REGISTRATION REPORT

Part A

Risk Management

Product code: UBI 4336.01

Product name: RANCONA 450 FS

Active substance:

ipconazole, 452 g/L

COUNTRY: FRANCE

Interzonal

Interzonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: ARYSTA LIFESCIENCE GREAT BRITAIN Ltd

Date: 2018/01/18 (Decision)

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PART A – Risk Management

The company ARYSTA LIFESCIENCE GREAT BRITAIN Ltd has requested marketing authorisation in France for the product RANCONA 450 FS (product code: UBI 4336.01), containing 452 g/L ipconazole, for use as a seed treatment 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 RANCONA 450 FS (UBI 4336.01) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RANCONA 450 FS (UBI 4336.01) have been made using endpoints agreed in the EU peer review of ipconazole.

This document describes the specific conditions of use and labelling required for France for the registration of RANCONA 450 FS (UBI 4336.01).

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 ARYSTA LIFESCIENCE GREAT BRITAIN Ltd's application to market RANCONA 450 FS (UBI 4336.01) in France as a seed treatment fungicide (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

Ipconazole

Commission Implementing Regulation (EU) No 571/2014 of 26 May 2014 approving the active substance ipconazole, 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 (EU) No 571/2014 were as follows : 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 ipconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the risk to granivorous birds; 2. the protection of workers and operators; 3. the risk to fish. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the acceptability of the long-term risk to granivorous birds;

(b) the acceptability of the risk to soil macro-organisms; (c) the risk of enantio-selective metabolisation or degradation; (d) the potential endocrine-disrupting properties of ipconazole for birds and fish. The applicant shall submit to the Commission, the Member States and the Authority the information under (a) and (b) by 31 August 2016, the information under (c) within two years after adoption of the pertinent guidance document on evaluation of isomer mixtures and the information under (d) within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of test guidelines agreed at EU level.
An EFSA conclusion is available (EFSA Journal 2013;11(4):3181) plus Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for ipconazole in light of confirmatory data. EFSA supporting publication 2017:EN-1260. A Review Report is available (SANCO/11789/2013 rev 1 20 March 2014).

1.3 Regulatory approach

The present applications (2014-1190, 2017-2731) 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 4th 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-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

[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
[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

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 RANCONA 450 FS (UBI 4336.01), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided a letter of access.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	RANCONA 450 FS (UBI 4336.01)
Authorisation number	2180865
Function	Seed treatment fungicide
Applicant	ARYSTA LIFESCIENCE GREAT BRITAIN Ltd
Composition	452 g/L ipconazole
Formulation type (code)	Flowable concentrate for seed treatment (FS)
Packaging	HDPE containers (20 L, 200 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. Specific target organ toxicity after repeated exposure, Category 2.
Environmental hazards	Hazardous to the aquatic environment, Chronic Hazard, Category 1.

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

Hazard pictograms		
Signal word	Warning	
Hazard statements	H361d	Suspected of damaging the unborn child
	H373	May cause damage to organs through prolonged or repeated exposure
	H410	Very 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 5	To protect birds and wild mammals, the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
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]: Before sowing.
Other mitigation measures: -
The label must include the following recommendations: − Specify the optimal rate of application according to the crops treated and disease to control. 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.

2.3 Product uses

Please note:

GAP rev. , date: 2019-01-18

PPP (product name/code):	RANCONA 450 FS (UBI 4336.01)	Formulation type:	Flowable concentrate for seed treatment (FS) [a, b]
Active substance 1:	Ipconazole	Conc. of a.s. 1:	452 g/L [c]
Applicant:	ARYSTA LIFESCIENCE GREAT BRITAIN Ltd	Professional use:	☒
Zone(s):	Interzonal [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide for seed treatment		

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 e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR, DE, HU, IT, RO	Maize ZEAMX Sorgho Miscanthus Moha Millet	F	*Fusarium* spp. FUSASP *Rhizoctonia solani* RHIZSO *Fusarium graminearum* (GIBBZE) *Fusarium roseum* (FUSARO)	Seed treatment	Seed before sowing (drilling) BBCH 00	(a) 1 (b) 1	0.055 L/tonne seed	0.055 L product/tonne seed = 24.86 g ipconazole per tonne seed At a maximum seed rate of 35 kg/ha, the application rate is 0.87 g ipconazole per hectare	0.11 - 0.55 L water per tonne seed	BBCH 00	**Acceptable**
3	FR, DE, HU, IT, RO	Maize ZEAMX Sorgho Miscanthus Moha Millet	I	Head smut *Ustilago reiliana f. sp. zeae*, synonym *Sphacelotheca reiliana* SPHTRE	Seed treatment	Seed before sowing (drilling) BBCH 00	(a) 1 (b) 1	0.18 L/tonne seed	0.18 L product/tonne seed = 81.36 g ipconazole per tonne seed At a maximum seed rate of 35 kg/ha, the application rate is 2.85 g ipconazole per hectare	0.36 – 1.8 L water per tonne seed	BBCH 00	**Acceptable**

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.

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

Commercial packaging:

- 20 L HDPE container
- 200 L HDPE barrel
- 1000 L HDPE tank

The formulation RANCONA 450 FS (UBI 4336.01) is a flowable concentrate for seed treatment. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a dark beige/brown opaque mobile liquid. It is not explosive and has no oxidising properties. The product has a flash point above 110 °C. In 1 % w/v aqueous solution, its pH is 8.8 at 23.4 °C. Suspensibility and persistent foam performed at the maximum application rate are required post-authorisation. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. Stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. The persistent foam determined at the maximum application rate after two-year storage is required post-authorisation. The technical characteristics are acceptable for this type of formulation.

An analytical method for the determination of 1,2,4-triazole in surface water.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance ipconazole in the formulation is available and validated. As the active substance does not contain any relevant impurity, no pertinent analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of ipconazole in plants (high-water-content and dry crop), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of ipconazole in foodstuffs of animal origin are not necessary (no MRL is set).

According to the EFSA conclusions, an analytical method for the determination of 1,2,4-triazole in soil and surface water is required.

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Endpoints used in risk assessment

Active substance: **ipconazole**

ADI	0.015 mg/kg bw/d			Efsa (2013)
ARfD	0.015 mg/kg bw			
AOEL	0.015 mg/kg bw/d			
Dermal absorption	Based on an *in vitro* human study performed on formulation (*pro rata* correction):			
		Concentrate (tested) 452 g/L	Dilution (pro rata) 226 g/L	Dilution (pro rata) 45.2 g/L
	In vitro (human) %	0.4	0.8	4
		Concentrate (used in formulation) 452 g/L	Spray dilution(used in formulation) 226 g/L	Spray dilution(used in formulation) 45.2 g/L
	Dermal absorption endpoints %	**0.4**	**0.8**	**4**

UBI 4336.00, containing 450 g/L ipconazole, has low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

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

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[11]	Equipment	Application rates L product/tonne seed (g a.s./tonne seed)	Spray dilution (L/tonne seed)	Model
Maize	Seed treatment	Seed treatment	0.055 L/tonne seed corresponding to 24.86 g ipconazole/tonne seed	0.11 – 0.55 L Corresponding to dilution factors of 2 to 10	French Seed-TROPEX
			0.18 L/tonne seed corresponding to 81.36 g ipconazole/tonne seed	0.36 – 1.8 L Corresponding to dilution factors of 2 to 10	

Considering the proposed uses, operator systemic exposure was estimated using the French Seed tropex model:

Active ingredient (application rate)	AOEL (mg/kg bw/day)	Dilution	scenario	% AOEL
Ipconazole (24.86 g a.s./tonne seed)	0.015	Diluted (1:2)	Scenario 3*	57
		Diluted (1:10)	Scenario 3*	56
Ipconazole (81.36 g a.s./tonne seed)		Diluted (1:2)	Scenario 3*	57
		Diluted (1:10)	Scenario 3*	56

*Scenario 3: Gloves (except during bagging) and respiratory protective equipment (RPE) (P2 level minimum) during cleaning

[11] Open field or glasshouse

One operation was considered for the phases of calibration and cleaning. Two operations were considered for the preparation phase. Seven hours were considered for the bagging phase.

According to the model calculations, it may be concluded that the risk for the operator using UBI 4336.00 on maize seeds is acceptable with gloves (except during bagging) and RPE during cleaning at the 1:2 and 1:10 dilutions.

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

3.1.3.3 Bystander Exposure

Not relevant for seed treatment.

3.1.3.4 Worker Exposure

Calculations of the exposure of workers have been performed using the generic Seed-TROPEX model as revised by France.

Exposure to ipconazole for workers loaded and sowing seeds treated with UBI 4336.00 represents 27 % (75th percentile) of the AOEL when using the Seed-TROPEX model as revised by France.

Therefore it may be concluded that seeds treated with UBI 4336.00 may be loaded and sown without any unacceptable risk to workers without the use of gloves.

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

3.1.3.5 Resident Exposure

Not relevant for seed treatment.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

The preparation UBI 4336.01 (RANCONA 450 FS) contains ipconazole.

Summary for ipconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg.(EC) n° 839/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1, 2, 3	Maize, *Panicum* sp., sorghum	Yes	Yes (3 NEU + 3 SEU)	Yes	Yes	Yes	No	No	Zero-residue situation

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

As residues of ipconazole 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.

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. Nevertheless, the studies on the nature and magnitude of ipconazole residues in rotational crops indicate that triazole derivative metabolites (TDMs) may be of concern in rotational crops. Noting that these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment would be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole

compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

Miscanthus is not intended for human consumption and is not fed to livestock; Hungarian millet[12] can be fed to livestock but its contribution to the dietary burden is considered to be covered by maize.

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 UBI 4336.01 (RANCONA 450 FS)

Crop	PHI for UBI 4336.01 (RANCONA 450 FS) requested by applicant	PHI/withholding period* sufficiently supported for	PHI for UBI 4336.01 (RANCONA 450 FS) proposed by zRMS	zRMS Comments (if different PHI proposed)
		ipconazole		
Maize	NR (seed treatment)	NR	NR	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

3.1.4.2 Consumer exposure

The data available are considered sufficient for risk assessment. An exceedence of the current MRL of 0.01* mg/kg for ipconazole as laid down in Reg. (EU) No. 396/2005 is not expected.

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

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

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

Data gaps: none.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active 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 values of ipconazole and its metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw values derived for ipconazole and its metabolite are used for the ecotoxicological risk assessment.

[12] *Setaria italica* subsp. *moharica*

PECgw values for ipconazole and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. 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 DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

Several azole active substances can be applied on the same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedence of the regulatory limit of 0.1 µg/L cannot be excluded. To ensure that the regulatory limit in groundwater is not exceeded for 1,2,4-triazole, all applicants of azole-based products are requested to set up a groundwater monitoring dedicated to this metabolite within two years.

3.1.6 Ecotoxicology

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

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

The risks for birds and mammals are acceptable when the following recommendations are respected (cf. Section2.2.2):

- SPe 5: To protect birds and wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
- SPe 6: To protect birds and wild mammals. remove spillages.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of RANCONA 450 FS (UBI 4336.01) is considered acceptable for all the requested uses on maize. The data provided do not provide information on dose adjustment for other crops: French millet (*Panicum miliaceum*), Hungarian millet (*Setaria italica* subsp. *moharica*), Chinese silver grass (*Miscanthus sinensis*) and sorghum (*Sorghum bicolor*).
- the phytotoxicity level of RANCONA 450 FS (UBI 4336.01) is considered acceptable for all the requested uses on maize. The data provided do not provide information for phytotoxicity level of RANCONA 450 FS (UBI 4336.01) on *P. miliaceum, S. italica subsp. moharica*, *M. sinensis* and *S. bicolor*.
- the risks of negative impact on yield, quality, transformation processes, propagation and succeeding crops are considered negligible.
- the risk of resistance developing or appearing to ipconazole is considered to not require monitoring for the requested uses.

Restrictions: None.

Resistance monitoring data: None.

Post-authorisation data: None.

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

Several azole active substances can be applied on the same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedence of the regulatory limit of 0.1 µg/L cannot be excluded. To ensure that the regulatory limit in groundwater is not exceeded for 1,2,4-triazole, all applicants of azole-based products are requested to set up a groundwater monitoring dedicated to this metabolite within two years.

3.4.2 Post-authorisation data requirements

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

- Suspensibility and persistent foaming, performed at the maximum usage rate (i.e., 180 mL product in 360 mL water).
- The persistent foaming determined at the maximum usage rate (as above) after two years' storage at ambient temperature.
- An analytical method for the determination of 1,2,4-triazole in surface water.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 must 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 must reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

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 ***RANCONA 450 FS***

de la société	*ARYSTA LIFESCIENCE GREAT BRITAIN LTD*
enregistrées sous les	*n°2014-1190, 2016-2264, 2017-2731 et 2018-1516*

Vu les conclusions de l'évaluation de l'Anses du 10 décembre 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.

RANCONA 450 FS
AMM n°2180865

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Informations générales sur le produit	
Noms du produit	RANCONA 450 FS VORTEX
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE GREAT BRITAIN LTD Brooklands Farm Chetlenham Road Evesham WR11 2LS Royaume-Uni
Formulation	Suspension concentrée pour traitement des semences (FS)
Contenant	452 g/L - ipconazole
Numéro d'intrant	9630-2014.01
Numéro d'AMM	2180865
Fonction	Fongicide
Gamme d'usage	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 août 2025.

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, 18 JAN. 2019

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

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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	20 L
Fûts en polyéthylène haute densité	200 L
Cuves en polyéthylène haute densité	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
Toxicité spécifique pour certains organes cibles après une exposition répétée - Catégorie 2	H373 : Risque présumé d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation 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

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
00120037 Maïs*Trt Sem.* Champignons autres que pythiacées	**0,018 L/q**	**1/an**	BBCH 00	F (BBCH 00)	-	-	-	-
	Quantité maximale de semences : 35 kg/ha. Uniquement en station industrielle fixe ou mobile. Efficacité montrée sur *Sphacelotheca reiliana*. Efficacité montrée à la dose de 0,0055 L/q sur *Fusarium roseum*, *Fusarium graminearum* et *Rhizoctonia solani* et *Fusarium sp.* . Sélectivité du produit montrée sur maïs.							

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15551202 Maïs*Trt Sem.* Charbon des inflorescences	0,018 L/q	1/an	-
	Motivation du refus : L'usage est refusé puisque inclus dans l'usage N°00120037.		

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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 de la protection des semences dans les stations industrielles fixes ou mobiles

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Vêtement de travail polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- Combinaison de protection de catégorie III type 5/6 à porter par-dessus la combinaison précitée;

OU

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

• pendant l'ensachage

- Gants certifiés EN 374-2 à usage unique en cas d'intervention ;
- Vêtement de travail en polyester / coton 65 % / 35 % (combinaison ou ensemble veste + pantalon) ;
- Protections respiratoires certifiées : si le poste d'ensachage n'est pas équipé d'un système d'extraction des poussières, porter un demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;

• pendant le nettoyage

- Gants certifiés EN 374-3 ;
- Vêtement de travail en polyester / coton 65 % / 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 la combinaison précitée;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;

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/coton 65 % / 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) ;
- Lunettes certifié norme EN 166 (CE, sigle 3) ;

• pendant le semis

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

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• **pendant le nettoyage du semoir**

- Gants certifiés EN 374-3 ;
- Vêtement de travail en polyester/coton 65 % / 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 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P2 ou P3 (EN143) ou A2P3 (EN 14387);
- Lunettes certifié norme EN 166 (CE, sigle 3) ;

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

- Non pertinent pour ce type d'application.

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 5 : Pour protéger les oiseaux et les mammifères sauvages, les semences traitées doivent être entièrement incorporées dans le sol ; s'assurer que les semences traitées sont également incorporées en bout de sillons.

- 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)
Déterminer la suspensibilité du produit à la concentration maximale d'usage.	24	-
Déterminer la quantité de mousse persistante à la concentration maximale d'utilisation avant et après stockage 2 ans à température ambiante.	24	-
Fournir une méthode analytique validée pour la détermination du 1,2,4-triazole dans l'eau de surface.	24	-
Mettre en place un suivi dédié au métabolite 1,2,4-triazole afin de s'assurer du respect de la valeur seuil règlementaire de ce métabolite dans les eaux souterraines.	-	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :
- Préciser la dose d'emploi en fonction des cultures et des maladies.

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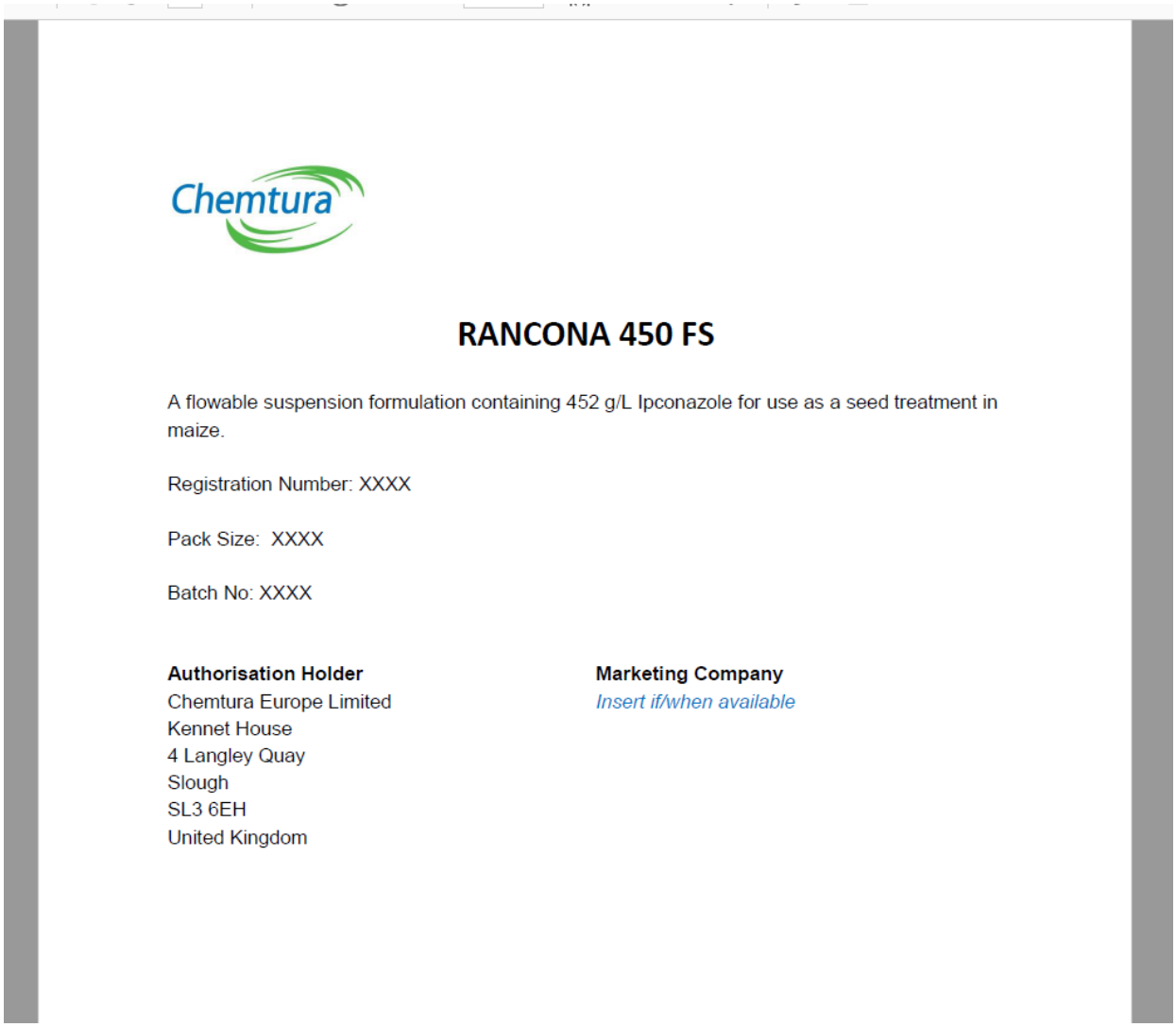
Appendix 2 – Copy of the draft product label as proposed by the applicant



Chemtura

RANCONA 450 FS

A flowable suspension formulation containing 452 g/L Ipconazole for use as a seed treatment in maize.

Registration Number: XXXX

Pack Size: XXXX

Batch No: XXXX

Authorisation Holder
Chemtura Europe Limited
Kennet House
4 Langley Quay
Slough
SL3 6EH
United Kingdom

Marketing Company
Insert if/when available

FOR USE ONLY AS AN AGRICULTURAL SEED TREATMENT			
Crop	**Maximum Individual dose**	**Maximum Number of Treatments**	**Latest Time of Application**
Maize (seed)	0.18 L product/tonne seed	One per batch	Pre-drilling

Rancona 450 FS

A flowable suspension formulation containing 452 g/L Ipconazole

WARNING

Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure.
Very toxic to aquatic life with long lasting effects

Obtain special instructions before use
Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
Avoid release to the environment.
Use personal protective equipment as required.
IF exposed or concerned: Get medical advice/ attention.
Collect spillage.

To avoid risk to human health and the environment, comply with the instructions for use.

DIRECTIONS FOR USE

Disease control

Rancona 450 FS is for the control of seed and soil borne disease in maize.

Maize (seed)	Seedling diseases (*Fusarium* spp., *Rhizoctonia solani*), Head Smut (*Sphacelotheca reiliana*)

Application rate

Maize (seed)	0.055 L product/tonne seed	Fusarium spp., *Rhizoctonia solani*
	0.18 L product / tonne seed	Head Smut (*Sphacelotheca reiliana*)

All varieties of maize may be treated.

Mixing and Application

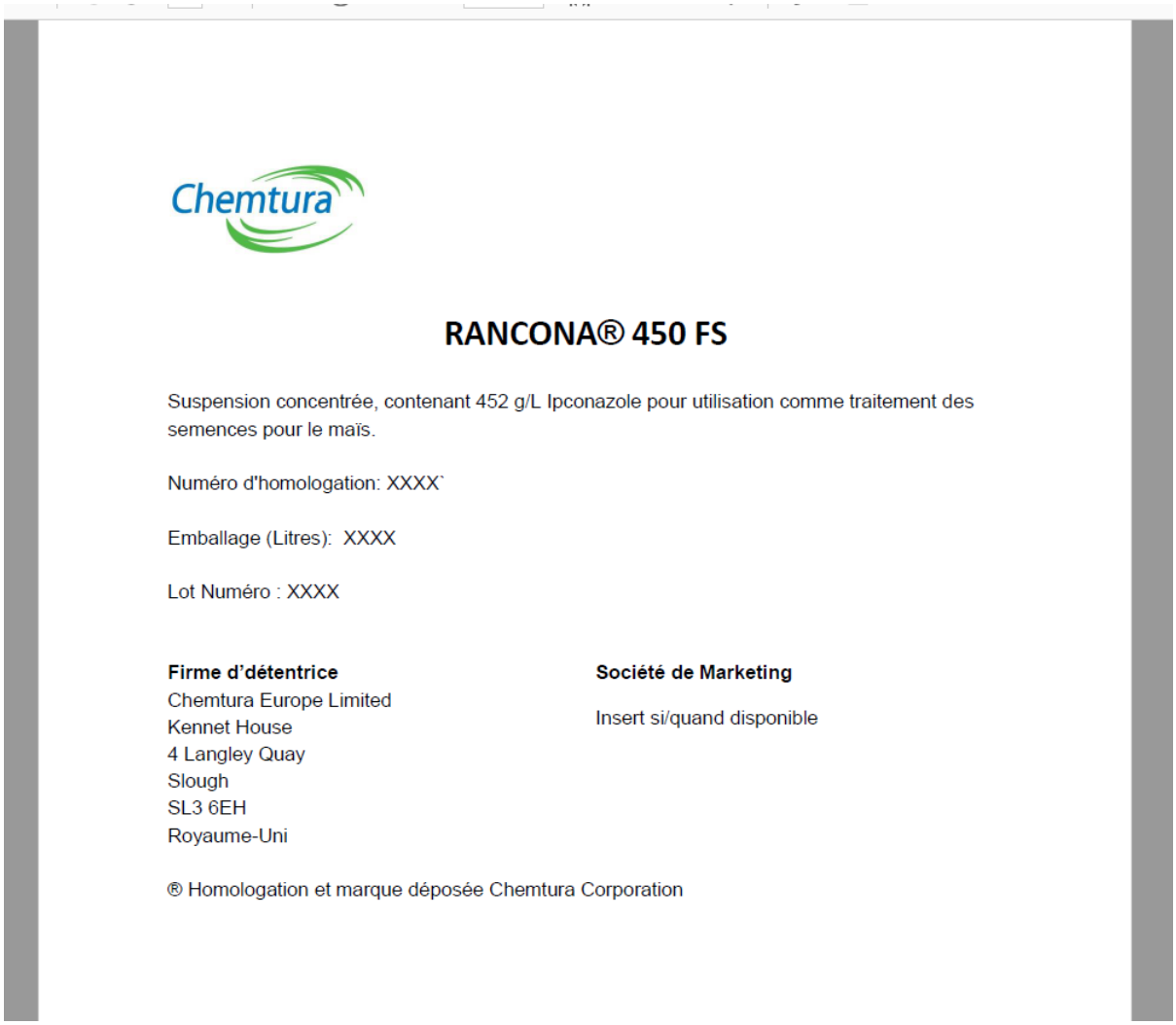
Before use ensure the homogeneity of the product by mixing.

Mix the required amount of Rancona 450 FS in water (Minimum 1:2).

Apply Rancona 450 FS through a conventional seed treater suitable for handling liquid products.

After applying clean the application equipment with water. Ensure the rinse water is kept away from any water source and disposed of in accordance with National Guidelines.

2014-04-04 LABEL CORE_Rancona 450 FS_French final draft, 04/04/2014



Chemtura

RANCONA® 450 FS

Suspension concentrée, contenant 452 g/L Ipconazole pour utilisation comme traitement des semences pour le maïs.

Numéro d'homologation: XXXX`

Emballage (Litres): XXXX

Lot Numéro : XXXX

Firme d'détentrice
Chemtura Europe Limited
Kennet House
4 Langley Quay
Slough
SL3 6EH
Royaume-Uni

Société de Marketing

Insert si/quand disponible

® Homologation et marque déposée Chemtura Corporation

A UTILISER POUR TRAITEMENT DES SEMENCES			
Culture	**Dose individuelle maximale/unité**	**Nombre maximum de traitements**	**Période d'application**
Le maïs (semences)	0.18 L produit /tonne semences	Un seul traitement par lot	Traitement des semences

Rancona 450 FS

(contient l'Ipconazole

ATTENTION

H361 Susceptible de nuire à la fertilité ou au fœtus
H373 Risque présumé d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée
H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme

Conseils de prudence / Prévention

P260 Ne pas respirer les poussières / fumées / gaz / brouillards / vapeurs / aérosols.
P273 Eviter le rejet dans l'environnement
P281 Utiliser un équipement de protection individuel requis

Conseils de prudence / Intervention

P308 + P313 EN CAS d'exposition prouvée ou suspectée: consulter un médecin
P391 Recueillir le produit répandu

Conseils de prudence / Élimination

P501 Éliminer le contenu/récipient dans une installation d'élimination des déchets agréée.

EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

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

Spe5 Pour protéger les oiseaux et les mammifères sauvages, le produit doit être incorporé dans le sol; s'assurer que le produit est également incorporé en bout de sillon

Délai de rentrée : non applicable

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Lire attentivement l'étiquette avant toute utilisation.

MODE D'EMPLOI

Les maladies contrôlée
RANCONA 450 FS : pour le control de fonte des semis et charbon des inflorescences dans le maïs.

Maïs (semences)	Font des semis (*Fusarium* spp., *Rhizoctonia solani*), Charbon des inflorescences (*Sphacelotheca reiliana*)

Dose recommandée

Maïs (semences)	0.055 L produit /tonne semences	Fusarium spp., *Rhizoctonia solani*
	0.18 L produit /tonne semences	Charbon des inflorescences (*Sphacelotheca reiliana*)

Toutes les variétés de maïs peuvent être traitées.

Mélange et Application
Avant utilisation, assurer l'homogénéité du produit en mélangeant.
Mélanger la quantité requise de Rancona 450 FS dans l'eau (Minimum 1:2).
Appliquer Rancona 450 FS par un appareil de Traitement de semences conventionnelles adapté pour le traitement des produits liquides.
Après l'application, nettoyer l'appareil d'application avec de l'eau. Rincer l'appareil et les emballages, incorporer l'eau de rinçage dans la préparation de la bouillie et recycler les emballages dans le cadre des collectes organisées par les organismes professionnels autorisée.

Precautions d'emploi

- Conserver le produit dans son emballage d'origine, hermétiquement fermé, à l'abri de la lumière, à la température ambiante, dans un endroit sec et bien ventilé et fermant à clé. Conserver hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
- Ne pas manger, ne pas boire ni fumer pendant l'utilisation
- Pendant toute la durée de manipulation du produit et de son application, veiller à porter une tenue de protection adaptée. Pour la protection de l'opérateur :
  - Le port de gants en nitrile, certifiés EN 374-3, et d'un vêtement de travail en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant est recommandé pendant le mélange/chargement, le calibrage, l'ensachage et le nettoyage du matériel.
  - En complément du vêtement de travail, le port d'un vêtement de protection contre
  - les produits chimiques liquides (tablier ou blouse) certifié catégorie III type 3 est recommandé lors du mélange/chargement et nettoyage du matériel.

- Le port d'une protection respiratoire de type P2 minimum est recommandée pendant le mélange/chargement et le nettoyage.

- Se conformer à la réglementation en vigueur concernant la gestion des fonds de cuve et des eaux de rinçage

Premiers secours

- Contact avec les yeux : Bien rincer avec beaucoup d'eau, y compris sous les paupières. Maintenir l'oeil bien ouvert pendant le rinçage. Si l'irritation oculaire persiste, consulter un médecin spécialiste.
- Contact avec la peau : Enlever les vêtements et les chaussures contaminés. Laver immédiatement et abondamment à l'eau pendant au moins 15 minutes. Appeler un CENTRE ANTIPOISON ou un médecin.
- Inhalation : Amener la victime à l'air libre. En cas d'arrêt respiratoire, pratiquer la respiration artificielle. Appeler un CENTRE ANTIPOISON ou un médecin.
- .Ingestion : Appeler immédiatement un médecin ou un centre AntiPoison. NE PAS faire vomir sauf sur instructions d'un médecin ou d'un centre anti-poison. Ne jamais rien faire avaler à une personne inconsciente.

Appendix 3 – Letter(s) of Access

Not applicable.