REGISTRATION REPORT

Part A

Risk Management

Product code: Bromuconazole 167 g/l + Tebuconazole 107 g/l EC

Product name(s): SOLEIL

Active Substance(s):

Bromuconazole, 167 g/L

Tebuconazole, 107 g/L

COUNTRY: FRANCE

NATIONAL ASSESSMENT

FRANCE

(marketing extension of use)

Applicant: **Nufarm S.A.S.**

Date: **2017/09/26 (Decision)**

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PART A – Risk Management

The company Nufarm S.A.S. has requested a label extension in France only for the product SOLEIL (formulation code: Bromuconazole 167 g/l + Tebuconazole 107 g/l EC).

This document describes the specific conditions of use and labelling required for extension of the registration of SOLEIL containing bromuconazole and tebuconazole in France.

The risk assessment conclusions are based on the already existing registration of the preparation SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) in France (Marketing authorisation n°2130266 based on application n°2010-1480). Therefore, the national evaluation of the current application is limited to the points not covered by the existing registration.

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

SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) is an emulsifiable concentrate formulation containing 167 g/L bromuconazole and 107 g/L tebuconazole for use as a fungicide on wheat and maize for seed production. The aim of this registration application is to gain label extension against diseases in wheat.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

Bromuconazole

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 bromuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment, Member States shall pay particular attention to: - operator's safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; - protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones. The Member States concerned shall ensure that the applicant presents to the Commission: - further information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; - information to further address the long term risk to herbivorous mammals. They shall ensure that the applicant at whose request bromuconazole has been included in this Annex provides such

confirmatory information to the Commission by 31 January 2013 at the latest. The Member States concerned shall ensure that the applicant submits to the Commission further information addressing the potential endocrine disrupting properties of bromuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
An EFSA conclusion is available (EFSA Journal 2010; 8(8): 1704). A Review Report is available (SANCO/12620/2010 final, 8 March 2016).

Tebuconazole

Commission Implementing Regulation (EU) No 921/2014 of 25 August 2014 approving the active substance tebuconazole, 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 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 tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: - the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; - the dietary exposure of consumers to the tebuconazole (triazole) metabolites; - the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; - the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. The Member States concerned shall request the submission of further information to confirm the risk assessment for birds and mammals. They shall ensure that the notifier at whose request tebuconazole has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest. The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
An EFSA conclusion is available (EFSA Journal 2014; 12(1): 3485). A Review Report is available (SANCO/171/08 rev 2, 11 July 2014).

1.3 Regulatory approach

The present application (2014-2637) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1].

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/20092, implementing regulation and French regulation.

[1] French Food Safety Agency, Afssa, before 1 July 2010

Since the application is intended for use in France only, the draft Registration report Part B section 2, 4, 5 and 6 and Part A were not circulated for comments.

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

The French Order of 4 may 2017 [2]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[3], 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[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] 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 SOLEIL, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 2, 4, 5 and 6.

1.5 Letter(s) of Access

[2] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000034603791&dateTexte=&categorieLien=id

[3] 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

[4] 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

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

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 2, 4, 5 and 6.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC)
Authorisation number	2130266
Function	Fungicide
Applicant	Nufarm S.A.S.
Composition	Bromuconazole 167 g/L Tebuconazole 107 g/L
Formulation type (code)	Emulsifiable concentrate (EC)
Packaging	PE/PA can (5 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	Aspiration hazard: Category 1; Serious eye damage/eye irritation: Category 1; Specific target organ toxicity - Single exposure: Category 3, Narcosis; Reproductive toxicity: Category 2	
Environmental hazards	Chronic aquatic toxicity: Category 1; Acute aquatic toxicity: Category 1	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H304	May be fatal if swallowed and enters airways
	H318	Causes serious eye damage
	H336	May cause drowsiness or dizziness
	H361d	Suspected of damaging the unborn child
	H400	Very toxic to aquatic life
	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)	-	

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies
Spa 1	To avoid the development of resistance against bromuconazole and tebuconazole, the number of application is limited to 1 application per crop cycle on wheat due. To manage the risk of resistance with the product SOLEIL, it is recommended to follow the limitations of use by chemical group recommended by the national note on resistance management in cereal diseases.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 for the details
Re-entry period : refer to the decision of product authorisation
Pre-harvest interval : F- Application must be made at growth stage BBCH 69 at the latest
Other mitigation measures: refer to the decision of product authorisation.
The label must reflect the conditions of authorisation.

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

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2017/09/26

PPP (product name/code)	**SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC)**	**Formulation type:**	**EC**
active substance 1	**Bromuconazole**	**Conc. of as 1:**	**167 g/L**
active substance 2	**Tebuconazole**	**Conc. of as 2:**	**107 g/L**
Applicant:	**Nufarm S.A.S.**	**professional use**	☒
Zone(s):	**France**	**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 (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**		
Winter wheat, spring wheat, triticale and spelt	France	SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC)	F	Blight *(Fusarium graminearum)*	EC	BMZ 167 g/L TBZ 107 g/L	Foliar spray	BBCH 49-69	1	Not relevant	BMZ 0.07-0.13 TBZ 0.043-0.085	150 - 300	BMZ 0.200 TBZ 0.128	F	Acceptable (1 application on culture per campaign)

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

Refer to the decision of product authorization.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances and impurities in the formulation are available and validated.

Analytical methods are available in the monographs and this dossier and validated for the determination of residues of Bromuconazole and Tebuconazole in plants (dry), food of animal origin, soil, water (surface and drinking) and air.

However, a new residue definition has been set for Tebuconazole in food of animal origin. Therefore, a highly specific analytical method, including a total hydrolysis step, and its ILV, validated in accordance with guidance document SANCO/825/00 rev. 8.1 and the current residue definition, are required, in post authorization, for the determination of Tebuconazole, Hydroxy-tebuconazole and their conjugates in all matrices of animal origin (muscle, fat, liver, kidney, eggs and milk), within 24 months.

The active substances are 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

Refer to the decision of product authorization.

Refer to the Decision in Appendix 1 for the details on personal protective equipment.

3.1.4 Residues and Consumer Exposure

Selection of critical uses and justification:

The critical GAPs with respect to consumer intake and risk assessment for the preparation SOLEIL (fBromuconazole 167 g/l + Tebuconazole 107 g/l EC) are presented in Registration Report Part B section 4 paragraphs IIIA 8. 3 Residue trials.

Overall conclusion:

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.2 mg/kg for bromuconazole and of 0.3 mg/kg for tebuconazole as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of bromuconazole and tebuconazole residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorization of the intended use.

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

Summary of the evaluation:

The preparation SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) is composed of bromuconazole and tebuconazole.

Table 3.1-1: Summary for bromuconazole

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wheat	Yes	Yes	Yes	Yes	Yes	No	No	/

As residues of bromuconazole only exceed the trigger values defined in Reg (EU) No 283/2013 in one case, there is no need to investigate the effect of industrial and/or household processing.

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

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

Table 3.1-2: Summary for tebuconazole

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg EU 2016/1003	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wheat	Yes	Yes	Yes	Yes	**Yes**	No	No	

As residues of tebuconazole only exceed the trigger values defined in Reg (EU) No 283/2013 in one case, there is no need to investigate the effect of industrial and/or household processing.

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

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

Table 3.1-3: Information on SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) (KCA 6.8)

Crop	PHI for SOLEIL(Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) proposed by applicant	PHI sufficiently supported for		PHI for SOLEIL(Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Bromuconazole	Tebuconazole		
Wheat	F*	BBCH 69	BBCH 69	F	/

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed

endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

PEC soil and PECsw derived for bromuconazole and tebuconazole and its metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PECgw for bromuconazole and tebuconazole and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[8]. 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.

3.1.6 Ecotoxicology

No new risk assessment for birds (except secondary poisoning), mammals (except secondary poisoning), bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants is provided in the core dossier for SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) since the precedent assessment is deemed to be acceptable and is reported in this core dossier.

The updated of aquatic organisms risk assessment allows to concluded that SOLEIL pose acceptable risk for aquatic organisms when a buffer zone of 5m is applied.

Based on the guidance documents, the risks for birds and mammals, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses of SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC).

3.1.7 Efficacy

Considering that no new data was submitted:

- On the basis of data provided during the initial registration of the preparation SOLEIL, the efficacy and the selectivity of the preparation SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) is always considered as satisfactory in the claimed conditions.
- On the basis of data provided during the initial registration of the preparation SOLEIL, the risk of negative impact on yield, quality, transformation processes, propagation, non-target organisms, succeeding crops, adjacent crops is always considered as acceptable.
- The risk of resistance development or appearance of different active substances is always considered as low for rusts. To avoid the development of resistance to tebuconazole and bromuconazole, the number of application of the preparation SOLEIL (Bromuconazole 167 g/l + Tebuconazole 107 g/l EC) is limited at 1 application on wheat per campaign due to *Septoria sp.*. Any new information, which would change the assessment of the risk of resistance, should be provided to the competent authorities for all uses.

[8] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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

- All authorisation holders of triazole-containing products must put in place dedicated monitoring for the relevant metabolite 1,2,4- triazole in groundwater within 24 months.
- Any new information, which would change the assessment of the risk of resistance, should be provided to the competent authorities

3.4.2 Post-authorisation data requirements

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

- A highly specific analytical method, including a total hydrolysis step, and its inter-laboratory validation, validated in accordance with guidance document SANCO/825/00 rev. 8.1 and the current residue definition, are required, for the determination of Tebuconazole, Hydroxy-tebuconazole and their conjugates in all matrices of animal origin (muscle, fat, liver, kidney, eggs and milk).

3.4.3 Label amendments

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

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'extension d'usage 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'extension d'usage majeur du produit phytopharmaceutique ***SOLEIL***

de la société	*NUFARM S.A.S.*
enregistrée sous le	*n°2014-2637*

Vu les conclusions de l'évaluation de l'Anses du 7 novembre 2016,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

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.

SOLEIL
AMM n°2130266

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Informations générales sur le produit	
Noms du produit	SOLEIL DJEMBE SAKURA
Type de produit	Produit de référence
Titulaire	NUFARM S.A.S. 28 Boulevard Camélinat BP 75 92230 GENNEVILLIERS Cedex FRANCE
Formulation	Concentré émulsionnable (EC)
Contenant	107 g/L - tébuconazole 167 g/L - bromuconazole
Numéro d'intrant	2130455
Numéro d'AMM	2130266
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 26 SEP. 2017

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

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
Toxicité spécifique pour certains organes cibles à la suite d'une exposition unique - Catégorie 3	H336 : Peut provoquer somnolence ou des vertiges
Danger par aspiration - Catégorie 1	H304 : Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
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.**	

SOLEIL
AMM n°2130266

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Liste des nouveaux 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
15103202 Blé*Trt Part.Aer.*Fusarioses	**1,2 L/ha**	**1/an**	entre les stades BBCH 49 et BBCH 69	F (BBCH 69)	5	-	-	-
	1 application par an et par culture sur l'ensemble du complexe de maladies							

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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 d'une application effectuée à l'aide d'un pulvérisateur à rampe

- **Pendant le mélange/chargement**
  - Gants en nitrile certifiés EN 374-3 ;
  - Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  - EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
  - Lunettes ou écran facial norme EN 166 (CE, sigle 3).

- **Pendant l'application**
  - Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;

  Si application avec tracteur sans cabine
  - Gants en nitrile certifiés EN 374-3 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

  Si application avec tracteur avec cabine
  - Gants en nitrile certifiés EN 374-3 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine.

- **Pendant le nettoyage du matériel de pulvérisation**
  - Gants en nitrile certifiés EN 374-3 ;
  - Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  - EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
  - Lunettes ou écran facial norme EN 166 (CE, sigle 3).

Pour le travailleur amené à intervenir sur les parcelles traitées, porter

- une combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant et des gants en nitrile certifiés EN 374-3.

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

- 48 heures.

SOLEIL
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anses
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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 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Gestion des résistances

- Spa 1 : Pour éviter le développement de résistance de la septoriose au bromuconazole et au tébuconazole, le nombre d'applications du produit SOLEIL est limité à une application maximum par campagne sur blé.

Afin de gérer au mieux les risques de résistance avec le produit SOLEIL, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par la "Note commune INRA, ANSES, ARVALIS - Institut du Végétal pour la gestion de la résistance aux fongicides utilisés pour lutter contre les maladies des céréales à pailles".

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode d'analyse, comportant une étape d'hydrolyse totale, et sa validation inter-laboratoires, validées conformément au document guide SANCO/825/00 rev. 8.1 et à la définition de résidu actuelle, pour la détermination du tébuconazole, de l'hydroxy-tebuconazole et de leurs conjugués, dans toutes les denrées d'origine animale (muscle, graisse, foie, rein, œufs et lait).	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.	24	-
Fournir, aux autorités compétentes, toute nouvelle information, susceptible de modifier l'évaluation du risque de résistance pour l'ensemble des usages.	-	-

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Appendix 2 – Letter(s) of Access

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