

REGISTRATION REPORT

Part A

Risk Management

Product code: ESAR 120F

Product name(s): GENIUS SC

Active Substance(s):

Tebuconazole, 250 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: EXCLUSIVAS SARABIA S.A.

Date: 2018/11/07

Table of Contents

1	DETAILS OF THE APPLICATION	3
1.1	APPLICATION BACKGROUND	3
1.2	ACTIVE SUBSTANCE APPROVAL	3
1.3	REGULATORY APPROACH.....	4
1.4	DATA PROTECTION CLAIMS	5
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION.....	6
2.1	PRODUCT IDENTITY	6
2.2	CLASSIFICATION AND LABELLING	6
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>6</i>
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>6</i>
2.2.3	<i>Other phrases linked to the preparation</i>	<i>7</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT	10
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties.....</i>	<i>10</i>
3.1.2	<i>Methods of analysis.....</i>	<i>10</i>
3.1.3	<i>The active substance is neither toxic nor very toxic hence no analytical method is required for the determination of the residues in biological fluids and tissues.Mammalian Toxicology.....</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour</i>	<i>14</i>
3.1.6	<i>Ecotoxicology</i>	<i>14</i>
3.1.7	<i>Efficacy</i>	<i>14</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	16
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	16
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.....	16
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>16</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>16</i>
3.4.3	<i>Label amendments</i>	<i>16</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION.....	17
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	23
	APPENDIX 3 – LETTER(S) OF ACCESS.....	27

PART A – Risk Management

The company EXCLUSIVAS SARABIA S.A. has requested marketing authorisation in France for the product GENIUS SC (formulation code: ESAR 120F), containing 250 g/L tebuconazole 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 GENIUS SC (ESAR 120F) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of GENIUS SC (ESAR 120F) have been made using endpoints agreed in the EU peer review(s) of tebuconazole.

This document describes the specific conditions of use and labelling required for France for the registration of GENIUS SC (ESAR 120F).

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 EXCLUSIVAS SARABIA S.A.'s application to market GENIUS SC (ESAR 120F) 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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Tebuconazole

Commission Implementing Regulation (EU) No 921/2014 of 25 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance tebuconazole.

Specific provisions of Regulation (EU) No 921/2014 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 potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole;

—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 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 (2015-1570) 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, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 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

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

² SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

³ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

“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 GENIUS SC (ESAR 120F), 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.

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)	GENIUS SC (ESAR 120F)
Authorisation number	-
Function	fungicide
Applicant	EXCLUSIVAS SARABIA S.A.
Composition	250 g/L tebuconazole
Formulation type (code)	Suspension concentrate (SC)
Packaging	-

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Skin sensitisation, category 1 Eye irritation, category 2 Reproductive toxicity, category 2	
Environmental hazards	Hazardous to the aquatic environment, Chronic, Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction
	H319	Causes serious eye irritation
	H361d	Suspected damaging the unborn child
	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)		Contains 2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (CAS No. 4719-04-4).

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

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

N/A: not registered in France.

2.2.3 Other phrases linked to the preparation

N/A: not registered in France.

2.3 Product uses

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

Use should be crossed out when the applicant no longer supports this use.

GAP, date: 2018-11-07

PPP (product name/code): **GENIUS SC (ESAR 120F)**
Active substance 1: tebuconazole
Applicant: **EXCLUSIVAS SARABIA S.A.**
Zone(s): Southern ^(d)
Verified by MS: yes
Field of use: fungicide

Formulation type: **SC** ^(a, b)
Conc. of as 1: **250 g/L** ^(c)
Professional use:
Non professional use:

1	2	3	4	5	6				7			13	14
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Use- No. (e)	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Pome fruits (apple, pear, quince, medlar, nashi, azarole)	F	<i>Venturia inequalis, oidium, stemphilium</i>	Foliar spray	BBCH 60-89	1-3	14-20	a) 0.60 L/ha b) 1.8 L/ha	a) 0.150 kg as/ha b) 0.450 kg as/ha	1000-1500	14	Not acceptable (MRL)
2	FR	Peach (PRNPS), Apricot (PRNAR, Nectarine (PRNPN))	F	<i>Monilia sp, oidium</i>	Foliar spray	BBCH 60-89	1-3	14-20	a) 0.60 L/ha b) 1.8 L/ha	a) 0.150 Kg ai/ha b) 0.450 Kg ai/ha	1000-1500	7	Not acceptable (lack of ecotoxicological and environmental datas)
3	FR	Plum (PRNDO), jujube tree (ZIPJU), cherries (PRNCE)	F	<i>Monilia sp</i>	Foliar spray	BBCH 60-89	1-3	14-20	a) 0.60 L/ha b) 1.8 L/ha	a) 0.150 Kg ai/ha b) 0.450 Kg ai/ha	1000-1500	7	Not acceptable (MRL)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
4	FR	Olive	F	<i>Gloeosporium olivarum</i> <i>Cyloconium oleaginum</i>	Foliar spray	Pre-flowering (BBCH 51-6559)	1 (-)	Na	a) 0.600 L/ha b) 0.600 L/ha	a) 0.150 Kg ai/ha b) 0.150 Kg ai/ha	1000	n-p-F	Not acceptable (lack of ecotoxicological and environmental datas))
5	FR	Onion (ALLCE), garlic (ALLSA), Shallot (ALLAS)	F	<i>Botritis sp.</i> , <i>Cladosporium</i> , <i>Sclerotinia</i> , <i>Roya</i>	Soil spray or irrigation Foliar spray	At seeding or transplanting BBCH 40 to 21 days after harvest	1(-) 1-2	Na 21	a) 2.0 L/ha b) 2.0 L/ha a) 1.0 L/ha b) 2.0 L/ha	a) 0.500 Kg ai/ha b) 0.500 Kg ai/ha a) 0.250 Kg ai/ha b) 0.500 Kg ai/ha	--	NP 21	Not acceptable (MRL)
6	FR	Garlic (ALLSA)	F	<i>Roya</i> , <i>stenphilium</i> <i>Puccinia alii</i>	Foliar spray	BBCH 40 to 21 days after harvest	1-2	21	a) 1.0 L/ha b) 2.0 L/ha	a) 0.250 Kg ai/ha b) 0.500 Kg ai/ha	1000	21	Not acceptable (MRL)

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

GENIUS SC (ESAR 120F) is a 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 a white liquid with mild odour. It is not explosive and has no oxidising properties. The product has a flash point above 100°C. It has a self-ignition temperature of 487°C. In a 1% aqueous solution, it has a pH value of 7.2 at 21°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. As the stability was performed on HDPE packaging, the HDPE/EVOH packaging can be considered as acceptable. Its technical characteristics are acceptable for a SC formulation.

The mention “The container must be rinsed at least twice before disposal” should be added on the label.

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

3.1.2 Methods of analysis

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

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of the residues of tebuconazole in plants (high water, high oil commodities), soil, water (surface and drinking) and air.

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

Endpoints used in risk assessment:

Active Substance: tebuconazole			
ADI	0.03 mg kg bw/d	EU agreed endpoint (EU 2009)*	
ARfD	0.03 mg/kg bw/d	EU agreed endpoint (EU 2009)*	
AOEL	0.03 mg/kg bw/d	EU agreed endpoint (EU 2009)*	
Dermal absorption	Based on an in vitro/human study performed on formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 250 g/L	Spray dilution (tested) 0.1 g/L
	In vitro (human) %	0.68%	44.48%
		Concentrate (used in formulation) 250 g/L	Spray dilution (used in formulation) 0.1 g/L
	Dermal absorption endpoints %	0.7%*	44%**

*The same toxicological reference values were retained in EFSA'S conclusions on tebuconazole in 2014 (EFSA Journal 2014;12(1):3485)

** Considering the high variability of the results, all cells have been taken into account for the setting of the dermal absorption values of GENIUS SC (ESAR 120F).

3.1.3.1 Acute Toxicity

GENIUS SC (ESAR 120F) containing 250 g/L tebuconazole has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin but is irritating to the rabbit eye and is a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate L product/ha (g a.s/ha)	Model
Orchards (stone fruit trees and olive trees)	F	Tractor-mounted/trailed broadcast air assisted sprayer	0.6 L PPP/ha (150 g a.s/ha)	BBA
Olive trees	F	Hand held sprayer high level target	0.6 L PPP/ha (150 g a.s/ha)	BBA
Low crops (Onions, garlic)	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	1 L PPP/ha (250 g a.s/ha)	BBA
Onions – Ferti irrigation	F	Exposure during mixing and loading only Application by automated irrigation	2 L PPP/ha (500 g a.s/ha)	BBA-Mixing and loading

Considering proposed uses, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL tebuconazole
Orchards (stone fruit trees and olive trees)	Tractor-mounted/trailed broadcast air assisted sprayer	Working coverall and gloves during mixing/loading and application	57.2%
Olive trees	Hand held sprayer high level target	Working coverall and gloves during mixing/loading and application	29.8%
Low crops (onions, garlic)	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	27.8%
Onions	Ferti irrigation *Only mixing/loading phase (automated application)	Gloves during mixing/loading	1.1%

According to the BBA model calculations, it can be concluded that the risk for the operator using GENIUS SC (ESAR 120F) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application for all crops claimed except for ferti-irrigation on onions for which only mixing loading phase of the treatment is realized by the operator wearing gloves (automated 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 31% of the AOEL of tebuconazole for an application on pome and stone fruit trees and olive trees and 2.6% of the AOEL of tebuconazole for an application on low crops (onions and garlic).

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to GENIUS SC (ESAR 120F).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection and harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure with PPE is estimated to 88% of the AOEL of tebuconazole for an application on high crops (pome and stone fruit trees and olive trees) and the exposure with PPE is estimated to 73% of the AOEL of tebuconazole for an application on low crops (onions and

garlic). For ferti-irrigation on onions, worker exposure with PPE is estimated to 37 % of the AOEL of tebuconazole for inspection/maintenance tasks.

It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working overall and gloves, when re-entering crops treated with GENIUS SC (ESAR 120F) .

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin et al., (2008) model.

Exposure is estimated to 6.5% of the AOEL of tebuconazole for adults and to 10% of the AOEL of tebuconazole for children, for an application with a vehicle mounted on high crops (pome and stone fruit trees and olive trees).

For an application with a hand held sprayer on olive trees, residential exposure is estimated to 4.2% of the AOEL of tebuconazole for adults and to 6.8% of the AOEL of the active substance for children.

For an application with a vehicle mounted on low crops (garlic and onions), residential exposure is estimated to 2.1% of the AOEL of tebuconazole for adults and to 3.4% of the AOEL of the active substance for children.

It is concluded that there is no unacceptable risk of residential exposure or to the bystander after incidental short-term exposure to GENIUS SC (ESAR 120F).

3.1.3.6 Relevance of metabolites

The metabolite 1,2,4-triazole is considered toxicologically relevant based on its harmonized classification for reproductive toxicity (H361d category 2).

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for tebuconazole as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, zRMS agrees with the authorization of the proposed uses.

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

Data required in post-authorization: /

Summary of the evaluation

Summary for tebuconazole

Use- No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/626	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Pome fruits (apple, pear, quince, medlar, nashi, azarole))	Yes	No (8 SEU/0NEU)	/	/	/	No	/	
2	Peach (PRNPS),	Yes	Yes	Yes	Yes	Yes		No	

Use- No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) 2017/626	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	Apricot (PRNAR, Nectarine (PRNPN)								
3	Plum (PRNDO), jujube tree (ZIPJU), cherries (PRNCE)	Yes	No (0 trial)	/	/	/		/	
4	Olive	Yes	Yes	Yes (for BBCH 59 instead of 65)	Yes	Yes		No	
5	Onion (ALLCE), garlic (ALLSA), Shallot (ALLAS)	Yes	No (3 SEU trials/ 0 NEU)	/	/	/		/	
6	Garlic (ALLSA)	Yes	No (0 trial)						

The effects of processing on the nature of tebuconazole residues have been investigated at EU level. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops. Nevertheless, the studies on the nature and magnitude of tebuconazole residues in rotational crops indicate that triazole derivative metabolites might be of concern in rotational crops. Noting that these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment would be performed for TDMs in rotational crops as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

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.

Summary for GENIUS SC (ESAR 120F)

Crop	PHI for GENIUS SC (ESAR 120F) proposed by applicant	PHI/ Withholding period* sufficiently supported for Tebuconazole	PHI for GENIUS SC (ESAR 120F) proposed by zRMS	zRMS Comments (if different PHI proposed)
	Stone fruits (peaches and apricots)	7	Yes	
Olive trees	F – BBCH 65	Yes but for BBCH 59	F	All residue trials were

Crop	PHI for GENIUS SC (ESAR 120F) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GENIUS SC (ESAR 120F) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Tebuconazole		
				conducted with BBCH 55-59

NR: not relevant

* Purpose of withholding period to be specified

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values 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 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 conclusions or agreed in the assessment based on new data provided.

PEC_{SOIL} derived for the active substance and metabolite 1,2,4-triazole are used for the ecotoxicological risk assessment. For all intended uses, no reliable FOCUS STEP 3-4 PEC_{sw} were derived by the Applicant for the active substance. Therefore the risk assessment cannot be finalised for all intended uses.

For all intended uses, PEC_{GW} for tebuconazole do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000⁸. However, no reliable PEC_{gw} for 1,2,4-triazole were available for all intended uses. Major deviations were found in the input parameters selected by the notifier. Therefore, the risk cannot be finalised for all 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.

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

3.1.6 Ecotoxicology

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

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. However, the risks for aquatic organisms, birds eating fish and mammals eating fish cannot be finalised for all the intended uses of GENIUS SC (ESAR 120F) as no PEC_{sw} could be validated for tebuconazole.

3.1.7 Efficacy

Considering the data submitted:

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.

- The efficacy level of GENIUS SC (ESAR 120F) is considered as acceptable for all the claimed uses, except on uses of *Stemphylium vesicarium* of pear and *Sclerotium sp.*, *Botrytis sp.* (soil spray or irrigation) of onion for which assessment is not possible due to the lack of data or possible extrapolation.
- The phytotoxicity level of GENIUS SC (ESAR 120F) is considered as negligible for all the claimed uses.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible.
- There is a risk of resistance development or appearance to tebuconazole for *Venturia inaequalis* of apple and *Monilia sp.* of peach requiring a monitoring for these 2 diseases.

To avoid the development of resistance of tebuconazole, the number of application of GENIUS SC (ESAR 120F) is limited to 3 applications per crop cycle on apple and pear.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. 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

N/A: not registered in France.

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: not registered in France.

3.4.2 Post-authorisation data requirements

N/A: not registered in France.

3.4.3 Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision



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 réglementaire,

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

*de la société **EXCLUSIVAS SARABIA S.A.***

enregistrée sous le n°2015-1570

Vu les conclusions de l'évaluation de l'Anses du 12 avril 2018,

Considérant qu'en l'absence de données suffisantes, l'absence de risque de dépassement des limites maximales de résidus en tébuconazole n'a pas pu être démontrée pour les usages sur cerisiers, oignons, pommiers et pruniers,

Considérant également qu'en l'absence de données suffisantes, l'absence de risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores et l'absence de risque de contamination des eaux souterraines par le métabolite 1,2,4-triazole ne peuvent être démontrées,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

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



Informations générales sur le produit	
Nom du produit	GENIUS SC
Type de produit	Produit de référence
Titulaire	EXCLUSIVAS SARABIA S.A. Cami de l'Albi rec nou s/n 25110 ALPICAT, LERIDA ESPAGNE
Formulation	Suspension concentrée (SC)
Contenant	250 g/L - tébuconazole
Numéro d'intrant	157-2015.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 07 NOV. 2018

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 refusés		Dose d'emploi	Nombre maximum d'applications	Décalai avant récolte (jours)
12203208 Cerisier-Trt Part.Aer.* Monilioses		0,6 L/ha	3/an	7
	Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
16803204 Oignon*Trt Part.Aer.* Pourriture grise et sclérotinioses		1 L/ha	2/an	21
	Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
16053201 Oignon*Trt Part.Aer.* Rouille(s)		1 L/ha	2/an	21
	Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			

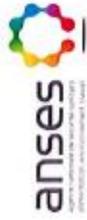
GENIUS SC
AMM n°.



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16421202 Oignon*Tri Sem. Plantis* Champignons autres que pythiacées	2 L/ha	1/an	F (au semis)
Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
12503203 Olivier*Tri Part.Aer.* Maladie de l'oeil de paon	0,6 L/ha	1/an	F (BBCH 59)
Motivation du refus : L'usage est refusé en raison d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
12553233 Pêcher*Tri Part.Aer.* Monilioses	0,6 L/ha	3/an	7
Motivation du refus : L'usage est refusé en raison d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			

GENIUS SC
AMM n°.



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12553224 Pêcheur*Trt Part.Aer.* Oidium(s)	0,6 L/ha	3/an	7
Motivation du refus : L'usage est refusé en raison d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
12603202 Pommier*Trt Part.Aer.* Oidium(s)	0,6 L/ha	3/an	14
Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			
12613208 Pommier*Trt Part.Aer.* Stemphylose	0,6 L/ha	3/an	14
Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.			

GENIUS SC
AMM n°.



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12603203 Pommier**Tr Part.Aer.* Tavelure(s)	0,6 L/ha	3/an	14
<p>Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.</p>			
12653204 Prunier**Tr Part.Aer.* Monilioses	0,6 L/ha	3/an	7
<p>Motivation du refus : L'usage est refusé en raison d'un manque d'essais résidus permettant d'exclure le risque de dépassement des limites maximales de résidus en tébuconazole et d'un manque de données permettant d'exclure le risque de dépassement des valeurs seuils en métabolite 1,2,4-triazole dans les eaux souterraines et le risque d'effet inacceptable pour les organismes aquatiques et les vertébrés terrestres piscivores.</p>			

GENIUS SC
AMM n°.

Page 6 sur 6

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

(Central)

GENIUS SC

FUNGICIDE
SUSPENSION CONCENTRATE (SC)

Composition :

Tebuconazole 250 g/L

Reg. No.- xxxxxx

Content: xx L

Batch Nr :

Manufacturing date :

Manufacturer: EXCLUSIVAS SARABIA S.A.
Cami de l'Albi-Rec Nou s/n
25110-ALPICAT (LERIDA)
SPAIN

**READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER
THAT IS INCONSISTANT WITH THE LABEL MAY BE AN OFFENCE.**

**FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION
PRODUCTS.**

(Left)

	<p>H317: May cause an allergic skin irritation H319: Causes serious eye irritation H361d: Suspected of damaging the unborn child H411: Toxic to aquatic life with long lasting effects</p> <p>P201: Obtain special instructions before use P202: Do not handle until all safety precautions have been read and understood P261: Avoid breathing vapours/spray P264: Wash with water and soap, thoroughly after handling P272: Contaminated work clothing should not be allowed out of the work place P280: Wear protective gloves, protective clothing and eye protection P281: Use personal protective equipment as required P302+P352: IF ON THE SKIN: wash with plenty of water and soap. P333+P313: If skin irritation or a rash occurs: Get medical advice/attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do-continue rinsing. P308+P313: If eye irritation persists get medical advice/attention. P321: Specific treatment (see ... on this label) P363: Wash contaminated clothing before reuse. P405: Store locked up P501: Dispose of contents/container in accordance with local/regional/national/international regulation.</p>
---	--

SAFETY PRECAUTIONS

Operator Protection

WHEN USING DO NOT EAT, DRINK OR SMOKE.
AFTER CONTACT WITH SKIN OR EYES, WASH IMMEDIATELY with plenty of water.
DO NOT BREATHE SPRAY.
WASH HANDS AND EXPOSED SKIN before meals and after work.

Environmental Protection

Sp1: 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].

Sp3: To protect aquatic organisms respect an unsprayed buffer zone of *10 m in grapes and 10 meters with 50% reducing drift nozzles or 20 m with normal nozzles, for all other crops (pome and stone fruit trees (including cherries and plums) and olives trees, tomatoes and aubergines, rice, spring and winter cereals, onion, garlic and other bulb vegetables and ornamental)* to non-agricultural land/surface water bodies

Storage and Disposal

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS.
KEEP OUT OF REACH OF CHILDREN.
KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place.
WASH OUT CONTAINER THOROUGHLY, empty washings into spray tank and dispose of safely.

(right)

Directions for use:

GENIUS SC is a Suspension Concentrate (SC) formulation containing 250 g/L of tebuconazole used as a protective and systemic fungicide against several diseases (powdery mildew, botrytis, rust and others) in a range of crops.

Harvest interval: follow harvest intervals where recommended.

Use the rates recommended to ensure good spray coverage.

Recommendations	Rate of use	PHI
Table and wine grapes Disease: powdery mildew (<i>Uncinula necator</i>) and <i>Botrytis</i> and other diseases. Applications in spring-summer (BBCH81 to summer) Maximum number of applications: 3 per season Interval between applications: 14 days	0.04% (40 ml GENIUS SC /100 L water) Spray volume: 1000 L/ha Equivalent to 400 ml GENIUS SC/Ha	14 days
Olive trees Disease: Leaf spot of olive (<i>Cycloconium oleaginum</i>) Applications before flowering. Maximum number of applications: 1 per season	0.06% (60 ml GENIUS SC /100 L water) Spray volume: 1000 L/ha Equivalent to 600 ml GENIUS SC/Ha	n.a.
Pome fruit trees (apples and pears) Diseases: Apple and pear scab (<i>Venturia sp.</i>), powdery mildew (<i>Podosphaera leucotricha</i>) and others diseases. Applications from flowering to harvest Maximum number of applications: 3 per season Interval between applications: 21 days	0.05% (50 ml GENIUS SC /100 L water) Spray volume: 1500 L/ha Equivalent to 750 ml GENIUS SC/Ha	14days
Stone fruit trees (peach, nectarine, apricot, cherries and plums) Diseases: Powdery mildew (<i>Sphaerotheca pannosa</i>), <i>Monilia laxa</i> and others diseases. Applications from flowering to harvest. Maximum number of applications: 3 per season Interval between applications: 21 days	0.05% (50 ml GENIUS SC /100 L water) Spray volume: 1500 L/ha Equivalent to 750 ml GENIUS SC/Ha	7 days
Rice Diseases: Blast of rice (<i>Pyricularia oryzae</i>) and stem rot of rice (<i>Helminthosporium s. irregulare</i>) and others diseases. Applications from BBCH 69 Maximum number of applications: 2 per season Interval between applications: 21 days	1 Lt/ha Spray volume: 300 - 500 L/ha	35 days
Cereals (wheat, barley, oat and rye) Diseases: Powdery mildew (<i>Blumeria graminis</i>), net blotch of barley (<i>Helminthosporium sp.</i>), rust (<i>Puccinia sp.</i>) and other diseases. Applications from BBCH 69 Maximum number of applications: 2 per season Interval between applications: 21 days	1 Lt/ha Spray volume: 300 - 500 L/ha	28 days

Recommendations	Rate of use	PHI
Tomato and aubergines <i>Botritis, Cladosporium, Sclerotinia, Roya</i> Applications at infestation in all stages Maximum number of applications: 2 per season Interval between applications: 10days	0.05-0.1% (50-100 ml GENIUS SC /100 L water) Spray volume: 800-1000 L/ha Equivalent to 0.50-1.0 ml GENIUS SC/ha.	3 days
Bulb vegetables (Garlic and onion) Leaf blight of onion (<i>Botryotinia squamosa</i>) and grey mold neck (<i>Botrytis</i>) Applications at transplanting. Maximum number of applications:1 per season	1-2 Lt/ha with fertirrigation.	n.d.
Bulb vegetables (Garlic and onion) Rust (<i>Puccinia sp</i>) Applications from BBCH40 to 21 days before harvest Maximum number of applications:2 per season Interval between applications: 21 days	0.05-0.1% (50-100 ml GENIUS SC /100 L water) Spray volume: 800-1000 L/ha Equivalent to 0.50-1.0 ml GENIUS SC/ha.	21
Ornamentals <i>Botritis, Oidium, Septoria, Sclerotinia, Roya</i> Applications at infestation in all stages Maximum number of applications: 2 per season Interval between applications: 14 days	0.04% (40 ml GENIUS SC /100 L water) Spray volume: 500-1000 L/ha	n.a.

APPLICATION

Mixing

Ensure the sprayer is clean and calibrated before use.
Half fill the spray tank with clean water and begin agitation. Add the required amount of GENIUS SC and the remaining water. Continue agitation until spraying is complete.

Water Volume

Ensure sufficient water volumes are used to give good crop coverage. For conventional treatment the water volumes recommended are the minimum. For glasshouse crops apply high volume using sufficient water to ensure thorough crop coverage.

Caution

Always avoid spraying crops that are under stress at time of application.

Compatibility

GENIUS SC is compatible with many plant protection products.
Always consult the mixture product label first and apply under the approved conditions.
Follow the country regulation before any tank mixing with any other approved plant protection products.

CONDITIONS OF SALE

All goods supplied by us are of high grade and we believe them to be suitable but, as we cannot exercise control over their storage, handling mixing or use or the weather conditions before, during and after application which may affect the performance of the goods, all conditions and warranties, statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded, and no responsibility will be accepted by us or re-sellers for any failure in performance, damage or injury whatsoever arising from their storage, handling, application or use. These conditions cannot be varied by our staff or agents whether or not they supervise or assist in the use of such goods.

Appendix 3 – Letter(s) of Access

Not applicable.