

REGISTRATION REPORT

Part A

Risk Management

Product code: A8384A

Product name: MILFAL

Active substances:

cyproconazole, 40 g/L

chlorothalonil, 375 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal of marketing authorisation)

Applicant: SYNGENTA FRANCE S.A.S.

Date: 20/03/2018

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PART A – Risk Management

The company SYNGENTA FRANCE S.A.S. has requested renewal of marketing authorisation in France for the product MILFAL (formulation code: A8384A), containing 40 g/L cyproconazole and 375 g/L chlorothalonil 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 MILFAL (A8384A) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MILFAL (A8384A) have been made using endpoints agreed in the EU peer reviews of both cyproconazole and chlorothalonil.

This document describes the specific conditions of use and labelling required for France for the registration of MILFAL (A8384A).

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 SYNGENTA FRANCE S.A.S.'s application to market MILFAL (A8384A) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Cyproconazole

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 cyproconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the dietary exposure of consumers to the residues of triazole derivative metabolites (TDMs);
- the risk to aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of confirmatory information as regards:

- (a) the toxicological relevance of the impurities in the technical specification;
- (b) analytical methods for the monitoring of cyproconazole in soil, body fluids and tissues;
- (c) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin;
- (d) the long term risk to herbivorous mammals;
- (e) the possible environmental impact of the preferential degradation and/or conversion of the mixture of isomers.

The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 30 November 2011, the information set out in points (b), (c) and (d) by 31 May 2013 and the information set out in point (e) two years after the adoption of specific guidance.

An EFSA conclusion is available (EFSA Journal 2010; 8(11):1897).

A Review Report is available (SANCO/10344/2011 final, 17 May 2013.)

Chlorothalonil

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 chlorothalonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account.

In this overall assessment Member States must pay particular attention to the protection of:

- aquatic organisms,
- groundwater, in particular with regards to the active substance and its metabolites R417888 and R611965 (SDS46851), when the substance is applied in regions with vulnerable soil and/or climate conditions.

Conditions of use should include risk mitigation measures, where appropriate.

There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (SANCO/4343/2000 final (revised), 28 September 2006).

1.3 Regulatory approach

The present application (2013-1711) was evaluated by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the voluntary zonal procedure for all Member States of the Southern zone taking into account the worst-case uses (“risk envelope approach”)². When risk mitigation measures were necessary, they are adapted to the situation in France.

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

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

The French Order of 4th May 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ 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 MILFAL (A8384A), 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

Not necessary: the applicant has provided sufficient data to show that access is not required.

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity


Product name (code)	MILFAL (A8384A)
Authorisation number	9300194
Function	Fungicide
Applicant	SYNGENTA FRANCE S.A.S.
Composition	40 g/L cyproconazole 375 g/L chlorothalonil
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE containers holding 5 L product

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	Skin sensitisation, Hazard Category 1 Acute toxicity (inhalational), Hazard Category 4 Serious eye damage/eye irritation, Hazard Category 1 Carcinogenicity, Hazard Category 2, Specific target organ toxicity - Single exposure, Hazard Category 3, Respiratory tract irritation Reproductive toxicity, Hazard Category 1B																
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1 Hazardous to the aquatic environment, Chronic Hazard, Category 2																
Hazard pictograms																	
Signal word	Danger, Warning																
Hazard statements	<table border="1"> <tr> <td>H317</td><td>May cause an allergic skin reaction.</td></tr> <tr> <td>H332</td><td>Harmful if inhaled</td></tr> <tr> <td>H318</td><td>Causes serious eye damage</td></tr> <tr> <td>H351</td><td>Suspected of causing cancer</td></tr> <tr> <td>H335</td><td>May cause respiratory irritation</td></tr> <tr> <td>H360D</td><td>May damage the unborn child</td></tr> <tr> <td>H400</td><td>Very toxic to aquatic life</td></tr> <tr> <td>H410</td><td>Very toxic to aquatic life with long-lasting effects.</td></tr> </table>	H317	May cause an allergic skin reaction.	H332	Harmful if inhaled	H318	Causes serious eye damage	H351	Suspected of causing cancer	H335	May cause respiratory irritation	H360D	May damage the unborn child	H400	Very toxic to aquatic life	H410	Very toxic to aquatic life with long-lasting effects.
H317	May cause an allergic skin reaction.																
H332	Harmful if inhaled																
H318	Causes serious eye damage																
H351	Suspected of causing cancer																
H335	May cause respiratory irritation																
H360D	May damage the unborn child																
H400	Very toxic to aquatic life																
H410	Very toxic to aquatic life with long-lasting effects.																
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>																

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		
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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: The product is no more authorised in France

2.2.4 Other phrases linked to the preparation

N/A: The product is no more authorised in France

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.

GAP rev. 1, date: 2018-03-20

PPP (product name/code): MILFAL/(A8384A)
Active substance 1: cyproconazole
Active substance 2: chlorothalonil
Applicant: SYNGENTA FRANCE S.A.S.
Zone(s): southern zone ^(d)
Verified by MS: yes
Field of use: fungicide

Formulation type: SC ^(a, b)
Conc. of a.s 1.: 40 g/L ^(c)
Conc. of a.s. 2: 375 g/L ^(c)
Professional use: ☒
Non-professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	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 (day s)	Remarks: e.g. safener/synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. Number a) per use b) per crop/season	Minimum interval between applications (days)	L A8384A / ha a) max. rate per appl. b) max. total rate per crop/season	g cyproconazole / ha a) max. rate per appl. b) max. total rate per crop/season	g chlorothalonil / ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
4	France	Grass lawns	F	<i>Puccinia coronata</i> <i>Puccinia spp.</i> <i>Sclerotinia spp.</i> <i>Rhizoctonia</i> <i>Corticium fuciforme</i> <i>Fusarium</i>	downward foliar spray	At beginning of symptoms	a) 1 b) 1		a) 4.5 b) 4.5	a) 180 b) 180	a) 1688 b) 1688	300-800	n/a	Not acceptable (risk to operators, residents [exposure to chlorothalonil], risk of groundwater contamination, risk to aquatic and terrestrial organisms and efficacy [inefficacious against <i>Rhizoctonia</i> at the requested rate])

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

3 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 MILFAL (A8384A) is suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a beige liquid with a chemical odour. It is not explosive and has no oxidizing properties. The product has a flash point above 101°C. It has a self-ignition temperature of above 650 °C. In aqueous dispersion (1%), it has a pH value of 8.37 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a suspension concentrate (SC) formulation.

The formulation is not classified for the physical-chemical part

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated. As the active substance cyproconazole does not contain relevant impurities, no analytical method is required.

As relevant impurities (hexachlorobenzene and decachlorobiphenyl) are by-products of the manufacturing process for chlorothalonil and as such cannot be formed by storage of the formulation, an analytical method for their determination in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods for the determination of residues of cyproconazole and chlorothalonil in plants and foodstuffs of animal origin are not necessary, as the product is not intended to be used on edible crops.

Analytical methods are available in the Draft Assessment Reports (DARs) and this dossier and validated for the determination of residues of cyproconazole and chlorothalonil in soil, water (surface and drinking) and air.

However, analytical methodology available in the DAR for the determination of chlorothalonil in soil is not highly specific (validation data only provided for one ion). A fully validated confirmatory method should be provided for re-registration of the active substance at EU level.

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

The active substance chlorothalonil is very toxic (T+). Analytical methods available in the DAR for its determination in body fluids and tissues are not highly specific. A fully validated confirmatory method should be provided for re-registration of the active substance at EU level.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

MILFAL (A8384A) containing 40 g/L cyproconazole and 375 g/L chlorothalonil, has a low acute oral and dermal toxicity, is acutely toxic by inhalation, is not irritating to the rabbit skin but is severely irritant to the rabbit eye and a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Turf/ Plants, lawn (open air)	Vehicle- mounted/trailed tank and hand-held lance - Downward spraying	4.5 L/ha (1687.5 g chlorothalonil, 180 g cyproconazole)	300-800	French study from UPJ 2009- 2010 ⁸ dedicated to non- agricultural areas ZNA-MODOP

Considering the proposed uses, operator systemic exposure was estimated using the same UPJ study (*op. cit.*) dedicated to non-agricultural areas:

Model	Crop	Equipment	PPE and/or working coverall	% AOEL cyproconazole	% AOEL chlorothalonil
French study from UPJ 2009- 2010	Turf/ Plants, lawn	Vehicle- mounted/trailed tank and hand-held lance - Downward spraying	Working coverall and gloves during mixing/loading and application	30	273
		Tractor- mounted/trailed boom sprayer: hydraulic nozzles		19	171

According to the model calculations, **it can be concluded that the risk for the operator using MILFAL (A8384A) is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.**

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 1.6 % of the AOEL of cyproconazole and 16 % of the AOEL of chlorothalonil.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to MILFAL (A8384A).

3.1.3.4 Resident Exposure

Residential exposure was assessed according to the BREAM model. Exposure is estimated to be 90 % of the AOEL of cyproconazole and 963 % of the AOEL of chlorothalonil (for children).

It may be concluded that there is an unacceptable risk of residential exposure after incidental short-term exposure to MILFAL (A8384A).

The zRMS also proposed a resident exposure assessment via the air, using only the active substance concentrations found by French organisations accredited for air quality monitoring. Cyproconazole and chlorothalonil have been

⁸ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group "produits phytosanitaires : substances et préparations chimiques" Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

found at concentrations of up to 1.44 and 36,4 ng/m³, respectively. Based on these data, the respiratory exposure of residents near the treatment areas were estimated to be less than 0.1 and 1 % of cyproconazole's and chlorothalonil's ADI and AOEL, respectively.

3.1.3.5 Worker Exposure

A8384A is a fungicide for use in non-crop areas (plants, lawns). There is no need for workers to re-enter the treated area and therefore estimates of worker (re-entry) exposure are not necessary for the proposed uses.

In the case of use in production of lawns, worker exposure was assessed according to EUROPOEM II. Exposure is estimated to be 11 % of the AOEL of cyproconazole and 94 % of the AOEL of chlorothalonil with a working coverall and gloves.

It may be concluded that there is no unacceptable risk to the worker wearing a working coverall and gloves.

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

3.1.4 Residues and Consumer Exposure

Not relevant: no uses on edible crops are proposed.

3.1.5 Environmental fate and behaviour

The predicted environmental concentrations (PECs) of the active substances and their metabolites in soil, surface water and groundwater could not all be validated by the zRMS, as deviations from EU endpoints or from current guidance were found. Additional information was therefore requested from the applicant to allow completion of the risk assessment. However, the applicant did not provide any additional data and informed the zRMS that the risk assessment should be finalised based on the data available. **Therefore assessment could not be finalised for certain aspects.**

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The acute and long-term risks of MILFAL (A8384A) to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with cyproconazole, chlorothalonil and the metabolite R182281 (SDS-3701), and maximum residues occurring on food items following applications according to the proposed use pattern. Risk of secondary poisoning was also assessed for cyproconazole, as this compound has a log P_{OW} > 3.0. The risk to birds from exposure via drinking water was also assessed.

The acute TER values all exceeded the trigger values of 10, indicating an acceptable risk to birds following use of MILFAL (A8384A) according to the proposed use pattern. The long-term TER values for cyproconazole and chlorothalonil were below the trigger of 5 for herbivorous and insectivorous birds, indicating a potential risk to birds following use of MILFAL (A8384A) according to the proposed use pattern.

A refined risk assessment was provided for herbivorous and insectivorous birds in golf courses using refined values. After refinement, TER values for insectivorous birds were still below the trigger for chlorothalonil and cyproconazole, indicating a potential risk. Without any further refinement, there is an unacceptable risk to birds from dietary exposure after use of MILFAL (A8384A).

The TER_{LT} values for drinking water exposure were above the trigger value of 5, indicating acceptable long-term risk to birds from the proposed use of MILFAL (A8384A).

The risk for secondary poisoning could not be addressed since no valid PEC_{sw} is available for cyproconazole.

Mammals

The acute and long-term risks of MILFAL (A8384A) to mammals were assessed from toxicity exposure ratios

between toxicity endpoints, estimated from studies with cyproconazole, chlorothalonil and the metabolite R182281 (SDS-3701), and maximum residues occurring on food items following applications according to the proposed use pattern. Risk of secondary poisoning was also assessed for cyproconazole, as this compound has a $\log P_{OW} > 3.0$. The risk to mammals from exposure via drinking water was also assessed.

The TER values, calculated for recommended scenarios, all exceeded the trigger values of 10 for acute and of 5 for long-term risk (including drinking water exposure) except for the long-term risk posed by cyproconazole to herbivorous mammals. The data provided by the applicant for the refined risk assessment, based on mammal observations on golf courses, do not allow determining PT values and moreover show that herbivorous mammals could use potentially treated golf areas. Therefore, based on the available data, the risk assessment cannot be concluded as acceptable for herbivorous mammals.

The risk of secondary poisoning could not be addressed since no valid PEC_{sw} is available for cyproconazole.

Soil organisms

The acute and long-term TER values all exceeded the trigger values of 10, indicating an acceptable risk to birds following use of MILFAL (A8384A) according to the proposed use pattern.

The TER_{LT} values for drinking water exposure were above the trigger value of 5, indicating acceptable long-term risk to birds from the proposed use of MILFAL (A8384A).

The risk for secondary poisoning could not be addressed, since no valid PEC_{soil} and PEC_{sw} are available for chlorothalonil and cyproconazole.

The acute and long-term TER values all exceed the trigger values of 10, indicating an acceptable risk to mammals following use of MILFAL (A8384A) according to the proposed use pattern.

The TER_{LT} values for drinking water exposure were above the trigger value of 5, indicating acceptable long-term risk to mammals from the proposed use of MILFAL (A8384A).

The risk of secondary poisoning could not be addressed since no valid PEC_{soil} and PEC_{sw} are available for chlorothalonil and cyproconazole.

3.1.6.2 Effects on Aquatic Species

No valid PEC_{sw} is available for cyproconazole and chlorothalonil (see Part B, Section 5 for details). **Therefore the risk to aquatic organisms could not be addressed. The risk evaluation cannot be finalised with respect to contamination of groundwater.**

3.1.6.3 Effects on Bees and Other Arthropod Species

All hazard quotients (HQs) for MILFAL (A8384A), cyproconazole and chlorothalonil are less than 50, indicating that the risk to bees is acceptable following use of MILFAL (A8384A) according to the proposed use pattern.

The risk to non-target arthropods following exposure to MILFAL (A8384A) was addressed based on Tier II data on the indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* in accordance with the ESCORT 2 Guidance document. Exposure was based on a single application at 4.5 L/ha with off-field drift rates associated with 1 m. The HQ for in-field and off-field exposure of *A. rhopalosiphi* were less than the ESCORT 2 trigger. The HQ for in-field exposure of *T. pyri* were above the trigger value but the expected fast dissipation of MILFAL (A8384A) indicates a possible recovery of in-field arthropod populations.

The HQs for off-field exposure are below the trigger value, indicating an acceptable risk to non-target arthropods following applications of MILFAL (A8384A).

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The acute and chronic TER values for MILFAL (A8384A), cyproconazole and chlorothalonil are greater than the

triggers of 10 and 5, respectively, indicating that the risk to earthworms is acceptable following use of MILFAL (A8384A) according to the proposed use pattern.

No valid $PEC_{soil\ accu}$ values were available for metabolites (see Part B, Section 5). Therefore the risk to soil macro-organisms could not be addressed.

3.1.6.5 Effects on organic matter breakdown

None.

3.1.6.6 Effects on Soil Non-target Micro-organisms

The risk of MILFAL (A8384A) to soil micro-organisms was evaluated by comparison of no-effect concentrations (NOECs), derived from laboratory tests, with maximum PEC values. All no effect levels exceed the relevant PECS values, indicating that the risk to soil micro-organisms is acceptable following use of A8384A according to the proposed use pattern.

No valid $PEC_{soil\ accu}$ values were available for metabolites (see Part B, Section 5). Therefore the risk to micro-organisms could not be addressed.

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

The risk to terrestrial non-target plants in off-crop areas is acceptable following use of MILFAL (A8384A) when a buffer zone of 5 metres is considered.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- the efficacy of MILFAL (A8384A) is considered satisfactory, except on *Rhizoctonia*;
- the selectivity of MILFAL (A8384A) is considered satisfactory;
- the risk of negative impact (on quality, succeeding and adjacent crops) is considered negligible;
- the risk of resistance developing or appearing is considered to be low.

Crop	Targets	Application rate (product)	Number of applications per year	French efficacy section conclusion	Comments
Turf	<i>Sclerotinia</i> spp.	4,5 L/ha	1	Favourable	-
	<i>Puccinia coronata</i>			Favourable	
	<i>Puccinia</i> spp.			Favourable	
	<i>Laetisaria (Corticium) fuciforme</i>			Favourable	
	<i>Microdochium (Fusarium) nivale</i>			Favourable	
	<i>Rhizoctonia</i> spp			Unfavourable at 4.5 L/ha	

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted due to unacceptable risk for operators, residents [exposure of children to chlorothalonil], risk of groundwater contamination, risk for aquatic and terrestrial organisms, and efficacy [*Rhizoctonia* at 4.5 L/ha].

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

3.4 N/A: authorisation no more granted in France 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: authorisation no more granted in France

3.4.2 Post-authorisation data requirements

N/A: authorisation no more granted in France

3.4.3 Label amendments

N/A: authorisation no more granted in France

Appendix 1 – Copy of the French Decision



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

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

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

Vu la demande de renouvellement de l'autorisation de mise sur le marché du produit phytopharmaceutique
MILFAL

de la société SYNGENTA FRANCE SAS

enregistrée sous le n°2013-1711

Vu les conclusions de l'évaluation de l'Anses du 18 décembre 2017,

Vu le courrier d'intention de retrait de l'Anses du 13 mars 2018,

Considérant que l'estimation de l'exposition, liée à l'utilisation du produit MILFAL, est supérieure au niveau acceptable d'exposition au chlorothalonil pour l'opérateur et le résident (enfant) ;

Considérant l'impossibilité de finaliser l'évaluation du risque de contamination des eaux souterraines, du risque pour les organismes aquatiques et les organismes terrestres,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont pas remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après est retirée en France dans les conditions précisées dans la présente décision.



Informations générales sur le produit	
Nom du produit	MILFAL
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 12 Chemin de l'Hobit 31790 Saint Sauveur FRANCE
Formulation	Suspension concentrée (SC)
Contenant	375 g/L - chlorothalonil 40 g/L - cyproconazole
Numéro d'intrant	9300194
Numéro d'AMM	9300194
Fonction	Fongicide
Gamme d'usages	Professionnel

Conditions générales de retrait : sans délais de grâce

A Maisons-Alfort, le

20 MARS 2018

FW

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)



ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages retirés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
18503206 Gazons de graminées* Trt Part.Aer.*Dollar spot	4,5 L/ha	1/an	Non applicable
Motivation du retrait : L'usage est retiré en raison d'un risque sanitaire inacceptable pour les opérateurs et les résidents (enfants), d'un risque inacceptable pour les organismes terrestres et aquatiques et d'un risque de contamination des eaux souterraines.			
18503211 Gazons de graminées*Trt Part.Aer.* Fil rouge	4,5 L/ha	1/an	Non applicable
Motivation du retrait : L'usage est retiré en raison d'un risque sanitaire inacceptable pour les opérateurs et les résidents (enfants), d'un risque inacceptable pour les organismes terrestres et aquatiques et d'un risque de contamination des eaux souterraines.			
18503201 Gazons de graminées*Trt Part.Aer.* Fusarioses, complexe à helminthosporioses	4,5 L/ha	1/an	Non applicable
Motivation du retrait : L'usage est retiré en raison d'un risque sanitaire inacceptable pour les opérateurs et les résidents (enfants), d'un risque inacceptable pour les organismes terrestres et aquatiques et d'un risque de contamination des eaux souterraines.			
18503205 Gazons de graminées* Trt Part.Aer.*Rhizoctoniose	4,5 L/ha	1/an	Non applicable
Motivation du retrait : L'usage est retiré en raison d'un risque sanitaire inacceptable pour les opérateurs et les résidents (enfants), d'un risque inacceptable pour les organismes terrestres et aquatiques, de contamination des eaux souterraines et d'une efficacité insuffisante.			
18503203 Gazons de graminées* Trt Part.Aer.*Rouille(s)	4,5 L/ha	1/an	Non applicable
Motivation du retrait : L'usage est retiré en raison d'un risque sanitaire inacceptable pour les opérateurs et les résidents (enfants), d'un risque inacceptable pour les organismes terrestres et aquatiques et de contamination des eaux souterraines.			

MILFAL
AMM n°9300194

Page 3 sur 3

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

2) Le volume du fond de cuve restant, dilué mais non pulvérisable, peut être vidangé sur une parcelle ou rutilisé pour la préparation d'une autre bouteille sous conditions spécifiées dans l'arrêté du 12 septembre 2006.

3) Lorsque le pulvérisateur est nettoyé sur le siège de l'exploitation, il est recommandé de le faire sur une zone spécialement équipée pour recueillir et confiner les eaux de lavage.

4) Les effluents phytopharmaceutiques générés sur l'exploitation lors de ces manipulations et non épanchés (fonds de cuve non épanchés, eaux de lavage et de rinçage, écoulements accidentels, etc.), doivent être traités selon les conditions prévues dans l'arrêté du 12 septembre 2006 : utilisation d'un système de traitement des effluents reconnu par le ministère de l'écologie – exemple : « Helioscop ».

✓ **Stockage des produits :**

1) Toujours conserver les produits dans leur emballage d'origine.

2) Les stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermé à clé.

3) Produit réversible au gel.

✓ **Gestion des emballages :**

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Remplir de l'emballage interdit.

Rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur (ou dans la cuve de rinçage pour l'injection directe). Éliminer les emballages vides via une collecte organisée par un service de collecte spécifique (exemple : Adivalor).

**Bonnes Pratiques
Phytopharmaceutiques**

10 gestes responsables
et professionnels

AVANT L'APPLICATION

- 1 ▶ Stocker les produits dans un local phytopharmaceutique conforme et fermé à clé.
- 2 ▶ Bien lire l'étiquette et les précautions d'emploi avant utilisation.
- 3 ▶ Se protéger efficacement (gants, lunettes, masque, combinaison, bottes).
- 4 ▶ Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application.
- 5 ▶ Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouteille (clapet anti-retour, dispositif de surverse).
- 6 ▶ Rincer les emballages trois fois, vider l'eau de rinçage dans la cuve, ou utiliser l'incorporeur.

PENDANT L'APPLICATION

7 ▶ Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouteille dans les cultures par temps calme, sans vent fort pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.

APRÈS L'APPLICATION

- 8 ▶ Appliquer après dilution les fonds de cuve et les eaux de rinçage sur la parcelle.
- 9 ▶ Nettoyer les équipements de protection. Se laver les mains. Prendre une douche.
- 10 ▶ Recycler les emballages en contact direct avec le produit dans le cadre des collectes Adivalor.

PAGE 10

MAXIMUM TYPE AREA
131mm x 93mm

FONGICIDE

HOMOLOG. MILFAL 05/2013

Milfal®

syngenta.

Contient : 40 g/l (2,3 %) de cyproconazole,
275 g/l (51 %) de chlorothalonyl

Pour le gazon.
Contre le dollar spot, le mildiou, les rouilles,
les fusarioses et le rhizoctonia.

CONSULTER CE LIVRET AVANT TOUTE UTILISATION.

Nomenclature et données techniques
Syngenta Agri S.A.S.
1, avenue des Frères
FRANCE 69100 SAINT-GENIS-LE-MONT
Tél. 01 39 40 20 00
www.syngenta.fr
Ce produit est un produit phytosanitaire. Il est soumis à la réglementation des produits phytosanitaires. Il doit être utilisé conformément aux instructions.

40379 5 L

3 550910 056255

S-PAC

DESCRIPTION: 100 LITRE FANFOLD
100 P/L 1000-40 000

SCALE: 1:1

ISSUE NO: 07/2013

ISSUE DATE: 05/2013

256292

SYNGENTA

SYNGENTA S.A.S. 1, avenue des Frères 69100 SAINT-GENIS-LE-MONT FRANCE

COULEUR:

Milfal®

Appel en cas d'urgence : 15 ou centre anti-poison puis
signalez vos symptômes au réseau Phyt attitude (appel gratuit depuis un poste fixe).

N° Vert 0 800 887 887

Numéro d'urgence Syngenta : N° Vert 0 800 803 264

Renseignements techniques : N° Indigo 0 825 00 05 52

En cas d'accident de transport : 06 11 07 32 91

40 g/L (3,3 %) de cyproconazole* - 375 g/L (31 %) de chlorothalonil*
Suspension concentrée (SC) - AMM n° 9300194

BRAND LOGO/NAME
LOGO NOM DE MARQUE

CULTURE	USAGES	DOSES
Gazons de graminées	le fil rouge (<i>Corticium fuciforme</i>), la rouille noire et la rouille couronnée, le dollar spot (<i>Sclerotinia</i>)	4,5 L/ha
	les fusarioses et le Rhizoctonia	

Danger

H317 - Peut provoquer une allergie cutanée.
H318 - Provoque des lésions oculaires graves.
H332 - Nocif par inhalation.
H335 - Peut irriter les voies respiratoires.
H351 - Susceptible de provoquer le cancer.
H361d - Susceptible de nuire au fœtus.
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

Délai de rentrée sur les parcelles traitées : 48 heures.

P102 - Tenir hors de portée des enfants.
P280 - Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/ du visage.
P302 + P352 - EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon.
P305 + P351 + P338 - EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P308 + P313 - En cas d'exposition prouvée ou suspectée: consulter un médecin.
P501 - Eliminer le contenu/récipient dans une installation d'élimination des déchets agréée.

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 / Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).
SPe 3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres minimum* par rapport aux points d'eau.

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

* distance minimale obligatoire à respecter en attendant une notification officielle.
© Marque enregistrée et *Substances actives d'une société du groupe Syngenta.

www.syngenta-pro.fr

FICHES DE DONNÉES DE SÉCURITÉ : www.quickfds.com

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S-PAC	<small>DESCRIPTION:</small> LBL S PANEL RH 130X140 MM	<small>SCALE:</small> 1:1	<small>ISSUE NO:</small> SYN003	<small>ISSUE DATE:</small> 30.07.2009	256206
<small>CODE : 403/9</small> <small>Milfal - 5 L - Etiquette D05 - 130x140mm</small>		<small>Version : B 13/05/13</small> <small>1371448</small>		<small>COULEURS</small>	

Appendix 3 – Letter(s) of Access

Not applicable