REGISTRATION REPORT

Part A

Risk Management

Product code: MTL + PTZ FS 120

Product name: REDIGO M

Active substances:

prothioconazole, 100 g/L

metalaxyl, 20 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: BAYER S.A.S.

Date: 30/07/2018

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PART A – Risk Management

The company BAYER S.A.S. has requested marketing authorisation in France for the product REDIGO M (product code: MTL + PTZ FS 120), containing 100 g/L prothioconazole and 20 g/L metalaxyl, for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to REDIGO M (MTL + PTZ FS 120) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of REDIGO M (MTL + PTZ FS 120) have been made using endpoints agreed in the EU peer reviews of both prothioconazole and metalaxyl.

This document describes the specific conditions of use and labelling required for France for the registration of REDIGO M (MTL + PTZ FS 120).

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 letters of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of BAYER S.A.S.'s application to market REDIGO M (MTL + PTZ FS 120) in France as a fungicide (product uses described under point 2.3). France acted as 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

Prothioconazole

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows: PART A Only uses as fungicide 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 prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety in spray applications. Conditions of use shall include adequate protective measures, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin,

— a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds, — information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment. They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2007) 106, 1-98). A Review Report is available (SANCO/3923/07 - final, 10 December 2007).

Metalaxyl

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as fungicide 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 metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.
An EFSA conclusion is available for metalaxyl-M (EFSA Journal 2015; 13(3): 3999). A Review Report is available (SANCO/10476/2010 rev.1, 12 March 2010).

1.3 Regulatory approach

The present application (2013-1121; 2014-1056, 2017-2173) 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 out in the Decision letter.

The French Order of 4 May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[3] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[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) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of REDIGO M (MTL + PTZ FS 120), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letters of Access

The applicant has provided letter of access.

[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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	REDIGO M (MTL + PTZ FS 120)
Authorisation number	2180124
Function	Fungicide
Applicant	BAYER S.A.S.
Composition	100 g/L prothioconazole 20 g/L metalaxyl
Formulation type (code)	Flowable concentrate for seed treatment (FS)
Packaging	High density polyethylene (HDPE): 5 L, 10 L, 20 L, 25 L, 50 L, 200 L, 220 L, 1000 L High density polyethylene/polyamide (HDPE/PA) or high density polyethylene/ethylene vinyl alcohol (HDPE/EVOH): 5 L, 10 L, 25 L, 50 L, 200 L, 220 L, 1000 L

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Reproductive toxicity category 2	
Environmental hazards	Hazardous to the aquatic environment - Chronic Hazard, category 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H361d	Suspected of damaging fertility or the unborn child
	H411	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)	-	-

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

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

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment

	near surface water. Avoid contamination *via* drains from farmyards and roads.
SPe 6	To protect birds and wild mammals, remove spillages.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details
Re-entry period[9]: not applicable (seed treatment)
Pre-harvest interval[10]: F[11] (seed treatment – BBCH 00)
The label must include the following recommendations: - EUH 208 "Contains metalaxyl, 1,2-benzisothiazol-3(2H)-one and a mixture of 5-chloro-2-methyl-1,2-isothiazol-3(2H)-one and 2-methyl-1,2-isothiazol-3(2H)-one. May produce an allergic reaction." - Specify on the label the selectivity of the PPP on different sweet corn varieties The label must reflect the conditions of authorisation.

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

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

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

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

2.3 Product uses

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

GAP rev. 1, date: 2018-07-30

PPP (product name):	**REDIGO M (MTL + PTZ FS 120)**	Formulation type:	**FS** [a, b]
Active substance 1:	Prothioconazole	Conc. of a.s. 1:	**100 g/L** [c]
Active substance 2:	Metalaxyl	Conc. of a.s. 2:	**20 g/L** [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	**BAYER S.A.S.**	Professional use:	☒
Zone(s):	interzonal [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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]	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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]	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
1	France	Maize (ZEAMX), common millet (PANMI), hungarian millet (SETIM), japanse plume grass (MISSI), sorghum (SORVU)	F	*Fusarium* spp. (FUSASP) *Pythium* spp. (PYTHSP) Damping-off disease complex (ZZYYFF)[1]	Seed treatment	BBCH 00	1	-	a) max 0.015 L per Unit (2 Units per ha) b) max 0.03 L/ha (1 Unit = 50 000 kernels[12])	a)+b): max 0.0006 kg metalaxyl and 0.003 kg prothioconazole per hectare	Min 0.1 L Max 1.9 L/ 100 kg kernels	F	-	**Acceptable**
2	France	Sweet corn (ZEAMS)	F	*Fusarium* spp. (FUSASP) *Pythium* spp. (PYTHSP) Damping-off disease complex (ZZYYFF) [1]	Seed treatment	BBCH 00	1	-	a) max 0.015 L per Unit (2 Units per ha) b) max 0.03 L/ha (1 Unit = 50 000 kernels)	a)+b): max 0.0006 kg metalaxyl and 0.003 kg prothioconazole per hectare	Min 0.1 L Max 1.9 L/1 00 kg kernels	F	-	**Acceptable**

[1]: Damping-off disease complex (ZZYYFF) is primarily made up of PYTHSP, FUSASP and RHIZSO.

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.

[12] Remark by izRMS: the sowing rate is 2 Units or 100 000 kernels/ha

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/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

REDIGO M (MTL + PTZ FS 120) is a flowable concentrate for seed treatment (FS). All studies have been performed in accordance with the current requirements. The appearance of the product is a red water-based liquid formulation, with a bitter almond-like odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 485 °C and a flash point > 97 °C. In aqueous solution (1 % v/v), it has a pH value of 5.8 at ambient temperature. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for an FS formulation. The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances and relevant impurities (toluene [methylbenzene] and prothioconazole-desthio from prothioconazole and 2,6-dimethylaniline from metalaxyl) in the formulation are available and validated.

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

To update the dossier and to be in accordance with SANCO 825/00/rev8.1, the following analytical methods are required in post authorization:

- A fully validated method with ILV for the determination of metalaxyl residue in foodstuff of animal origin

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

The metabolite prothioconazole-desthio is toxic (T). An analytical method has been provided and is validated for the determination of this metabolite in blood.

3.1.3 Mammalian Toxicology

The following endpoints were used for risk assessment.

Active substance: **metalaxyl**			
ADI	0.08 mg/kg body weight/day		EU agreed endpoint
ARfD	0.5 mg/kg body weight		EU agreed endpoint
AOEL	0.08 mg/kg body weight/day		EU agreed endpoint
Dermal absorption	Based on an *in vitro* rat/human study performed on formulation:		
		Concentrate (tested) 20 g/L	Spray dilution (tested) 0.75 g/L
	In vitro (human) %	3 %	12 %
		Concentrate (used in formulation) 20 g/L	Spray dilution (used in formulation) 1 g/L
	Dermal absorption endpoints %	**3 %**	**12 %**

Active substance: **prothioconazole**			
ADI	0.05 mg/kg body weight/day		EU agreed endpoint
ARfD	0.2 mg/kg body weight		EU agreed endpoint
AOEL	0.2 mg/kg body weight/day		EU agreed endpoint
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)

		100 g/L	
	Dermal absorption endpoints %	**25 %**	-

Substance: **prothioconazole-desthio**			
ADI	0.01 mg/kg body weight/day		EU agreed endpoint
ARfD	0.01 mg/kg body weight		EU agreed endpoint
AOEL	0.01 mg/kg body weight/day		EU agreed endpoint
Dermal absorption	Based on an *in vivo* monkey study performed on a similar formulation:		
		Concentrate (used in formulation) 100 g/L	Spray dilution (used in formulation)
	Dermal absorption endpoints %	**20 %**	-

For a seed treatment, only the dermal absorption value of undiluted formulation is used. The table below summarises the endpoints used for risk assessment:

Prothioconazole	
AOEL	0.2 mg/kg body weight/day
Dermal absorption	Undiluted formulation: 25 %
Prothioconazole-desthio	
AOEL	0.01 mg/kg body weight/day
Dermal absorption	Undiluted formulation: 20 %
Metalaxyl	
AOEL	0.08 mg/kg body weight/day

3.1.3.1 Acute Toxicity

REDIGO M (MTL + PTZ FS 120) has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin and eye, nor a skin sensitiser.

3.1.3.2 Operator Exposure and Worker Exposure

The critical use patterns (worst cases) are summarised below.

Crop	**Formulation**		**Application rate per treatment**			**Equipment type / Model**
	Type	**Conc of a.s. (g/L)**	**Max dose product**	**Min Water**	**Maximum application rate**	
Maize	FS	Metalaxyl: 20 g/L Prothioconazole: 100 g/L	0.015 L/U (= 0.015 L/15 kg seeds ⇔ 1 L/t)	2 to 23*	Metalaxyl : 20 g a.s./t Prothioconazole : 100 g a.s./t	Seed treatment / SeedTropex

** Corresponding to 0.1 L to 1.9 L water applied to 100 kg seed corresponding to 0.0175 L to 0.3325 L water/unit taking into account a thousand grain weight of 350 g.*

According to the model calculations for metalaxyl and based on the field study for prothioconazole and its metabolite prothioconazole-desthio, it may be concluded that the risk for the operator using REDIGO M (MTL + PTZ FS 120) during seed treatment or for worker loading and sowing treated seeds with REDIGO M (MTL + PTZ FS 120) is acceptable with appropriate personal protective equipment.

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

3.1.3.3 Bystander Exposure

REDIGO M (MTL + PTZ FS 120) is used as seed treatment; therefore, bystander exposure estimation is considered to be not relevant.

The currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory) show a range of values, reaching the maximum value for metalaxyl of 0.97 ng/m³ and 0.08 ng/m³ (maximum daily and weekly measurements, respectively). Based on these data, the respiratory exposure of people living near sprayed areas was estimated to be less than 0.1 % of the ADI and the AOEL of metalaxyl for an adult and for a child.

3.1.3.5 Relevance of metabolites

Expected estimated concentrations in groundwater exceed the threshold of 0.1 µg/L (0.329 µg/L) for the metabolite CGA 108906 of metalaxyl.

A summary of the available studies on metabolite CGA 108906 is available upon request.

Toxicological studies with metalaxyl and its metabolite CGA 108906 : Available upon request

The provided IQV studies for which Bayer provided a letter of access are considered equivalent to the new protected studies provided for the renewal of metalaxyl-M (see matching table below).

Considering the available information, the metabolite CGA 108906 may be considered to be not relevant according to EU guidance SANCO/221/2000 on the relevance of groundwater metabolites.

Table 3.1.3.5-2: Matching table for the equivalence of genotoxicity studies

Provided upon request.

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment purposes. Any exceedance of the current maximum residues limits (MRLs) for metalaxyl (0.01 mg/kg for maize and sweet corn) and prothioconazole (0.1 mg/kg for maize and 0.02 mg/kg for sweet corn) as laid down in Regulation (EU) No 396/2005 is not expected.

The chronic and short-term intakes of metalaxyl and prothioconazole residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with authorisation for the intended uses.

Summary of the evaluation

Summary for prothioconazole

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 2016/1902	Chronic risk for consumers identified?	Acute risk for consumers identified?
Maize	Yes	Yes	Yes	Yes	Yes	No	No
Sweet corn	Yes	Yes	Yes	Yes	Yes		No

As residues of prothioconazole do not exceed the trigger values defined in Regulation (EU) No 2016/1902, there is no need to investigate the effect of industrial and/or household processing.

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

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

Summary for metalaxyl

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 2017/1164	Chronic risk for consumers identified?	Acute risk for consumers identified?
Maize	Yes	Yes	Yes	Yes	Yes	No	No
Sweet corn	Yes	Yes	Yes	Yes	Yes		No

As residues of metalaxyl do not exceed the trigger values defined in Regulation (EU) No 2017/1164, there is no need to investigate the effect of industrial and/or household processing.

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

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

Summary for REDIGO M (MTL + PTZ FS 120)

Crop	PHI for REDIGO M (MTL + PTZ FS 120) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for REDIGO M (MTL + PTZ FS 120) proposed by zRMS
		prothioconazole	metalaxyl	
Maize	F**	Yes	Yes	F
Sweet corn	F	Yes	Yes	F

* *Purpose of withholding period to be specified.*

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

3.1.5 Environmental fate and behaviour

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

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

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

PECgw values for metalaxyl, prothioconazole and their metabolites do not exceed the level of 0.1 µg/L, except for the metabolite CGA 108906 (max. PECgw of 0.329 µg/L). Since this metabolite is not considered to be relevant according to guidance document SANCO/221/2000 rev. 10, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

For birds and mammals, the risk assessment for metalaxyl and prothioconazole showed that all toxicity-to-exposure-ratios (TER) meet the a priori acceptability criteria of current regulatory requirements. In order to refine the assessment for the metabolite prothioconazole-desthio, a lower nominal application rate based on formation rates of the metabolite on treated seeds derived from a field study were applied. All refined TER values meet the required trigger except for small omnivorous mammals feeding on seeds contaminated with prothioconazole-desthio. However, based on a weight of evidence approach, a risk for small mammals feeding on seeds contaminated with prothioconazole-desthio is not expected. Thus there is an acceptable risk to birds and mammals from dietary exposure after use of the product as described in this dossier.

No risk to birds and mammals resulted from exposure via drinking water. The risk from secondary poisoning of birds and mammals via prey like earthworms and fish is considered acceptable.

3.1.6.2 Effects on Aquatic Species

The TER values for metalaxyl, prothioconazole and their metabolites meet the required trigger for acute and chronic risk based on FOCUS Step 2 PECsw values, indicating an acceptable risk to aquatic organisms.

3.1.6.3 Effects on Bees and Other Arthropod Species

The Tier 1 risk assessment showed that the hazard quotients (oral and contact) are below the EU trigger value. This indicates that the use of the product according to the proposed use pattern does not constitute an unacceptable risk towards bees.

In the case of a seed treatment, the risk assessment for non-target arthropods is considered acceptable.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

As demonstrated by acute and chronic studies, no unacceptable effects on earthworms are to be expected from the application of the product according to the proposed use pattern.

The tests with Collembola and Hypoaspis also indicate that no adverse effects on other soil non-target macro-organisms are to be expected from the use of the product.

3.1.6.5 Effects on Soil Non-target Micro-organisms

The risk assessment indicates that no adverse effects on soil micro-organisms are to be expected when the product is applied according to the proposed use pattern.

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

In the case of a seed treatment, any exposure of non-target terrestrial plants in the off-crop area to the seed dressing product itself and the active substances of the product, respectively, is not expected to be significant.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy of REDIGO M (MTL + PTZ FS 120) is considered satisfactory based on trials on maize only.
- The selectivity of REDIGO M (MTL + PTZ FS 120) is considered satisfactory on maize. The selectivity on sweet corn should be specified on the label
- The risk of negative impact on yield, quality, transformation processes, propagation and succeeding crops is considered acceptable for maize.
- The risk of resistance developing or appearing is considered low to moderate. Any new information that may alter the resistance risk evaluation must be provided to the competent authorities (Anses-France).

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can be granted** as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- A fully validated method with its inter-laboratory validation (ILV) for the determination of metalaxyl residues in foodstuffs of animal origin.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

Specify product susceptibility levels for the various varieties of sweet corn.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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 et les demandes associées du produit phytopharmaceutique ***REDIGO M***

de la société *BAYER SAS*

enregistrées sous les *n°2013-1121, 2014-1056, 2017-2173*

Vu les conclusions de l'évaluation de l'Anses du 28 février 2018,

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.

REDIGO M
AMM n°2180124

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Informations générales sur le produit	
Nom du produit	REDIGO M
Type de produit	Produit de référence
Titulaire	BAYER SAS Département Homologation France, 16, rue Jean-Marie Leclair, CS 90106, 69266 LYON CEDEX 09, France
Formulation	Suspension concentrée pour traitement des semences (FS)
Contenant	20 g/L - métalaxyl 100 g/L - prothioconazole
Numéro d'intrant	9886-2013.01
Numéro d'AMM	2180124
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 juillet 2020.

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

La directrice générale déléguée
en charge du pôle des produits réglementés

Françoise WEBER

30 JUIL. 2018

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bidons en polyéthylène haute densité	5 L ; 10 L ; 20 L
Bidons en polyéthylène haute densité / éthylène vinyl alcool	5 L ; 10 L
Bidons en polyéthylène haute densité / polyamide	5 L ; 10 L
Fûts en polyéthylène haute densité	25 L ; 50 L ; 200 L
Fûts en polyéthylène haute densité / éthylène vinyl alcool	25 L ; 50 L ; 200 L
Fûts en polyéthylène haute densité / polyamide	25 L ; 50 L ; 200 L
Cuves en polyéthylène haute densité	220 L ; 1000 L
Cuves en polyéthylène haute densité / éthylène vinyl alcool	220 L ; 1000 L
Cuves en polyéthylène haute densité / polyamide	220 L ; 1000 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Toxiques pour la reproduction - catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
Pour les phrases P se référer à la règlementation en vigueur. EUH208 : Contient du métalaxyl, de la 1,2-benzisothiazol-3(2H)-one et un mélange de 5-chloro-2-méthyl-1,2-isothiazol-3(2H)-one et de 2-méthyl-1,2-isothiazol-3(2H)-one. Peut produire une réaction allergique. **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
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16661202 Maïs doux*Trt Sem. Plants*Champignons autres que pythiacées	**15 mL/unité**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	1 unité : 50000 graines (densité de semis : 2 unités/ha).							
16661201 Maïs doux*Trt Sem. Plants*Champignons (pythiacées)	**15 mL/unité**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	1 unité : 50000 graines (densité de semis : 2 unités/ha).							
00120037 Maïs*Trt Sem.*Champignons autres que pythiacées	**15 mL/unité**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	1 unité : 50000 graines (densité de semis : 2 unités/ha).							
15551201 Maïs*Trt Sem.*Champignons (pythiacées)	**15 mL/unité**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	1 unité : 50000 graines (densité de semis : 2 unités/ha).							

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

Dans le cadre du traitement de semences dans les stations industrielles:

- **pendant le mélange/chargement + calibrage**
  - Gants certifiés EN 374-3 ;
  - Vêtement de travail polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
  - Combinaison de protection de catégorie III type 5/6 à porter par-dessus le vêtement précité ;

  OU

  - Gants certifiés EN 374-3 ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
  - Blouse ou tablier à manches longues de catégorie III type 3 (PB) à porter par-dessus le vêtement précité ;

- **pendant l'ensachage**
  - Gants certifiés EN 374-2 à usage unique en cas d'intervention ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;

- **pendant le nettoyage**
  - Gants certifiés EN 374-3 ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
  - Combinaison de protection de catégorie III type 5/6 ou blouse ou tablier à manches longues de catégorie III type 3 (PB) à porter par-dessus le vêtement précité ;
  - Protection respiratoire certifiée P2 minimum ;

Pour le semeur, porter

Dans le cadre de la manipulation des semences lors de la phase de semis :

- **pendant le chargement du semoir**
  - Gants certifiés EN 374-3 ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
  - Blouse ou tablier à manches longues de catégorie III type 3 (PB) porté sur le vêtement de travail ;
  - Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P2 ou P3 (EN143) ou A2P3 (EN 14387);

- **pendant le semis**
  - Gants certifiés EN 374-2 à usage unique en cas d'intervention sur le semoir ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon).

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- **pendant le nettoyage**
  - Gants certifiés EN 374-3 ;
  - Vêtement de travail en polyester 65 %/coton 35 % (combinaison ou ensemble veste + pantalon) ;
  - Blouse ou tablier à manches longues de catégorie III type 3 (PB) à porter par-dessus la combinaison précitée;

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

- Non applicable

Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit 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.

Protection de la faune

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer les semences traitées accidentellement répandues.

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 les données de validation d'une méthode et de sa validation inter-laboratoires pour la détermination des résidus du métalaxyl dans les matrices d'origine animale.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Préciser le niveau de sensibilité au produit des diverses variétés de maïs doux.

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

REDIGO M
PROJET DE TEXTE D'ETIQUETTE

24 avril 2013

REDIGO M

Contient 100 g/l prothioconazole
20 g/l metalaxyl
sous forme de suspension concentrée pour traitement des semences(FS)

AMM N° : < AMM N°>
Produit fongicide pour le traitement des semences de maïs
200 L

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

100g/litre de prothioconazole
20 g/l metalaxyl

Tableaux des usages :

Culture	Cibles / Usages	Doses	Spécifications d'usage	DAR (en jours) ou Stades cultures (NC=non concerné)	Précautions environnement (voir légendes)
Maïs	Fonte des semis	15.0 ml/unité (50 000 graines)	1 trait./an	NC	1a
Maïs	Fonte des semis : Pythium sp., Fonte des semis : Fusarium sp.	15.0 ml/unité (50 000 graines)	1 trait./an	NC	1a
Maïs doux	Fonte des semis : Pythium sp., Fonte des semis : Fusarium sp.	15.0 ml/unité (50 000 graines)	1 trait./an	NC	1a

En raison de la diversité des lignées parentales utilisées en maïs et de la difficulté de tester le matériel génétique des sélectionneurs, l'utilisation de la préparation REDIGO M sur cultures destinées à la production de semences est sous la seule responsabilité des sélectionneurs de semences.

Limites maximales en résidus de substances actives : se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse :http://ec.europa.eu/sanco_pesticides/public/index.cfm

1. Organismes aquatiques
1a. La réglementation en vigueur n'impose pas le respect d'une ZNT minimale par rapport aux points d'eau lors du semis de semences traitées.

Champ d'activité :

Mode d'emploi :

- Préparation de la bouillie
Avant emploi, agiter REDIGO M, présenté sous forme de suspension concentrée, jusqu'à l'obtention d'une suspension homogène.
La mise en œuvre du produit doit être adaptée, par la personne habilitée, en fonction des spécificités de la machine et du process de traitement utilisés.

Pour le cas d'une application par bouillie :

Préparation de la bouillie
- Introduire environ 80 % du volume d'eau prévu
- Ajouter sous agitation REDIGO M et le ou les produits TS à associer
- Compléter avec le volume d'eau nécessaire à l'obtention du volume de bouillie souhaité. Maintenir sous agitation lente pendant la durée du traitement pour garantir l'homogénéité de la bouillie.
- La bouillie ainsi préparée doit être utilisée dans les 3 jours.

Volume de la bouillie : Pour un traitement de qualité et donc pour assurer une couverture régulière de la semence, adapter le volume de bouillie en fonction du matériel d'application et des caractéristiques de la semence (espèce, PMG). Pratiquer un premier test puis ajuster de nouveau le volume d'eau.

Recommandation générale
Veiller à bien mettre en œuvre les mesures permettant une maîtrise de la qualité d'application de REDIGO M et garantissant sa bonne tenue sur la semence ainsi qu'une couverture maximale de la semence. Pour toute information consulter notre numéro vert (0800 25 35 45).

- Mélanges et Compatibilités

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Pour connaître le détail pratique de cette mise en œuvre, il est nécessaire de contacter au préalable le 0 800 25 35 45.

- Conditions de traitement (époque, stade, seuil d'intervention)

Attention : en cas de recours à des techniques culturales nouvellement mises en œuvre par l'utilisateur ou présentant une quelconque spécificité, l'utilisateur doit en informer son fournisseur avant toute utilisation du produit, afin que ce dernier puisse en vérifier la faisabilité avec le fabricant du produit.

Précautions à prendre :

- Pour le stockage

- Pour des raisons d'assurance qualité, stocker à des températures comprise entre -10 et + 40 °C
- Ne pas laisser les fûts exposés en plein air, stocker impérativement à l'abri du soleil.
- Conserver le produit dans son emballage d'origine, dans des locaux fermés à clé, à l'écart de tout aliment et boisson y compris ceux pour les animaux, et hors de portée des enfants. Les locaux doivent être frais et ventilés.

- Pour l'emploi

- Porter des gants et un vêtement de protection appropriés pendant toutes les phases d'utilisation du produit.
- Ne pas boire, fumer ou manger pendant cette phase de travail.
- Aérer les locaux de préparation de bouillie de traitement de semences.
- Les reliquats de bouillie et les eaux de rinçages doivent être récupérées et utilisées pour la préparation de la bouillie suivante.
- En cas d'accident ou de malaise, consulter immédiatement un médecin (si possible lui montrer l'étiquette).
- Eliminer les fonds de cuve conformément à la réglementation en vigueur.

- Pour l'élimination du produit et de l'emballage

Emballage : réemploi interdit
- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Ne pas réutiliser les emballages vides et les éliminer via une collecte organisée par les distributeurs partenaires de la filière Adivalor ou un autre service de collecte spécifique.

REDIGO M ® AMM N° : < AMM N°>
100 g/l prothioconazole, soit 9.35 % (m/m)
20 g/l metalaxyl, soit 1.87 % (m/m)
Autres composants dangereux
Tristyril phénol éthoxylé, sulfaté (16 OE)

Attention

H361d Susceptible de nuire au foetus
H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
EUH208 Contient Métalaxyl. Peut déclencher une réaction allergique

P281 Utiliser l'équipement de protection individuel requis.
P501 Éliminer le contenu/récipient dans le lieu d'élimination conformément à la réglementation locale.

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

Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Premiers secours
Conseils généraux
Enlever immédiatement tout vêtement souillé et le mettre à l'écart. S'éloigner de la zone dangereuse. Maintenir et transporter la victime en position latérale de sécurité.

Inhalation
Amener la victime à l'air libre. Garder la victime au repos et la maintenir au chaud. Appeler immédiatement un médecin ou un centre AntiPoison.

Contact avec la peau
Nettoyer avec une grande quantité d'eau et du savon, si disponible, avec du polyéthylèneglycol 400, puis rincer avec de l'eau.

Contact avec les yeux
Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Après les 5 premières minutes, enlever les lentilles cornéennes, si présentes, continuer à rincer l'oeil. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.

Ingestion
Ne PAS faire vomir. Appeler immédiatement un médecin ou un centre AntiPoison. Rincer la bouche.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel au 0 800 25 35 45 ou être consultée sur les sites internet : www.bayer-agri.fr et www.quickfds.com .
En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Point gélif : -10 °C
40 °C

UN : 3082


9 - Matières et objets dangereux divers


- Dangereux pour l'environnement

® Marque déposée Bayer
Bayer S.A.S - Bayer CropScience
16, rue Jean-Marie Leclair - CS 90106 - F-69266 Lyon Cedex 09
Fabrication CEE

Date de fabrication/n° de lot : voir sur l'emballage

BPP_4
Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
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.

Appendix 3 – Letters of Access

Provided upon request.