REGISTRATION REPORT

Part A

Risk Management

Product code: PYRUS 400 SC

Product name(s): PYRUS

Active Substance:

pyrimethanil, 400 g/L

COUNTRY: FRANCE

Southern Zone / Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: **Arysta Lifescience Benelux SPRL**

Date: **18/05/2016**

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PART A – Risk Management

The company Arysta Lifescience Benelux SPRL has requested marketing authorisation in France for the product PYRUS (formulation code: PYRUS 400 SC), containing 400 g/L pyrimethanil 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 PYRUS where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PYRUS have been made using endpoints agreed in the EU peer review of pyrimethanil.

This document describes the specific conditions of use and labelling required for France for the registration of PYRUS.

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 Benelux SPRL's application to market PYRUS in France as a fungicide (product uses described under point 2.3). France acted as a zonal / interzonal Rapporteur Member State (zRMS / izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone / European Union.

1.2 Active substance approval

Pyrimethanil

Regulations 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. Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac.
Specific provisions of regulation were as follows : PART A Only uses as fungicide may be authorised. PART B In this overall assessment Member States: -must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones, — -must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. The Member States concerned shall request the submission of further studies to confirm the risk assessment to fish. They shall ensure that the notifiers at whose request pyrimethanil has been included in this Annex provide such

studies to the Commission within two years from the entry into force of this Directive.
An EFSA conclusion is available (EFSA Journal 2006; 61, 1-70). A Review Report is available (SANCO/10019/2006 final, 23 November 2010).

1.3 Regulatory approach

The present application (2012-1655) 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 Southern zone / European Union, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone / 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 12 September 2006[3] provides that:

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

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, 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.

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

- an authorization granted for a « reference » crop applies also for "linked" crops unless formally stated in the decision
- the "reference" and "linked" crops are defined in appendix 1 of this French order.

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

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

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1 French Food Safety Agency
2 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
3 http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
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

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 PYRUS, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of Access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	PYRUS (PYRUS 400 SC)
Authorisation number	N/A : no acceptable use at FR level
Function	fungicide
Applicant	Arysta Lifescience Benelux SPRL
Composition	400 g/L pyrimethanil
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE bottle (1 L) HDPE canister (5 L, 10 L, 20 L) HDPE/EVOH bottle (0.1 L, 0.25 L, 0.5 L, 1 L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-
Health hazards	-
Environmental hazards	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Hazard pictograms	

Signal word	Warning	
Hazard statements	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)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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

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

N/A: no acceptable use

2.2.4 Other phrases linked to the preparation

N/A: no acceptable use

2.3 Product uses

Please note:
When the conclusion is "not acceptable, the intended use is highlighted in grey and the main reason(s) reported in the remarks.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2016-05-18

PPP (product name/code)	**PYRUS / (PYRUS 400 SC)**	**Formulation type:**	**< GCPF code>**
active substance 1	**pyrimethanil**	**Conc. of as 1:**	**400 g/L**
Applicant:	Arysta Lifescience Benelux SPRL	**professional use**	☒
Zone(s):	**southern/EU**	**non professional use**	☐

Verified by MS: **yes**

Crop and/ or situation (a)	**Zone**	**Product code**	**F G or I (b)**	**Pests or Group of pests controlled (c)**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days) (l)**	**Remarks: (m)**
					Type (d-f)	**Conc. of as (i)**	**method kind (f-h)**	**growth stage & season (j)**	**number min max (k)**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
Grapevine	Southern Zone	PYRUS	F	Grey mould : *Botrytis cinerea*	SC	400 g/L	Foliar spray	**1)** Flower-hoods fallen - end of flowering : BBCH 66-69 **2)** Berries touching: BBCH 77-79 **3)** Begin-ning of ripening: BBCH 81-85 (summer/autumn)	2 max	14 days	0.1 0.5	200 1000	1	21	**Not acceptable (risks for operators and workers)**
Strawberry	Southern Zone/EU	PYRUS	F & G	Grey mould : *Botrytis cinerea*	SC	400 g/L	Foliar spray	From flowering (BBCH 60) up to PHI	2 max	21 days (every 3 anti-Botrytis application)	0.05 0.16	500 1500	0.8	3	**Not acceptable (risks for workers)**

Lettuce	Southern Zone/EU	PYRUS	F & G	Grey mould : *Botrytis cinerea*	SC	400 g/L	Foliar spray	After planting until BBCH 18	2 max	7 days	0.08 0.133	600 1000	0.8	14	**Not acceptable (risks for workers)**
Tomato	Southern Zone/EU	PYRUS	G & F	Grey mould : *Botrytis cinerea*	SC	400 g/L	Foliar spray	From pre-flowering (BBCH 59) up to PHI	2 max	7 days (every 3 anti-Botrytis application)	0.05 0.16	500 1500	0.8	3	**Not acceptable (risks for workers)**
Cucumber	EU	PYRUS	G	Grey mould : *Botrytis cinerea*	SC	400 g/L	Foliar spray	From pre-flowering (BBCH 59) up to PHI	2 max	10 days	0.08 0.133	600 1000	0.8	3	**Not acceptable (risks for workers, no residue data)**
Apple	Southern Zone	PYRUS	F	Apple scab *Venturia inaequalis*	SC	400 g/L	Foliar spray	From leaf development (BBCH 10) until end of flowering (BBCH 69) (spring)	2 max	7 days	0.026 0.26	150 1500	0.4	56	**Not acceptable (risks for workers)**

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation PYRUS (PYRUS 400 SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements. The appearance of the formulation is a white opaque liquid without any detectable odour. It is not explosive and has no oxidizing properties. It has a self-ignition temperature > 600°C and a flash point > 110°C. In aqueous solution (1% w/v), its pH is 6.7 at 20°C. Stability data indicate a shelf life of at least 2 years at ambient temperature (in HDPE and HDPE/EVOH). Its technical characteristics are acceptable for a suspension concentrate (SC) formulation.
The formulation is not classified for the physical-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance and relevant impurity in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of pyrimethanil in plants (plants with high water content and acidic plants), soil, water (surface and drinking) and air.
An analytical method and its ILV for the determination of residues of pyrimethanil in foodstuff of animal origin are necessary to update the dossier.
The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of resides in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

PYRUS is of low acute toxicity by oral, dermal route or via inhalation. PYRUS is neither irritating to rabbit skin nor to the eyes. In a Magnusson and Kligman test with guinea pigs, PYRUS is not a skin sensitiser.

The label must contain the following statement: “EUH208: contains 1,2-benzisothiazol-3(2H)-one, may produce an allergic reaction”.

3.1.3.2 Operator Exposure

Dermal absorption
Dermal absorption values of pyrimethanil in SANBLITE are 25% for undiluted and 75% for diluted formulation (default values).

Operator exposure
Operator exposure to grapes, apples and pears, strawberry and lettuce has been performed according to the German model BBA.
The risk for the operator on grapevine (Tractor-mounted/trailed broadcast air-assisted sprayer) is not acceptable.

An additional evaluation has been performed with the German model with similar entry parameters in the model as presented in the RR; however taking into account a protection factor of 90% for the working coverall:

OUTDOOR:

- **Grapevine**: Tractor-mounted/trailed broadcast air-assisted sprayer: with this consideration the estimation of operator exposure represented 167% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Hand-held sprayer: hydraulic nozzles: with this consideration the estimation of operator exposure **represented 140% of the AOEL** of pyrimethanil with working coverall and with gloves during mixing/loading and application.

- **Apple/pear**: Tractor-mounted/trailed broadcast air-assisted sprayer: with this consideration the estimation of operator exposure represented 33% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Hand-held sprayer: hydraulic nozzles: with this consideration the estimation of operator exposure represented 28% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Strawberry: Tractor-mounted/trailed boom sprayer: hydraulic nozzles: with this consideration the estimation of operator exposure represented 49% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

INDOOR:

Strawberry: Hand-held sprayer (knapsack): hydraulic nozzles: with this consideration the estimation of operator exposure represented 112% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Hand-held sprayer (lance): hydraulic nozzles: with this consideration the estimation of operator exposure represented 63% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Lettuce: Hand-held sprayer (knapsack): hydraulic nozzles: with this consideration the estimation of operator exposure represented 71.2% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

Automate: with this consideration the estimation of operator exposure represented 0.3% of the AOEL of pyrimethanil with working coverall and with gloves during mixing/loading and application.

3.1.3.3 Bystander Exposure

The exposure of bystanders present at the time of spraying was calculated using data presented in the report on EURO-POEM II.

Exposure is estimated 38% of AOEL of pyrimethanil on grapevine, 35% of AOEL of pyrimethanil on apple, pear, 3.5% of AOEL of pyrimethanil on strawberry (< 50 cm), for a 60 kg person located 5 metres away from the spraying operation and exposed for 5 minutes. The health risk to bystanders is therefore considered acceptable.

3.1.3.4 Worker Exposure

According to EUROPOEM model,

OUTDOOR:

For a time work of 8 hours (harvesting) with PPE:

375% of AOEL of pyrimethanil for the use on grapevine,

200% of AOEL of pyrimethanil for the use on apple, pear,

100% of AOEL of pyrimethanil for the use on strawberry and tomato (< 50 cm).

The risk for the worker for harvesting task is not acceptable.

INDOOR:
For a time work of 8 hours (harvesting) with PPE:
203% of AOEL of pyrimethanil for the use on strawberry and tomato (high crops worst-case).

The risk for the worker is not acceptable.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residue of pyrimethanil for enforcement and risk assessment in crops under consideration (tomato, eggplant, lettuce, strawberry, cucumber, zucchini, apple, pear and grapevine). Primary crop metabolism of pyrimethanil was investigated following soil or foliar applications in carrots, tomatoes, lettuces, apples and grapes, hereby covering 3 different crop groups. Metabolic patterns in the different studies were shown to be similar. Therefore, the relevant residue for foliar and post-harvest treatment in all crop groups is pyrimethanil for both enforcement and risk assessment.

Regarding the magnitude of residues in tomato, eggplant, lettuce, strawberry, apple, pear and grapevine, a sufficient number of residue trials are available to support all the intended GAPs in France, Spain, Greece, Portugal, Cyprus and Italy. These data allowed to estimate the expected residue concentrations in the relevant plant commodities, and to confirm that no MRL exceedance will result from intended uses: tomato, eggplant, lettuce, strawberry, apple, pear and grapevine.
For cucumber and zucchini, submitted trials were not considered as valid, then no data is available to support uses on these crops.

The effects of processing on the nature of active substance residues have been investigated. Data on effect of processing on the amount of residue have been submitted, but not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of pyrimethanil will be present in succeeding crops.

Considering dietary burden and based on the intended uses, the requested uses (or the new mode of calculation) modify the theorical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be overcame.

3.1.4.2 Consumer exposure

The toxicological profile of pyrimethanil was evaluated at EU level, which resulted in the proposal of ADI (0.17 mg/kg) that was considered in the frame of this evaluation. An ARfD was not deemed necessary.
Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for pyrimethanil. Based on EFSA PRIMo (rev2), chronic was considered as acceptable for all groups of consumers. Acute exposure was not assessed as an ARfD was not deemed necessary for this active substance.

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

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 PECs for the

active substance and its metabolite for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of pyrimethanil 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 review or agreed in the assessment based on new data provided.
PEC soil and PECsw derived for pyrimethanil and its metabolite are used for the eco-toxicological risk assessment, and mitigation measures are proposed.
PECgw for pyrimethanil and its metabolite do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.
Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

Implications for labelling resulting from environmental fate assessment:
There are no specific implications for labelling resulting from environmental assessment.

3.1.6 Ecotoxicology

The results of evaluations of the fate and behaviour of pyrimethanil and formulated product PYRUS 400SC in the environment as well as the ecotoxicity to non-target organisms are summarised below.

3.1.6.1 Effects on Terrestrial Vertebrates

Birds
The TER values for acute and long term risk are greater than the trigger of 10 and 5 respectively, indicating an acceptable acute and long term risk to birds from pyrimethanil following application of PYRUS 400 SC at all proposed label rates.
Mammals
The TER values for acute and long term risk are greater than the trigger of 10 and 5 respectively, indicating an acceptable acute and long term risk to mammals from pyrimethanil following application of PYRUS 400 SC at all proposed label rates.

3.1.6.2 Effects on Aquatic Species

Data on toxicity of PYRUS 400 SC to fish, invertebrates, algae and aquatic plants do not indicate that the formulation is any more toxic than expected based on the contact of active substance. All acute and chronic TER values for pyrimethanil exceed the required trigger values, indicating that pyrimethanil poses an acceptable long term risk to aquatic organisms following the proposed use of PYRUS 400 SC (both for indoor and outdoor uses).
Buffer zone of 5 metres is deemed necessary for all proposed uses.

3.1.6.3 Effects on Bees and Other Arthropod Species

Bees
All the hazard quotients were found to be less than 50, indicating that the active substances pose an acceptable risk to bees. Therefore an acceptable risk to bees is expected from the application of PYRUS 400 SC.
Non-target arthropods
The in-field HQ values indicate that PYRUS 400 SC does not pose an acceptable risk to non-target arthropods in in-field and off-field areas for grapevine, strawberry, raspberry, blackberry, lettuce, tomato, eggplant, zucchini and cucumber.
Apple and pear use is acceptable with a no treated zone of 5 metres.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The TER values for acute and long term risk are greater than the trigger of 10 and 5 respectively, indicating an acceptable acute and long term risk to earthworms from pyrimethanil following application of PYRUS 400 SC at all proposed label rates.

3.1.6.5 Effects on organic matter breakdown

Not necessary.

3.1.6.6 Effects on Soil Non-target Micro-organisms

No effect on the micro-organisms of the ground is expected after the treatments implementing PYRUS 400 SC following the GAPs.

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

PYRUS 400 SC poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses.

3.1.7 Efficacy

The product complies with the Uniform Principles.
Considering the data submitted:

- The efficacy of the preparation PYRUS 400 SC is considered as acceptable. However, the dose rate of 1 L/ha in grapes is not justified. A dose rate of 0.5 L/ha in grapes is proposed by Anses based on the current registrated uses of pyrimethanil in grapes.
- The selectivity of the preparation PYRUS 400 SC is considered as acceptable.
- The risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered as acceptable.
- In France, the risk of resistance development or appearance is considered as high against *Botrytis cinerea* and *Venturia inaequalis*.

The proposal of the limitation at 2 applications per year of the preparation PYRUS is considered acceptable due to the risk of resistance to apple scab in France.
Moreover, given the context of resistance to chemical group in the French vineyards, the number of applications per year of the preparation PYRUS will be restricted at 1 per year all active substances of this chemical family.

3.2 Conclusions arising from French assessment

For all intended uses, the exposure of workers is not acceptable. In addition, for use in grapes, the exposure of operators is also not acceptable.
Last, no residue data on cucumber and zucchini (field and protected uses) allow to confirm that no MRL exceedance will result from these intended uses.
Taking into account the above assessment, an authorisation cannot be granted in France:

A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A

3.4.2 Post-authorisation data requirements

The following data are required to update the dossier:

- An analytical method and its ILV for the determination of residues of pyrimethanil in foodstuff of animal origin are required in post-registration.

3.4.3 Data gaps

3.4.4 Label amendments (see label in Appendix 2):

N/A

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***PYRUS***

de la société *ARYSTA LIFESCIENCE BENELUX SPRL*

enregistrée sous le *n°2012-1655*

Vu les conclusions de l'évaluation du 11 mars 2016,

Considérant que, pour l'ensemble des usages revendiqués, l'utilisation de la préparation entraîne un risque inacceptable pour les opérateurs et/ou les travailleurs.

Considérant le manque de données relatives aux résidus pour les usages sur concombres et courgettes (plein champ et sous abri) qui ne permet pas de conclure sur le respect des limites maximales de résidus (LMR) en vigueur.

Considérant que les exigences visées à l'article 29 du règlement (CE) 1107/2009 ne sont donc pas respectées

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

PYRUS
AMM n°-

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Informations générales sur le produit	
Nom du produit	PYRUS
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE BENELUX SPRL 26/1, Rue de Renory 4102 OUGREE BELGIQUE
Formulation	Suspension concentrée (SC)
Contenant	400 g/L - pyriméthanil
Numéro d'intrant	961-2012.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 18 MAI 2016

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

PYRUS
AMM n°-

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

PYRUS

Fongicide pour la lutte contre la pourriture grise (*Botrytis cinerea*) sur vignes, fraisiers, laitue, concombre, courgettes, tomate, aubergines, et pour la lutte contre la tavelure (*Venturia inaequalis*) sur pommes et poires

Pour éviter les risques pour l'homme et l'environnement, respecter les conditions d'utilisation

Pyrus : 400 g/L Pyrimethanil (37.4 % poids)
SC (suspension concentrée)
AMM n° ..... Agriphar S.A – Rue de Renory, 26/1 – 4102 Ougrée, Belgique

Champ d'activité

Pyrus est un fongicide contenant 400 g/L de pyrimethanil, matière active appartenant à la famille des anilinopyrilidines. Pyrus peut être utilisé sur vigne, fraisier, laitue, tomate et concombre, pour lutter contre la pourriture grise (*Botrytis cinerea*), de façon préventive ou curative. Pyrus peut également être utilisé sur pommier et poirier pour lutter contre la tavelure (*Venturia inaequalis*)

Conditions d'emploi

Vigne : Pour une protection efficace de la vigne contre *Botritis cinerea*, un programme incluant 3 à 4 applications de différents fongicides de mode d'action différent, peut être mis en place, afin de limiter l'apparition de résistance. Pyrus peut être intégré à ce programme et appliqué entre les stages chute capuchons floraux (BBCH 66) au stade véraison (BBCH 85), sur toute variété.

Il est recommandé d'utiliser Pyrus 2 fois par an maximum, à la dose de 2.5 litres/ha, dans 100 à 800 L d'eau/ha. Les applications devront être effectuées au maximum à 2 des stades suivants :

A. Fin floraison – chute des capuchons floraux (BBCH 66-69) : une application à ce stade permet un bon contrôle des attaques précoces de Botrytis (contamination des jeunes grappes à la chute des fleurs) et limite la présence d'inoculum au moment de la véraison
B. Fermeture de la grappe (BBCH 77-79) : une application à ce stade protège du développement du champignon à l'intérieur des grappes, en particulier si des lésions causées par *Eudemis, Cochyllis,* ou *Argyrotaenia* peuvent favoriser le développement de la maladie
C. Début maturation des fruits - véraison (BBCH 81-85) : une application à ce stade, à adapter en fonction du type de vigne, en évitant la pénétration du produit dans les grappes, permet d'optimiser l'efficacité d'un programme anti-botrytis, sans effet sur la maturation des grains.

Il conviendra de localiser le traitement autour des grappes. Ne pas effectuer deux applications consécutives, afin de limiter le risque de développement de résistances. Respecter un délai avant récolte de 21 jours.

Faisier : contre la pourriture grise, en serre et en plein champ.
Pour une bonne protection des fraisiers contre la pourriture grise, un programme de traitement incluant des applications préventives de fongicides ayant un mode d'action différent, à intervalles de 7-10 jours, peut être mis en place, afin de limiter le développement

Préparation de la bouillie et précautions d'emploi

Remplir la cuve d'eau à moitié et commencer l'agitation. Ajouter la quantité déterminée de Pyrus et compléter le remplissage de la cuve avec de l'eau. Appliquer immédiatement et maintenir l'agitation pendant la durée du traitement. Veiller à une pulvérisation homogène sur l'ensemble de la culture.

Compatibilité

En cas d'utilisation en mélange avec un autre produit, il est obligatoire de réaliser un test préalable. Notre société décline toute responsabilité sur les conséquences résultant du mélange de différents produits. Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.

Stockage, Emballage et surplus de traitement

Conserver dans un endroit sec et bien aéré, à des températures entre 0°C et 30°C. Conserver dans l'emballage d'origine. Bien refermer l'emballage après emploi.
Rincer soigneusement l'emballage vide en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, le percer et ensuite l'apporter au point de collecte d'ADIVALOR.

PYRUS : 400 g/L Pyrimethanil (37.4 % poids)
SC (suspension concentrée)
AMM n° ……. Agriphar S.A
Rue de Renory 26/1
4102 Ougrée - Belgique

Dangereux pour l'environnement

R51/53:Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique

S2: Conserver hors de portée des enfants
S13: Conserver à l'écart des aliments et boissons y compris ceux pour animaux
S20/21: Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation
S23: Ne pas respirer les gaz, vapeurs
S29/35 : Ne pas jeter les résidus à l'égout, ne se débarrasser de ce produit et de son récipient qu'en prenant toutes les précautions d'usage
S51 : Utiliser seulement dans les zones bien ventilées
S61 : Eviter le rejet dans l'environnement. Consulter les instructions spéciales/ la fiche de donnée de sécurité

Distribué par : AGRIPHAR SA
F-59300 Valenciennes
RCS Valenciennes B302203914
Pour tout contact : Agriphar
Fiches de sécurité : www.quickfds.com

Fabriqué par : AGRIPHAR SA
Rue de Renory, 26/1
B – 4102 OUGREE (Belgique)
Tél : 00 32 43 85 97 21
Fax : 00 32 43 8!97 49

de résistances. Pyrus peut être intégré à ce programme et appliqué à partir de la floraison. Pyrus peut être appliqué lors d'1 sur 3 applications anti-botrytis, ce qui amène à un intervalle de 21 jours entre 2 traitements avec Pyrus.
Il est recommandé d'appliquer Pyrus 2 fois par saison maximum, à la dose de 2 litres/ha, dans 500 à 1500 litres d'eau/ha, lors d'1 application anti-botrytis sur 3.
Respecter un délai avant récolte de 3 jours.

Laitue : contre la pourriture grise, en serre et en plein champ.
Pour une bonne protection de la laitue contre la pourriture grise, un programme de traitement incluant des applications préventives de fongicides ayant un mode d'action différent, à intervalles de 7-10 jours, peut être mis en place, afin de limiter le développement de résistances. Pyrus peut être intégré à ce programme et appliqué dès la plantation et jusqu'au stade BBCH 18.
Il est recommandé d'appliquer Pyrus 2 fois par saison maximum, à la dose de 2 litres/ha, dans 600 à 1000 litres d'eau/ha.
Respecter un délai avant récolte de 14 jours.

Mitigation measures can be proposed at Member state level.

Tomate, aubergine : contre la pourriture grise, en serre et en plein champ.
Pour une bonne protection des tomates et aubergines contre la pourriture grise, un programme de traitement incluant des applications préventives de fongicides ayant un mode d'action différent, à intervalles de 7-10 jours, peut être mis en place, afin de limiter le développement de résistances. Pyrus peut être intégré à ce programme et appliqué en pré-floraison (BBCH 59) jusqu'au DAR.
Il est recommandé d'appliquer Pyrus 2 fois par saison maximum, à la dose de 2 litres/ha, dans 500 à 1500 litres d'eau/ha. Un intervalle de 7 jours doit être respecté entre 2 applications.
Respecter un délai avant récolte de 3 jours.

Mitigation measures can be proposed at Member state level.

Concombre, courgette : contre la pourriture grise, en serre
Pour une bonne protection des concombres et courgettes contre la pourriture grise, un programme de traitement incluant des applications préventives de fongicides ayant un mode d'action différent, à intervalles de 10 jours, peut être mis en place, afin de limiter le développement de résistances. Pyrus peut être intégré à ce programme et appliqué en pré-floraison (BBCH 59) jusqu'au DAR.
Il est recommandé d'appliquer Pyrus 2 fois par saison maximum, à la dose de 2 litres/ha, dans 600 à 1000 litres d'eau/ha. Un intervalle de 10 jours doit être respecté entre 2 applications.
Respecter un délai avant récolte de 3 jours.

Mitigation measures can be proposed at Member state level.

Pommier, poirier : contre la tavelure
Pour une bonne protection des pommiers et poiriers contre la tavelure, un programme de traitement incluant des applications préventives de fongicides ayant un mode d'action différent, à intervalles de 7 jours, peut être mis en place, afin de limiter le développement de résistances. Pyrus peut être intégré à ce programme et appliqué du stade développement des feuilles (BBCH 10) jusqu'à fin floraison (BBCH 69)
Il est recommandé d'appliquer Pyrus 4 fois par saison maximum, à la dose de 1 litres/ha, dans 150 à 1500 litres d'eau/ha. Un intervalle de 7 jours doit être respecté entre 2 applications.
Respecter un délai avant récolte de 56 jours.

Premiers soins

Enlever immédiatement les vêtements contaminés par le produit • En cas d'inhalation : transporter la victime à l'extérieur et donner de l'air frais • En cas de contact avec la peau : laver abondamment à l'eau et au savon • En cas de contact avec les yeux : rincer les yeux à l'eau courante pendant plusieurs minutes, enlever les lentilles de contact • En cas d'ingestion : rincer la bouche avec de l'eau, ne pas faire vomir • Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité (disponible sur www.quickfds.com)

Important

Pour éviter les risques pour l'homme et l'environnement, respectez 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 les traitements selon les bonnes pratiques en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation.
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que la conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture.
Le fabricant n'est pas responsable des risques de stockage, de l'utilisation et de la manipulation de produit puisqu'il n'a aucun contrôle sur celui-ci.

Pour éviter l'apparition de résistances, alterner les fongicides avec des modes d'action différents.

Date et lot de fabrication : voir emballage

Appendix 3 – Letter(s) of Access

BASF
The Chemical Company

BASF Agro B.V. Arnhem (NL) - Zürich Branch, 8036 Zürich-Wiedikon, Switzerland

ANSES
DPR - UGAmm
253 avenue du Général Leclerc
94701 MAISONS ALFORT Cedex
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May 07, 2014
Oliver Gernsheimer
Director
Tel. +41 44 781 99 50
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oliver.gernsheimer@basf.com

Ref : 2014/1126936

LETTER OF ACCESS

Right of Reference to Registration Dossier concerning Pyrimethanil (Directive 2006/74/EC)

We hereby agree that the studies listed in appendix to this Letter, owned and submitted to you by BASF Agro B.V. Arnhem (NL) Zürich Branch ("BASF Agro BV") or its Affiliates in support of registration of Pyrimethanil containing product (the "BASF Registration Data") may be referred to by the following company:

Agriphar S.A.,
Rue de Renory, 26/1,
B-4102 Ougrée, Belgium

in order to grant registration for the product **PYRUS,** SC containing 400 g/L of the active substance Pyrimethanil.

This access is granted as follows:

1. The right of referral gives access to the BASF Registration Data listed in Appendix to this Letter for the active substance Pyrimethanil.
2. **Agriphar** and its Affiliates are not authorised to receive any copies of the BASF Registration Data nor are Agriphar and its Affiliates authorised to inspect or view the BASF Registration Data or any specific document included therein in whole or in part.
3. The right of referral is valid only for use compliant with good plant protection practice and with the applicable laws and regulations.

Yours sincerely,

BASF Agro B.V., Arnhem (NL) – Zürich Branch

Oliver Gernsheimer
Director

Alexander Hauk
Manager Sourcing & Contracting

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