusarium, Pseudomonas, etc.)*	4	2 max	Non applicable
Concombre, courgette, cornichon et autres cucurbitacées à peau comestible	Champigons et bactéries du sol (*Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia, etc.)*	4	2 max	Non applicable
Melon, pastèque, potiron, potimarron et autres cucurbitacées à peau non comestible	Champigons et bactéries du sol (*Pythium, Rhizoctonia, Phytophthora, Fusarium, Erwinia, etc.)*	4	2 max	Non applicable
Fraisier	Champigons et bactéries du sol (*Pythium, Rhizoctonia, Phytophthora, Fusarium, Xanthomonas, etc.)*	4	2 max	Non applicable

RECOMMANDATIONS D'UTILISATION

Appliquer dans l'eau d'irrigation au goutte à goutte.
Appliquer 2 fois par culture à la dose de 4 L/ha :

- 1ère application à 4 L/ha 5 à 15 jours après le repiquage
- 2ème application à 4 L/ha, 14 jours après la 1ère application

Appendix 3 – Letter(s) of Access

Not applicable.