REGISTRATION REPORT

Part A

Risk Management

Product code: VBC-30127

Product name(s): MaxCel

Chemical active substance(s):

6-Benzyladenine, 20 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: Sumitomo Chemical Agro Europe S.A.S.

Date: 09/07/2019

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PART A
RISK MANAGEMENT

1 Details of the application

The company Sumitomo Chemical Agro Europe S.A.S. has requested a marketing authorisation in France for the product MAXCEL (product code: VBC-30127), containing 20 g/L 6-benzyladenine as a plant growth regulator for professional uses.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 0-10 and Part C, and where appropriate the addendum for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to MAXCEL (VBC-30127) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MAXCEL (VBC-30127) have been made using endpoints agreed in the EU peer review of 6-benzyladenine.

This document describes the specific conditions of use and labelling required for France for the registration of MAXCEL (VBC-30127).

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Appendix 4 of this document provides the list of data considered for national authorisation.Application background

The present registration report concerns the evaluation of Sumitomo Chemical Agro Europe S.A.S.'s application to market MAXCEL (VBC-30127) in France as a plant growth regulator (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 label extension of this product in France and in other Member States of the Southern zone.

The present application (2017-1648) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[2], 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.

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[1] 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

[2] 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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable", "not acceptable" in accordance with those criteria.

1.2 Letters of Access

Not necessary: the applicant is the owner of the active substance and PPP data.

1.3 Justification for submission of tests and studies

According to the applicant, data submitted here have not been previously reviewed at EU level and are required to be provided to support the authorisation of extension of use for this product at national level; an extension of the uses previously authorised.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of MAXCEL (VBC-30127), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	VBC-30127
Product name in MS	MAXCEL
Authorisation number	2090019
Low risk (article 47)	No
Function	Plant growth regulator
Applicant	Sumitomo Chemical Agro Europe S.A.S.
Active substance(s) (incl. content)	6-benzyladenine, 20 g/L
Formulation type	Soluble concentrate [SL]
Packaging authorised in France	Packaging not changed (HDPE Bottle 6L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[3] 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

2.2 Conclusion

The evaluation of the application for MAXCEL (VBC-30127) resulted in the **decision to refuse the label extension.**

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	None
Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	***For the P phrases, refer to the existant legislation***
Additional labelling phrases:	
	Contains 3, 4, 5-Trihydroxybenzoic acid propyl ester (CAS No. 121-79-9). May produce an allergic reaction. [EUH208]

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

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.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017 [4] provides that:

[4] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

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 "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" 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.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	refer to the Decision in Appendix 1 for the details
Worker protection:	
-	refer to the Decision in Appendix 1 for the details
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies.
	To protect non-target plants, respect an unspryed buffer zone of 5 meters to non agricultural land.
	To protect non-target arthropods, respect an unsprayed buffer zone of 5 meters to non-agricultural land

[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

Other specific restrictions	
Re-entry period	6 hours

2.5.2 Specific restrictions linked to the intended uses

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant.
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: 2019-07-09

PPP (product name/code):	MAXCEL (VBC-30127)	Formulation type:	SL [a, b]
Active substance 1:	6-Benzyladenine	Conc. of as 1:	20 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Sumitomo Chemical Agro Europe S.A.S.	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	**Yes**		

Field of use: Plant growth regulator

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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Pears	F	Fruit thinning and sizing and improved return bloom	High volume Airblast spraying	Fruit between 7 and 15 mm (BBCH 71-72) spring/summer	a) 1 b) 1	Not applicable	a) 7.5 b) 7.5	a) 150 b) 150	Adjust water volumes based on tree size and spacing (typically 1000 L/ha)	-	**Not acceptable** : risk not excluded for erthworms and bees. For return bloom,: efficacy not proved

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the registration of this formulation. The intended concentrations claimed for the extension use(s) (concentrations at 0.75% w/v) are covered by the concentrations authorized during the registration of this formulation.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data submitted:

- The efficacy level of MAXCEL (VBC-30127) is considered as satisfactory for the uses concerning thinning and sizing of pears. **However, due to the insufficient efficacy level for the use relating to the return bloom, this use cannot be supported on pears**.
- The selectivity level of MAXCEL (VBC-30127) is considered as acceptable. However, growth regulators, by definition, could cause symptoms of phytotoxicity and may, under stress conditions of the crop, reduce the yield of the crop.
- The risks of negative impact on yield and quality are considered as acceptable.
- The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, a specific attention should be paid to susceptible adjacent crops.
- The resistance risk evaluation to 6-benzyladenine is considered as not relevant for the intended uses.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The analytical methods for the determination of the active substance residues in plants submitted at European level and in the dossier of the formulation are considered validated.

3.4.2 Analytical methods for residues

No MRL/residue definition in food of animal origin is fixed. So no analytical method is necessary for the determination of residues in these matrices.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: **6-Benzyladenine**			
ADI	0.01 mg kg bw/d		EU(2011)
ARfD	Not relevant		
AOEL	0.03 mg/kg bw/d		
Dermal absorption	Based on an *in vivo* rat study performed on a similar formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 20 g/L	Diluted formulation (tested) 0.20 g/L
	In vivo (rat) %	13	6.5
		Concentrate (used in formulation) 20 g/L	Spray dilution (used in formulation) 0.15 g/L
	Dermal absorption endpoints %	**13%**	**7%**

3.5.1 Acute toxicity

MAXCEL (VBC-30127) containing 20 g/L 6-benzyladenine has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Risk envelop Pears	F	Vehicle mounted Upward spraying	7.5 L PPP/ha (150 g sa/ha)	1000	EFSA

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL 6-benzyladenine
Pears	Vehicle mounted Upward spraying	Working coverall and gloves during mixing/loading and application	13.45

According to the model calculations, it can be concluded that the risk for the operator using MAXCEL (VBC-30127) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

[7] Open field or glasshouse
[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

3.5.3 Worker exposure

Workers may have to enter treated areas after treatment for crop hand harvesting activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 59 % of the AOEL of 6-benzyladenine with PPE.

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.5.4 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[9].

Only resident exposure is provided since, according to the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 10 meters are taken.

Model (AOEM) - All pathways (mean)	**% AOEL 6-benzyladenine**
Resident (children)	17
Resident (adults)	8

3.6 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for 6-benzyladenine (6-BA) as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of 6-benzyladenine residues are unlikely to present a public health concern.

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

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

Summary for 6-BA

[9] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Pear	Yes	Yes (6N, 4S) Extrapolated from apples	Yes	Yes	Yes	No	NA

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Information on VBC-30127 (MAXCEL (VBC-30127)) (KCA 6.8)

Crop	PHI for VBC-30127 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for VBC-30127 proposed by zRMS	zRMS Comments (if different PHI proposed)
		6-BA		
Pear	None stated	Available trials support a PHI of 90 days	90	The no residue situation is supported by trials performed with a PHI of 90 days (+/- 25%)

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant, pears are a permanent crop.

3.6.1 Residues

Data on apples can be used to extrapolate on pears, quinces, medlars, and loquats.

As residues of 6-BA do not exceed the trigger values defined in Commission Regulation (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops are not required, as pears are permanent crops.

3.6.2 Consumer exposure

Considering dietary burden and based on the intended and authorised uses, no significant 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.

3.7 Environmental fate and behaviour (Part B, Section 8)

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 substance 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 6-benzyladenine in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.
PEC soil and PEC_{SW} derived for 6-benzyladenine are used for the ecotoxicological risk assessment.
PEC_{GW} for 6-benzyladenine do not occur at levels exceeding those mentioned in regulation EC 1107/2009. 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.

3.8 Ecotoxicology (Part B, Section 9)

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, aquatic organisms, mammals, non-target arthropods, soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

Mitigation measures are required for aquatic organisms (see the recommended Spe3).

According to the new data requirement (Regulations (EC) nº 284/2013), chronic and larval toxicity studies on bees and reproductive study on earthworms are required. **This information was not submitted by the applicant in this dossier, therefore the risk assessment for bees and earthworms cannot be finalised**.

3.9 Relevance of metabolites (Part B, Section 10)

Not relevant.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance 6-benzyladenine is not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'extension d'usages

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 ***MAXCEL***

de la société *VALENT BIOSCIENCES*

enregistrée sous le *n°2017-1648*

Vu les conclusions de l'évaluation de l'Anses du 2 avril 2019,

Considérant que les données fournies ne permettent pas d'exclure un risque inacceptable pour les abeilles et les vers de terre,

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

L'autorisation de mise sur le marché du produit référencé ci-après **n'est pas étendue** aux usages décrits dans la présente décision. Cependant, la classification harmonisée du produit est mise à jour et précisée en annexe.

MAXCEL
AMM n°2090019

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Informations générales sur le produit	
Noms du produit	MAXCEL CYLEX
Type de produit	Produit de référence
Titulaire	VALENT BIOSCIENCES Parc affaires telebase, 2 rue Claude Chappe, 69370 ST DIDIER AU MONT D'OR France
Formulation	Concentré soluble (SL)
Contenant	20 g/L - 6-benzyladénine
Numéro d'intrant	2040239
Numéro d'AMM	2090019
Fonction	Régulateur de croissance
Gamme d'usage	Professionnel

A Maisons-Alfort le, 09 JUIL. 2019

Caroline SEMAILLE
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 : Modification des modalités de l'autorisation

Classification du produit
La classification retenue est la suivante : Sans classement.
- EUH208 : Contient du 3,4,5-trihydroxybenzoic acid propyl ester. Peut produire une réaction allergique. 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.**

MAXCEL
AMM n°2090019

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Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12603810 Pommier*Trt Part.Aer.* Act. Floraison	7,5 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un niveau d'efficacité insuffisant. L'usage est également refusé en raison de l'absence de données sur la toxicité chronique vis à vis des abeilles et sur la reproduction des vers de terre, permettant d'exclure un risque inacceptable sur ces organismes.		
12603811 Pommier*Trt Part.Aer.* Act. Nouaison	7,5 L/ha	1/an	-
	Motivation du refus : L'usage est refusé sur poirier en raison de l'absence de données sur la toxicité chronique vis à vis des abeilles et sur la reproduction des vers de terre, permettant d'exclure un risque inacceptable sur ces organismes.		
12603813 Pommier*Trt Part.Aer.* Act. Qual. Fruits	7,5 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison de l'absence de données sur la toxicité chronique vis à vis des abeilles et sur la reproduction des vers de terre, permettant d'exclure un risque inacceptable sur ces organismes.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

MaxCel®

Régulateur de croissance
Action sur la nouaison, la floraison et la qualité des fruits à pépins

Conditionnement(s)

Emballages
5 litres (x4)

Palettes
330 litres

Fiche d'identité

Composition
20 g/l de 6-benzyladénine (1,9 % du poids)

Formulation
Concentré soluble (SL)

Autorisation de Mise sur le Marché n°
2090019

Détenteur de l'Autorisation de Mise sur le Marché

SUMITOMO Chemical Agro Europe S.A.S. Parc d'affaires de Crécy – 10A rue de la Voie Lactée - 69370 St-Didier-au-Mont-d'Or, RCS 379 603 087 - S.A.S. au capital de 3 990 010 €.

MaxCel® & Valent BioSciences sont des marques déposées de Valent BioSciences Corporation, USA.

Fabriqué par

Valent BioScience CORPORATION, 870 Technology Way, Libertyville, IL 60048 U.S.A.

Distribué par

PHILAGRO France – SAS au capital de 9 912 500 € - RCS Lyon B 389 150 582 - Parc d'Affaires de Crécy 10A rue de la Voie Lactée – 69370 Saint-Didier-au-Mont-d'Or – Tél. 04 78 64 32 64 – Fax. 04 72 53 04 58.

Bien lire l'étiquette avant toute utilisation et respecter les précautions d'emploi.

Préparation

Préparation de la bouillie et mise en œuvre

Remplir d'eau propre la cuve du pulvérisateur aux deux tiers de la quantité souhaitée. Mettre en route l'agitation (celle-ci doit être modérée, afin d'éviter la formation excessive de mousse lors de la préparation de la bouillie) et la maintenir pendant toute la durée de la mise en œuvre de l'application. Introduire la quantité nécessaire de produit dans le pulvérisateur. Compléter le niveau d'eau.

Mélanges et compatibilité

Seuls les mélanges autorisés peuvent être utilisés. Tout mélange doit être préalablement testé.

Précautions à prendre et mises en garde

En cas d'emballage incomplètement utilisé, le refermer et le stocker en lieu sûr.

Nettoyage du pulvérisateur et du matériel de préparation de la bouillie

Avant le traitement, vérifier que le matériel d'application et de préparation de la bouillie est propre, exempt de tout résidu d'application précédente. Certains produits nécessitent un nettoyage selon une procédure particulière (se référer aux consignes du fabricant).

Aussitôt après le traitement, rincer et nettoyer très soigneusement le matériel d'application et de préparation de la bouillie, conformément à la réglementation en vigueur.

Pour les emballages vides

Réemploi interdit. Bien vider lors de l'utilisation du produit. Rincer le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.

Les gestes responsables

Important - PRODUITS POUR LES PROFESSIONNELS

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage, qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole, en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité du produit vendu dans son emballage d'origine ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par l'Autorité Compétente.

Informations réglementaires

EUH208 : Contient du 3, 4, 5-trihydroxybenzoic acide propyl ester (CAS n°121-79-9). Peut produire une réaction allergique.

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

P261 Éviter de respirer les brouillards/vapeurs.

Délai de rentrée : 6 heures.

SP1 : 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.

Description des premiers secours

Généralités : en cas de contact/d'exposition, si des troubles apparaissent ou si les symptômes persistent, obtenir un avis médical (médecin, SAMU (15) ou centre antipoison).
Inhalation : sortir de l'atmosphère nocive. Mettre à l'air frais et au repos.
Peau : retirer les vêtements souillés. Les laver avant de les réenfiler. Laver immédiatement et abondamment la peau au savon et à l'eau.
Yeux : rincer complètement avec beaucoup d'eau. Les paupières doivent être écartées du globe oculaire pour assurer un rinçage complet.
Ingestion : NE PAS faire vomir. Ne rien faire avaler à une personne inconsciente. Si le patient est conscient, rincer la bouche immédiatement avec de l'eau.

Fiche de Données de Sécurité disponible sur simple appel au 04 78 64 32 18 ou sur Internet : www.quickfds.com
Numéro d'urgence : 0 800 21 01 55

Transport et stockage

Conserver à une température supérieure à -10°C.

Usages et doses autorisés

Les conditions d'usage de **MaxCel®** sont les suivantes :

Usage	Culture	Dose maximale d'emploi	Nombre maxi applications	DAR (jours)
Action sur la nouaison, la floraison et la qualité des fruits	Pommier Poirier Cognassier Nashi Pommette Nèfles	7,5L/ha	1 application/an	90

Zone non traitée : 5 mètres.

A la dose autorisée, l'utilisation de **MaxCel®** induit un éclaircissage des jeunes fruits, augmente la taille des fruits et favorise le retour à fleur.

PHILAGRO France ne préconise l'utilisation de ce produit que sur les cultures et usages mentionnés ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres usages tels que prévus par l'arrêté du 26 mars 2014.

Les limites maximales de résidus applicables dans les pays de l'Espace Economique Européen sont consultables à l'adresse suivante : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database.
Pour les autres pays susceptibles d'importer les denrées issues des cultures traitées, il est de la responsabilité de l'utilisateur du produit et de l'exportateur des denrées d'assurer la conformité en matière de quantité de résidus.

Traitement

Recommandations d'emploi

Veiller à la bonne répartition du produit sur le végétal par une pulvérisation de qualité et un volume d'eau suffisant.

Appliquer **MaxCel®** une seule fois dans la saison, lorsque le diamètre moyen du fruit central (bois de deux ans) se situe entre 7 et 15 mm lorsque la température maximale est de l'ordre de 20-25°C lors du traitement et se maintient dans les 2-3 jours qui suivent l'application. Traiter avec une quantité d'eau suffisante (1000 litres/hectare) afin d'assurer une bonne couverture des fruits et de la végétation sans provoquer de ruissellement. Les doses d'utilisation élevées sont à réserver aux vergers et aux variétés de pomme difficiles à éclaircir ou dans des conditions de basses températures.
Des températures supérieures à 30°C peuvent conduire à un éclaircissage plus important. Des pluies ou irrigations en aspersion survenant dans les 6 heures après l'application sont susceptibles de réduire l'activité de **MaxCel®** .

Variétés de pomme	Dosage MaxCel®
Akane, Belchard® Chantecler cov, Cameo® Cauddle cov, groupe Boskoop, groupe Braeburn, groupe Granny Smith, groupe Jonagold, groupe Pink Lady®, Honeycrunch® Honeycrisp cov, Idared, Jazz® Scifresh cov, Reinette Canada blanche et grise	3,75 - 5 l/ha
Ariane cov, Goldrush® Coop 38 cov, groupe Elstar, groupe Fuji, groupe Gala, groupe Golden, groupe Reine des Reinettes, groupe rouges américaines, groupe Rubinette®, Sundowner® Cripps Red cov, Tentation® Delblush cov, Pommes cidricoles	5 - 7,5 l/ha

Pour les autres variétés, consulter le technicien de votre organisation de producteurs.

Il est recommandé d'utiliser une eau de dilution dont le pH se situe entre 5 et 7. Eviter un pH supérieur à 8,5.
MaxCel® ne doit pas être utilisé sur des arbres ou des fruits subissant un stress quelconque.
Pour les travailleurs, porter des vêtements de protection pour manipuler les plantes traitées avec **MaxCel®**.

Nos recommandations tiennent compte des informations disponibles à la date de fabrication du produit.

PHILAGRO France – SAS au capital de 9 912 500 € - RCS Lyon B 389 150 582 - Parc d'Affaires de Crécy – 10A, rue de la Voie Lactée – 69370 Saint-Didier-au-Mont-d'Or – Tél. 04 78 64 32 64 – Fax 04 72 53 04 58 – PHILAGRO France est agréé par le Ministère de l'Agriculture sous la référence RH02089 pour la distribution de produits phytopharmaceutiques à destination des utilisateurs professionnels. Avant toute utilisation, assurez-vous que celle-ci est indispensable. Privilégiez chaque fois que possible les méthodes alternatives et les produits présentant le risque le plus faible pour la santé humaine et animale et pour l'environnement, conformément aux principes de la protection intégrée, consultez http://agriculture.gouv.fr/ecophyto. Pour les usages autorisés, doses, conditions et restrictions d'emploi : se référer à l'étiquette du produit, à www.phytodata.com et www.philagro.fr. Annule et remplace tout document antérieur de même nature. 10/2016

Appendix 3 Letter of Access

Not applicable.