

REGISTRATION REPORT

Part A

Risk Management

Product code: A9642C

Product name(s): Apron XL

Active Substance(s):

Metalaxyl-M, 339.2 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Label extension)

Applicant: SYNGENTA FRANCE SAS

Date: 28/05/2020

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PART A – Risk Management

The company SYNGENTA FRANCE SAS has requested a label extension of the marketing authorisation in France for the product APRON XL (product code: A9642C; marketing authorisation n° 2000122), containing 339.2g/L metalaxyl-M for use as a fungicide for seed treatment.

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 APRON XL (A9642C) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of APRON XL (A9642C) have been made using endpoints agreed in the EU peer review(s) of metalaxyl-M.

This document describes the specific conditions of use and labelling required for France for the registration of APRON XL (A9642C).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SYNGENTA FRANCE SAS's application to market APRON XL (A9642C) in France as a fungicide for seed treatment (product uses described under point 2.3). France acted as interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the label extension of this product in France and in other MSs of the European Union.

1.2 Active substance approval

Metalaxyl-M

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

particular attention should be given to the potential for groundwater contamination by the active substance or its degradation products CGA 62826, and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied, where appropriate
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A Review Report is available (SANCO/3037/99-final, 18 September 2002).
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1.3 Regulatory approach

The present application (2016-4472 and 2016-1041) 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 European Union, taking into account the worst-case uses (“risk envelope approach”)¹ – the highest application rates over the European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017² 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 1107/2009³, 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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 APRON XL (A9642C), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

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 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, as amended by>

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/AGRGI407093A/jo>

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

1.5 Letter(s) of Access

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	APRON XL (product code: A9642C)
Authorisation number	2000122
Function	fungicide
Applicant	SYNGENTA FRANCE SAS
Composition	339.2 g/L metalaxyl-M
Formulation type (code)	Emulsion for seed treatment (ES)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Classification not changed.

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

2.2.2 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 6	To protect birds and wild mammals remove spillages (treated seeds).

2.2.3 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 ⁸ : Not applicable (seed treatment)
Pre-harvest interval ⁹ : Application must be made at growth stage BBCH 00 (seed treatment)

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

⁸ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

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 izRMS. 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. 28/05/2020

PPP (product name/code): APRON XL/(A9642C)

Formulation type: **ES** ^(a, b)

Active substance 1: Metalaxyl-M

Conc. of as 1: 339.2 g/L ^(c)

Applicant: SYNGENTA FR SAS

Professional use: ☒

Zone(s): interzonal ^(d)

Non professional use: ☐

Verified by MS: yes

Field of use: Fungicide (seed treatment)

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)	mL product/100 kg seeds a) max. rate per appl. b) max. total rate per crop/season	g of a.s./ 100 kg seeds a) max. rate per appl. b) max. total rate per crop/season	g of a.s./ ha a) max. rate per appl. b) max. total rate per crop/season	Slurry volume ml/ 100 kg seeds min / max		
1	FR	Sugarbeet [BEAVC] (incl. fodder beet)	F	<i>Peronospora farinosa</i>	Seed treatment	BBCH 00	1	n/a	a) 200 b) 200	a) 67.84 b) 67.84	a) 2.65 b) 2.65 (Max 1.3 unit seeds/ha)	Not defined	BBCH00 (seed treatment)	Not acceptable (efficacy: the dose is not justified)
1	FR	Sugarbeet [BEAVC] (incl. fodder beet)	F	<i>Peronospora farinosa</i>	Seed treatment	BBCH 00	1	n/a	100 100	a) 33.92 b) 33.92	a) 1.325 B) 1.325 (Max 1.3 unit seeds/ha)	n/a	BBCH00 (seed treatment)	Acceptable (dose reduction)

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/L	(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	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The 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) (20% v/v) are covered by the concentration of 30% v/v authorized during the registration of this formulation.

3.1.2.2 Analytical methods for residues

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.

The intended uses are not used in animal feed. So, no analytical method is necessary for the determination of residues in these matrices

3.1.2 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: Metalaxyl-M		
ADI	0.08 mg kg bw/d	EU (2002)
ARfD	0.5 mg/kg bw	
AOEL	0.08 mg/kg bw/d	
Dermal absorption	Based on an in vitro human studies performed on formulation (EFSA 2012).	
		Concentrate (used in formulation) 339.2 g/L
	Dermal absorption endpoints %	1%

3.1.3.1 Acute Toxicity

APRON XL (A9642C) containing 339.2 g/L metalaxyl-M has a low toxicity in respect to inhalation and dermal toxicity and is not irritating to the rabbit skin but is irritating to rabbit eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

No model is available for the seed treatment of sugarbeet therefore, the operator exposure was based on an operator study Marcenac, F (2006) *Determination of Operator Exposure to Imidacloprid during Treatment of Sugar Beet Seeds with Imprimo® in France*, Rhodia Recherches et Technologies.

Summary of critical use patterns (worst cases):

Crop	F/G ¹⁰	Equipment	Application rate L PPP/q (g as/tonne)	Spray dilution (L/ha)	Model
Sugarbeet/ Beetroot	F	Seed treatment	0,2 L/q (678.4 g as/tonne)	-	Operator study Marcenac, F., (2006)

Considering proposed uses, operator systemic exposure was estimated using operator study (Marcenac,F (2006)):

Crop	Equipment	PPE and/or working coverall	% AOEL Metalaxyl-M
Sugarbeet /Beetroot	Seed treatment	Mixing/loading. Working coverall and gloves.	2%
		Seed coating (including supervision, maintenance and cleaning). Working coverall and gloves.	10%
		Loading and sowing Working coverall and gloves.	4.6%

Conclusion: The estimated operator to Metalaxyl-M during the treatment with PPE is acceptable.

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

3.1.3.3 Bystander Exposure

The only intended use of APRON XL (A9642C) is treatment of seed prior to sowing. Consequently, no bystander/resident scenario is given.

As regard the application method, bystander and residential exposure is supposed to be negligible.

3.1.3.4 Worker Exposure

The only intended use of A9642C is treatment of seed prior to sowing. Consequently, no re-entry scenario is given.

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

3.1.3 Residues and Consumer Exposure

The critical GAPs with respect to consumer intake and risk assessment for the preparation APRON XL (A9642C) are presented in **Erreur ! Source du renvoi introuvable.** They have been selected from the individual GAPs in the EU to support the national label extension on sugarbeet in France. The critical GAP on the intended use on sugarbeet is considered sufficiently supported by the new additional residue trials submitted by the applicant during commenting step.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0,01* mg/kg for metalaxyl-M as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of metalaxyl M 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.

¹⁰ Open field or glasshouse

3.1.4 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 substance and its 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 metalaxyl-M 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 and PEC_{sw} derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PEC_{gw} for metalaxyl-M and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹¹. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, type of use (seed treatment), and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.5 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 review for active substances and 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, 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.

zRMS recommends to consider the following **Spe 6 mitigation measure: “To protect birds and wild mammals remove spillages (treated seeds).”**

3.1.6 Efficacy

Considering the data submitted:

- the efficacy level of APRON XL (A9642C) is considered as satisfactory for the claimed use. However, **the dose of 0,2 L/Q is not justified and the lower dose of 0,1 L/Q seems sufficiently efficient.**
- the phytotoxicity level of APRON XL (A9642C) is considered as negligible for the claimed use.
- the risks of negative impact on yield, quality, propagation and succeeding crops are considered as negligible.
- **There is a risk of resistance development or appearance to metalaxyl-M for *Peronospora farinosa* which requires a monitoring.** In France, a monitoring of resistance to metalaxyl-M should be put in place on *Peronospora farinosa* (one monitoring for all products based on metalaxyl-M).

¹¹ 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

Set up a resistance monitoring for *Peronospora farinosa f. sp. betae* to the active substance metalaxyl-M on sugarbeet. Any new information which would change the resistance risk analysis must be provided to the competent authorities immediately

3.4.2 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

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

Appendix 1 – Copy of the French Decision



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 réglementaire,

*Vu la demande d'extension d'usage majeur et les données fournies en réponse aux demandes de post-autorisation du produit phytopharmaceutique **APRON XL**,*

de la société **SYNGENTA FRANCE SAS**

enregistrées sous les n°2016-4472 et 2016-1041

Vu les conclusions de l'évaluation de l'Anses du 25 mai 2020,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** à l'usage décrit 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.

Informations générales sur le produit	
Nom du produit	APRON XL
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE SAS 1228 Chemin de l'Habit, 31790 Saint Sauveur, France
Formulation	Emulsion pour traitement de semences (ES)
Contenant	339,2 g/L - métalaxyl-M
Numéro d'intrant	2000122
Numéro d'AMM	2000122
Fonction	Fongicide
Gamme d'usage	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

28 MAI 2020


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)

ANNEXE I : Modalités d'autorisation du produit

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 Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles	
15051202 Bellerave industrielle et fourragère* Tri Sem. Champignons autres que pythiacées	0,1 L/q	1/an	BBCH 00	F (BBCH 00)	-	-	-	-	-
Efficacité montrée sur mildiou (<i>Peronospora lamiae</i>) Diminution de la dose maximale d'emploi de 0,2 L/q à 0,1 L/q, puisque l'intérêt de la dose supérieure n'a pas été justifié.									

Protection de l'opérateur et du travailleur

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit.

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 de la production de semences dans les stations industrielles et les stations mobiles (traiteurs à façon) :

- **Pendant le mélange / chargement et l'enrobage des semences :**
 - Gants en nitrile certifiés EN 374-3 ;
 - Vêtement de travail polyester/coton 65 %/35 % (combinaison ou ensemble veste/pantalon) ;
 - EPI partiel (tablier à manches longues ou blouse) de catégorie III type 3 (PB) ou combinaison de protection catégorie III type 5/6 à porter par-dessus la combinaison précitée ;
 - Protection respiratoire certifiée minimum P2 ;
- **Pendant l'ensachage :**
 - Gants en nitrile certifiés EN 374-2 à usage unique en cas d'intervention sur le matériel ;
 - Vêtement de travail en polyester/coton 65 %/35 % (combinaison ou ensemble veste/pantalon) ;
 - Protection respiratoire certifiée minimum P2 : si le poste d'ensachage n'est pas équipé d'un système d'extraction des poussières.
- **Pendant le nettoyage :**
 - Gants en nitrile certifiés EN 374-3 ;
 - Vêtement de travail en polyester/coton 65 %/35 % (combinaison ou ensemble veste/pantalon) ;
 - EPI partiel (tablier à manches longues ou blouse) de catégorie III type 3 (PB) à porter par-dessus la combinaison précitée ;
 - Protection respiratoire certifiée minimum P2 ;

Pour le semeur, porter

- **Pendant le chargement du semoir :**
 - Gants en nitrile certifiés EN 374-3 ;
 - Vêtement de travail en polyester/coton 65 %/35 % (combinaison ou ensemble veste/pantalon) ;
 - EPI partiel (tablier à manches longues ou blouse) de catégorie III type 3 (PB) à porter par-dessus la combinaison précitée ;
 - Protection respiratoire certifiée minimum P2 ;
 - Lunettes de protection ou écran facial certifié EN 166 (CE, sigle 3) ;

- **Pendant le semis :**
 - Gants certifiés en nitrile EN 374-2 à usage unique en cas d'intervention sur le semoir ;
 - Vêtement de travail en polyester/coton 65 %/35 % (combinaison ou ensemble veste/pantalon).
- **Pendant le nettoyage :**
 - Gants en nitrile certifiés EN 374-3 ;
 - Vêtement de travail en polyester/coton 65 %/35 % (combinaison ou ensemble veste + pantalon) ;
 - EPI partiel (tablier à manches longues ou blouse) de catégorie III type 3 (P3) ou combinaison de protection catégorie III type 5/6 à porter par-dessus la combinaison précitée ;
 - Protection respiratoire certifiée minimum P2 ;
 - Lunettes de protection ou écran facial certifié EN 166 (CE, sigle 3) ;

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

- Non pertinent pour ce type d'application

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 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer les semences traitées accidentellement répandues.

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)	Réurrence (mois)
Mettre en place un suivi de la résistance de <i>Peronospora farinosa</i> f. sp. <i>betae</i> (mildiou de la betterave industrielle et fourragère) au métalaxyl-M. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-

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

Apron[®] XL

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

N° Vert 0 800 887 887

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

Renseignements techniques : N° Indigo 0 825 00 05 52

En cas d'accident de transport : 06 11 07 32 81

FICHES DE DONNÉES DE SÉCURITÉ : www.quickfds.com

339,2 g/l (31 %) de métalaxyl-M* - Emulsion pour le traitement de semences (ES)
AMM n° 2000122

CULTURES AUTORISÉES, UNIQUEMENT :	CIBLES	DOSES AUTORISÉES	DAR
Tournesol	Voir tableaux des usages à l'intérieur du livret		
Betterave industrielle et fourragère			
Betterave potagère			
Choux (pépinières), épinard, feuilles de bettes, navet, pourpier, radis, rutabaga			
Laitue, mâche et autres salades			
Plantes à parfum, aromatiques et médicinales non-alimentaires			
Porte-graines : betterave et maïs			
Bourrache, carthame, chenevis, courges à graines, onagre, pavot œillette, ricin, sésame			



Attention

H302 - Nocif en cas d'ingestion.

H319 - Provoque une sévère irritation des yeux.

P102 - Tenir hors de portée des enfants.

P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

P284 - Porter un équipement de protection respiratoire.

Se reporter aux tableaux du livret de l'étiquette pour le détail des protections aux différentes phases.

P301 + 312 : EN CAS D'INGESTION : appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.

P305 + P351 + P338 : EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P501 - Eliminer le contenu/réceptacle dans une installation d'élimination des déchets agréée.

Informations supplémentaires santé humaine :

EUH208 - Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.

Informations supplémentaires environnement :

SP1 - Ne pas polluer l'eau avec le produit ou son emballage.

Ne pas stocker la préparation à plus de 30 °C.

Agiter la préparation avant emploi après un stockage au froid.

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

Autres conditions d'utilisation et précautions d'usage : lire attentivement le livret.

® Marque enregistrée et *Substance active d'une société du groupe Syngenta.

APRON XL_ HOMOLO 11/2016

CODE : 0000 HOMOLO APRON XL - 70L - Clignette Dos	Version : A.75/11/16 18/12/16	COULEURS
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Appendix 3 – Letter(s) of Access

Not applicable.