

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product name: NEEMAZAL-T/S**

**Active substance:**

**Azadirachtin A: 9.8 g/L**

**COUNTRY: FRANCE**

**Interzonal**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation)**

**Applicant: Andermatt France**

**Date: 2018-12-05**

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## **PART A – Risk Management**

The company Andermatt France has requested marketing authorisation in France for the product NEEMAZAL-T/S, containing 9.8 g/L azadirachtin A for use as an insecticide.

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 NEEMAZAL-T/S where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NEEMAZAL-T/S have been made using endpoints agreed in the EU peer review of azadirachtin.

This document describes the specific conditions of use and labelling required for France for the registration of NEEMAZAL-T/S.

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 letters of Access.

### **1 DETAILS OF THE APPLICATION**

#### **1.1 Application background**

The present registration report concerns the evaluation of Andermatt France's application to market NEEMAZAL-T/S in France as an insecticide (product uses described under point 2.3). France acted as an interzonal Rapporteur Member State (izRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the European Union.

#### **1.2 Active substance approval**

##### **azadirachtin**

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

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

- the dietary exposure of consumers in view of future revisions of Maximum Residue Levels;
- the protection of non-target arthropods and aquatic organisms. Risk mitigation measures shall be applied where appropriate.

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

- the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material, residue definition and groundwater risk assessment.

The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013.

An EFSA conclusion is available (EFSA Journal 2011;9(3):1858).

A Review Report is available (SANCO/10311/2011 final, 11 March 2011).

### 1.3 Regulatory approach

The present application (2015-6076) 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”)<sup>1</sup> – 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 2017<sup>2</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>3</sup>, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>5</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>6</sup> is to supply “minor” crops with registered plant protection products.

<sup>1</sup> 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

<sup>2</sup> 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/AGR1632554A/jo/texte>

<sup>3</sup> 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

<sup>4</sup> 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

<sup>5</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

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 NEEMAZAL-T/S, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### 1.5 Letters of Access

A copy of the letters of access is reproduced in Part A, Appendix 3.

### 2 DETAILS OF THE AUTHORISATION

#### 2.1 Product identity

<b>Product name</b>	NEEMAZAL-T/S
<b>Authorisation number</b>	2140090
<b>Function</b>	Insecticide
<b>Applicant</b>	Andermatt France
<b>Composition</b>	9.8 g/L azadirachtin A
<b>Formulation type (code)</b>	Emulsifiable concentrate (EC)
<b>Packaging</b>	High density polyethylene (HDPE) containers : 250 mL, 1 L, 2.5 L, 5 L, 10 L, 25 L

#### 2.2 Classification and labelling

##### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1<sup>st</sup> June 2015.

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

<b>Physical hazards</b>	-
<b>Health hazards</b>	Reproductive toxicity, Hazard Category 2
<b>Environmental hazards</b>	Hazardous to the aquatic environment, Chronic, Hazard Category 2
<b>Hazard pictograms</b>	
<b>Signal word</b>	Warning
<b>Hazard statements</b>	H361d Suspected of damaging fertility or the unborn child
	H411 Toxic to aquatic life with long lasting effects
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>

<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>		
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*See Part C for justifications of the classification and labelling proposals.*

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

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 8	Dangerous to bees/To protect bees and pollinating insects do not apply to crop plants when in flower or during the honeydew production period/Do not use where bees are actively foraging/ Do not apply when flowering weeds are present.
	For greenhouse uses: May affect beneficial insects. Precaution should be taken when introducing pollinators.

### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>7</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>8</sup> : 48 hours
Pre-harvest interval <sup>9</sup> : - 3 days for uses on tomato, aubergine and Cucurbits with edible peel (cucumber, courgette, gherkin...). - Not applicable for uses on ornamentals.
Other mitigation measures: - Store no more than 15 months.
The label may include the following recommendations: - EUH208: Contains azadirachtin. May produce allergic reactions.
The label must reflect the conditions of authorisation.

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

<sup>8</sup> 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]

<sup>9</sup> 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. 1, date: 2018-12-05

PPP (product name/code):	<b>NEEMAZAL-T/S</b>	Formulation type:	<b>EC</b> <sup>(a, b)</sup>
Active substance:	Azadirachtin A	Conc. of as:	<b>9.8 g/L</b> <sup>(c)</sup>
Applicant:	<b>Andermatt France</b>	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	interzonal <sup>(d)</sup>	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		
Field of use:	insecticide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as*/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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 (i)	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as*/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>														
1	France	Pome fruit	F	Moths	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 54-71	3	7-10	a) 3 b) 9	a) 0.03 b) 0.09	500-1500	5	Product rate 2-3 L/ha	<b>Not acceptable</b> (missing data on efficacy)
	France	Pome fruit	F	Aphids	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 54-71	3	7-10	a) 3 b) 9	a) 0.03 b) 0.09	500-1500	5	Product rate 2-3 L/ha	<b>Not acceptable</b> (missing data on environment)
2	France	Peach, Apricots, nectarines	F	Aphids	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 10-75	3	7-10	a) 3 b) 9	a) 0.03 b) 0.09	500-1500	3	Product rate 2-3 L/ha	<b>Not acceptable</b> (missing data on environment)
3	France	Tomato, Pepper, Aubergine	F	White flies, leafminers, aphids, thrips	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 10-85	3	7-10	a) 3 b) 9	a) 0.03 b) 0.09	250-1500	3	Product rate 2-3 L/ha	<b>Not acceptable</b> (missing data on environment)
4	France	Ornamentals	F	White flies, leafminers,	Broadcast foliar spraying; kind: overall; type of	BBCH 10-85	3	7-10	a) 3 b) 9	a) 0.03 b) 0.09	250-1500	NA	Product rate 2-3	<b>Not acceptable</b> (missing data

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as*/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				aphids, thrips	equipment: any conventional spray equipment								L/ha	on environment)
<b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b>														
5	France	Tomato, Aubergine	G	White flies, leafminers, aphids, thrips	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 10-85	3	7	a) 3 b) 9	a) 0.03 b) 0.09	250-1500	3	Product rate 2-3 L/ha	Acceptable
6	France	Cucurbits with edible peel (Cucumber, courgette, gherkin...)	G	White flies, leafminers, aphids, thrips	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	Up to BBCH 85	3	7	a) 3 b) 9	a) 0.03 b) 0.09	800-1500	3	Product rate 2-3 L/ha	Acceptable
7	France	Ornamentals	G	White flies, leafminers, aphids, thrips	Broadcast foliar spraying; kind: overall; type of equipment: any conventional spray equipment	BBCH 10-85	3	7	a) 3 b) 9	a) 0.03 b) 0.09	250-1500	NA	Product rate 2-3 L/ha	Acceptable

\* As refers to azadirachtin A

**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.

<b>Remarks columns:</b>			
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 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 <sup>3</sup> 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

NEEMAZAL-T/S is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a honey-like brownish viscous liquid with a characteristic odour. It is not explosive, has no oxidizing properties and is not flammable. It has a self-ignition temperature of 390 °C. In aqueous solution (1 %), it has a pH value of 7.0 at 18 °C. There is no effect of low temperature on the stability of the formulation, since after 7 days at 0 °C the technical properties were not changed. After 14 days at 54 °C, the technical properties were not changed but there is a moderate degradation of the active substance' content. The stability data indicate a shelf life of one year at ambient temperature when stored in polyethylene terephthalate (PET), and 15 months when stored in high density polyethylene (HDPE). Its technical characteristics are acceptable for an emulsifiable concentrate formulation.

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

In the storage stability study (two years at room temperature in HDPE packaging), the content of azadirachtin A has decreased by more than 10 % in the formulation. Therefore, the preparation is not considered stable when stored during two years with regard to the data provided in the tested conditions. However after 15 months of storage at ambient temperature, the content in azadirachtin A is still higher than 90 %. Consequently a stability of 15 months in HDPE packaging can be accepted. **The formulation must not be stored more than 15 months.**

##### 3.1.2 Methods of analysis

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

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of azadirachtin A in plants (cucumber fruits, lemon fruits, oilseed rape seeds, wheat grains), soil, water (surface and drinking) and air.

##### 3.1.3 Mammalian Toxicology

The following endpoints were used for risk assessment purposes.

Active substance: <b>azadirachtin</b>		
ADI	0.1 mg/kg body weight/day	EU (2011)
ARfD	0.75 mg/kg body weight/day	
AOEL	0.1 mg/kg body weight/day	
Based on physico-chemicals properties of active substance (experts judgments, DAR azadirachtin):		
Dermal absorption	Concentrate (used in formulation)	Spray dilution (used in formulation)
	<b>Dermal absorption endpoints %</b>	<b>10</b>

###### 3.1.3.1 Acute Toxicity

NEEMAZAL-T/S has a low acute oral, inhalation and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitisier.

###### 3.1.3.2 Operator Exposure

Critical use patterns (worst cases) are summarized below.

Crop	F/G <sup>10</sup>	Equipment	Application rate (L product/ha)	Spray dilution	Model
Vegetables	F	tractor mounted/ trailed boom sprayer	3 L/ha (30 g azadirachtin A /ha)	250 L/ha	German model
Orchards	F	tractor mounted/ trailed broadcast air-assisted sprayer	3 L/ha (30 g azadirachtin A /ha)	500 L/ha	German model
Ornamentals	F	tractor mounted/ trailed boom sprayer Hand-held sprayer	3 L/ha (30 g azadirachtin A /ha)	250 L/ha	German model, UK-POEM
Vegetables Ornamentals	G	Hand-held sprayer	3 L/ha (30 g azadirachtin A /ha)	250 L/ha	German model, UK-POEM

Considering the proposed uses, operator systemic exposure was estimated using the German BBA model and UK-POEM model:

Crop	Equipment	PPE and/or working coverall	% AOEL azadirachtin A
Vegetables / Ornamentals	Tractor mounted / trailed boom sprayer	Working coverall and gloves during mixing/loading and application	0.4 %
Orchards	Tractor mounted / trailed broadcast air-assisted sprayer		0.9 %
Ornamentals	Hand-held sprayer		German Model : 0.5 % UK-POEM : 7.0 %

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

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

### 3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 0.4 % of the AOEL of azadirachtin A. It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to NEEMAZAL-T/S.

### 3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting activities. Therefore, worker exposure was estimated according to EUROPOEM II. Exposure is estimated to be 1.7 % of the AOEL of azadirachtin A for re-entry in field or in greenhouse.

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with NEEMAZAL-T/S.

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

### 3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment purposes. Any exceedance of the current maximum residues limits (MRLs) is not expected. The chronic and acute intakes of azadirachtine residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorization for the intended uses.

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

<sup>10</sup> Open field or glasshouse

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?
Pome-fruits	Yes	Yes	Yes	Yes	Y	No	No
Peach, apricots, nectarines	Yes	Yes	Yes	Yes	Y		No
Tomato, eggplant	Yes	Yes	Yes	Yes	Y		No
Cucurbits edible peel	Yes	Yes	Yes	Yes	Y		No
Ornamentals	As ornamentals are not intended for human or livestock consumption, no assessment was therefore performed.						

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 foodstuffs of animal origin is therefore not necessary.

#### Summary of the information on NEEMAZAL TS

Crop	PHI for NEEMAZAL-T/S proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for NEEMAZAL-T/S proposed by zRMS	zRMS Comments (if different PHI proposed)
		Azadirachtin		
Pome-fruits	nr	Yes	5 days	
Peach, apricots, nectarine	3 days	Yes	3 days	
Tomato, eggplant	3 days	Yes	3 days	

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).

#### **Waiting periods before planting succeeding crops**

Not relevant

#### **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 predicted environmental concentration (PEC) values for azadirachtin A and its metabolite azadirachtin H\* 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.

Note that according to the EU review of azadirachtin, further data on the relationship between azadirachtin A and the rest of the active substance in the neem seeds extract with respect to amount, biological activity and persistence, shall be submitted in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material. No such data were submitted by the applicant. **Therefore, unacceptable risk for environment cannot be excluded.**

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment by azadirachtin A is expected for all the intended uses.

#### Assessment for field uses

PEC soil values derived for azadirachtin A are used for the ecotoxicological risk assessment.

PECsw values (from FOCUS Step 1 to 3) derived for azadirachtin A can be used for the ecotoxicological risk assessment. PECsw values (FOCUS Step 4) provided by the applicant for azadirachtin A are only based on maximum Step 3 PECsw (with either multiple or single applications). According to current practices, FOCUS Step 4 are required for both multiple and single applications to finalize the risk assessment.

No PECsw values were provided for metabolite azadirachtin H\*.

**Then unacceptable risk for environment cannot be excluded.**

PECgw values for azadirachtin A and its metabolite azadirachtin H\* do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater.

Therefore, no unacceptable risk of groundwater contamination by azadirachtin A and its metabolite azadirachtin H\* is expected for the intended uses. No conclusions can be drawn for other potential components that may be formed. Therefore, the risk assessment for all intended uses cannot be finalized.

Assessment for greenhouse uses

For uses in greenhouse, exposure of soil and groundwater compartments was considered negligible.

For the surface water compartment, 0.1 % of the application rate was considered for PECsw calculations for azadirachtin A and its metabolite. Values are used for the ecotoxicological risk assessment.

**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 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.

Note that according to the EU review of azadirachtin, further data on the relationship between azadirachtin A and the rest of the active substance in the neem seeds extract with respect to amount, biological activity and persistence, shall be submitted in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material. No such data were submitted by the applicant. **Therefore, unacceptable risk for environment cannot be excluded.**

Assessment for field uses

Based on the guidance documents, the risks for terrestrial vertebrates, bees and soil micro-organisms can be considered acceptable for the intended uses of NEEMAZAL-T/S.

For aquatic organisms, no reliable FOCUS step 4 PECsw for azadirachtin A have been provided. In addition, even if the metabolite azadirachtin H\* can be considered as less toxic than the parent, the exposure of the aquatic organisms to this metabolite cannot be determined. Consequently, the risk assessment for aquatic organisms is not finalized.

For non-target arthropods, the risk can be considered acceptable with the following mitigation measures:

- A 50 meters unsprayed buffer zone to non-agricultural land for the uses on pome fruit and peach;
- A 20 meters unsprayed buffer zone to non-agricultural land for the use on ornamentals;
- A 5 meters unsprayed buffer zone to non-agricultural land for the use on tomato.

For soil macro-organisms, a new chronic toxicity study with earthworms and chronic toxicity studies with *Folsomia candida* and *Hypoaspis aculeifer* have to be provided according to Regulation (EU) No 284/2013. **Therefore, unacceptable risk for soil macro-organisms cannot be excluded**

For non-target plants, the risk can be considered acceptable with the following mitigation measure: a 5 meters unsprayed buffer zone to non-agricultural land for the uses on pome fruit and peach.

Assessment for greenhouse uses

Considering the intended uses of NEEMAZAL-T/S in glasshouse (close permanent structures), the exposure of terrestrial vertebrates, bees and other non-target arthropods, earthworms and other soil macro-organisms, soil micro-organisms and non-target terrestrial plants to azadirachtin A and its metabolite azadirachtin H\* is considered to be negligible.

The risks for aquatic organisms are acceptable for the intended uses of NEEMAZAL -T/S.

**3.1.7 Efficacy**

Considering the data submitted:

- The efficacy level of NEEMAZAL-T/S is considered acceptable for all the claimed uses, with the exception of the use on moths of pome fruits.
- The phytotoxicity level of NEEMAZAL-T/S is considered acceptable for all the claimed uses. However, considering the diversity of species and varieties in ornamental crops, it is recommended to test the crop safety of NEEMAZAL-T/S on a few plants of the same variety and at the same growth stage before using NEEMAZAL-T/S on a wide area.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding and adjacent crops are considered negligible.
- The risk of resistance development or appearance to azadirachtin is considered very low.

### **3.2 Conclusions arising from French assessment**

**Taking into account the above assessment, an authorisation can be granted for greenhouse uses only. 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**

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**

No further information is required.

#### **3.4.2 Post-authorisation data requirements**

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

- A test of persistence of foaming at the maximum use concentration (according to CIPAC method MT 47.2) before and after storage at ambient temperature.
- A confirmatory method for the determination of azadirachtin A in soil.

#### **3.4.3 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'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 **NEEMAZAL-T/S***

*de la société **ANDERMATT France***

*enregistrée sous le n°2015-6076*

*Vu les conclusions de l'évaluation de l'Anses du 26 décembre 2017,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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

<b>Nom du produit</b>	NEEMAZAL-T/S
<b>Type de produit</b>	Produit de référence
<b>Titulaire</b>	ANDERMATT France 166 BD DU MONTPARNASSE 75014 PARIS FRANCE
<b>Formulation</b>	Concentré émulsionnable (EC)
Contenant	9,8 g/L - azadirachtine A
<b>Numéro d'intrant</b>	2140142
<b>Numéro d'AMM</b>	2140090
<b>Fonction</b>	Insecticide
<b>Gamme d'usages</b>	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mai 2025.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort, le

05 DEC. 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 : Modalités d'autorisation du produit

### Vente et distribution

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

Emballage	Contenance
Bouteilles en polyéthylène haute densité	250 mL ; 1 L
Bidons en polyéthylène haute densité	2,5 L ; 5 L ; 10 L
Fûts en polyéthylène haute densité	25 L

### Classification du produit

La classification retenue est la suivante :

Catégorie de danger	Mention de danger
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
EUH208 : Contient de l'azadirachtine. Peut produire une réaction allergique.	
Pour les phrases P se référer à la réglementation en vigueur.	
<b>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.</b>	



**Liste des usages autorisés**  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée anthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16323103 Concombre*Trit Part.Aer.*Aleurodes	3 L/ha	3/an	jusqu'au stade BBCH 85	3	-	-	-	-
16323105 Concombre*Trit Part.Aer.*Chenilles phytophages	3 L/ha	3/an	jusqu'au stade BBCH 85	3	-	-	-	-
16323104 Concombre*Trit Part.Aer.*Mouches	3 L/ha	3/an	jusqu'au stade BBCH 85	3	-	-	-	-
16323106 Concombre*Trit Part.Aer.*Pucerons	3 L/ha	3/an	jusqu'au stade BBCH 85	3	-	-	-	-
16323107 Concombre*Trit Part.Aer.*Trips	3 L/ha	3/an	jusqu'au stade BBCH 85	3	-	-	-	-

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### Liste des usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée anthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17403102 Cultures florales et plantes vertes* Part.Aer.*Aleyrodes	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	Non applicable	-	-	-	-
17403108 Cultures florales et plantes vertes* Part.Aer.*Chenilles phytophages	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	Non applicable	-	-	-	-
17403107 Cultures florales et plantes vertes* Part.Aer.*Mouches	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	Non applicable	-	-	-	-

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.  
L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.  
L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.  
L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.



**Liste des usages autorisés**  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
17403104 Cultures florales et plantes vertes* Part.Aer: *Pucerons	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	Non applicable	-	-	-	-
17403106 Cultures florales et plantes vertes* Part.Aer: *Thrips	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	Non applicable	-	-	-	-
16953101 Tomate* Part.Aer: *Aleyrodes	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	3	-	-	-	-

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.  
L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.  
L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.



**Liste des usages autorisés**  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
16953113 Tomate* <sup>Trit</sup> Part.Aer.*Chenilles phytophages	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	3	-	-	-	-
16953106 Tomate* <sup>Trit</sup> Part.Aer.*Mouches	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	3	-	-	-	-
16953104 Tomate* <sup>Trit</sup> Part.Aer.*Pucerons	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	3	-	-	-	-
16953110 Tomate* <sup>Trit</sup> Part.Aer.*Thrips	3 L/ha	3/an	entre les stades BBCH 10 et BBCH 85	3	-	-	-	-

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.

L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.

L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

Uniquement autorisé sous abri.  
Intervalle minimum entre les applications : 7 jours.  
3 applications maximum par culture pour contrôler l'ensemble des ravageurs.

L'usage est refusé en plein champ en raison d'un manque de données permettant de lever les préoccupations relatives aux risques environnementaux.

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#### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12553122 Pêcher/Tir Part.Aer.*Pucerons	3 L/ha	3/an	3
	<b>Motivation du refus :</b> L'usage est refusé en raison de risques environnementaux.		
12603105 Pommier/Tir Part.Aer.*Chenilles phytophages	3 L/ha	3/an	5
	<b>Motivation du refus :</b> L'usage est refusé en raison de risques environnementaux et d'un manque de données efficacité.		
12603150 Pommier/Tir Part.Aer.*Pucerons	3 L/ha	3/an	5
	<b>Motivation du refus :</b> L'usage est refusé en raison de risques environnementaux.		



## **Conditions d'emploi du produit**

### **Stockage et utilisation du produit**

- Ne pas stocker plus de 15 mois.

### **Protection de l'opérateur et du travailleur**

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

#### ***Pour l'opérateur, porter***

##### **Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique**

###### **• pendant le mélange/chargement**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

###### **• pendant l'application**

###### ***Si application avec tracteur avec cabine***

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

###### ***Si application avec tracteur sans cabine***

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

###### **• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

##### **Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe**

###### **• pendant le mélange/chargement**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;



**• pendant l'application**

*Si application avec tracteur avec cabine*

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m<sup>2</sup> avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

*Si application avec tracteur sans cabine*

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m<sup>2</sup> avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

**• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

**Dans le cadre d'une application effectuée à l'aide d'une lance**

**• pendant le mélange/chargement**

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;

OU

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;

- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

**• pendant l'application : sans contact intense avec la végétation**

*Culture basse (< 50 cm)*

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;

- Bottes de protection certifiées EN 13 832-3 ;

*Culture haute (> 50 cm)*

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de protection de catégorie III type 4 avec capuche ;

- Bottes de protection certifiées EN 13 832-3 ;

**• pendant l'application : contact intense avec la végétation**

- Gants en nitrile certifiés EN 374-3 ;

- Combinaison de protection de catégorie III type 3 avec capuche ;

- Bottes de protection certifiées EN 13 832-3 ;



**• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;  
OU
- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

***Pour le travailleur, porter***

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m<sup>2</sup>) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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

- 48 heures.

**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 8 : Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer durant la floraison et les périodes de production d'essudats. Ne pas utiliser en présence d'abeilles. Ne pas appliquer lorsque des adventices en fleur sont présentes.
- Peut porter atteinte à la faune auxiliaire. Peut porter atteinte aux insectes pollinisateurs. Éviter toute exposition inutile.

**Exigences complémentaires post-autorisation**

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Déterminer la quantité de mousse persistante à la concentration maximale d'utilisation avant et après stockage à température ambiante.	24	-
Fournir une méthode analytique de confirmation pour la détermination de l'azadirachtine dans le sol.	24	-

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

# NeemAzal<sup>®</sup>-T/S

## Insecticide

Substance naturelle extraite du semis d'*Azadirachta indica*.

A utiliser comme insecticide sur fruits à pépins, pêches, nectarines, abricots, cultures légumières ou ornementales en pleins champs et sur cultures légumières ou ornementales sous serre, pour protéger contre les dommages provoqués par les insectes.

Utilisable en agriculture biologique conformément au règlement CE n° 834/2007

Homologué pour une utilisation professionnelle.

Sans danger pour les abeilles, dans les conditions d'utilisation recommandées.

Ne pas contaminer les eaux avec le produit, ni avec les emballages ayant contenu le produit. Ne pas rincer les équipements d'application près des eaux de surface. Eviter la contamination par les drains ou les fossés. L'emballage est à usage unique.

Maintenez hors de portée des enfants. Placer le produit à l'écart de tout aliment ou boisson.

En cas d'urgence, appeler le 15 ou le centre anti-poison. Fiche de données de sécurité disponible sur simple demande

PRODUIT POUR LES PROFESSIONNELS: Utilisez les produits phytosanitaires avec précaution. Avant toute utilisation, lisez l'étiquette et les informations concernant le produit.

## Premiers soins

**En cas d'inhalation:** passer à l'air frais, se reposer, en position à-demi verticale, desserrer les vêtements. Oxygène ou respiration artificielle en cas de difficulté de respiration. Consulter un médecin après une exposition importante. Le traitement symptomatique est conseillé.

**En cas de contact avec la peau:** retirer les vêtements contaminés. Consulter un médecin en cas d'irritation. Mettre les vêtements au lavage avant réutilisation. Après un contact avec la peau, laver immédiatement et abondamment à l'eau.

**En cas de contact avec les yeux:** Rincer abondamment à l'eau. Soulever les paupières du globe oculaire pour assurer le rinçage en profondeur. Consulter un médecin en cas d'irritation.

**En cas d'ingestion:** Ne pas provoquer de vomissements. Ne rien administrer par voie orale à une personne inconsciente. Rincer la bouche à l'eau. Consulter un médecin. A notre connaissance il n'existe aucun symptôme ni d'effet immédiat ou différé.

## Mode d'action

NeemAzal-T/S n'a pas d'effet immédiat sur les insectes. Après ingestion de la substance active, les insectes cibles cessent de s'alimenter et réduisent ainsi le niveau de dégât. Par ailleurs, leur développement et leur mue sont inhibés provoquant la mort après quelques jours.

NeemAzal-T/S doit être appliqué selon les conseils d'utilisation, dès l'apparition des premiers insectes ou symptômes.

### Recommandations d'emploi :

Remplir la cuve d'eau (pH 5-7) au 2/3, puis verser NeemAzal-T/S en maintenant l'agitation et compléter avec le volume d'eau désiré. Appliquer la bouillie dans la journée. Ne pas préparer plus de bouillie que nécessaire.

NeemAzal-T/S s'emploie à une dose variant de 2 à 3 L/ha, dans un volume de bouillie de 250 à 1500 L/ha. Veiller à assurer une couverture complète de la végétation.

Appliquez NeemAzal-T/S en soirée pour assurer une pénétration optimale à l'intérieur des tissus végétatifs. Traiter au tout début des infestations ou dès l'observation des premiers symptômes. Le traitement devra être répété en cas de pluie dans les 8 heures suivant la première application.

#### Pour utilisation contre :

Pucerons et Chenilles phytophages ou foreuses sur les arbres à pépins, pucerons sur pêches, nectarines, abricots, et pucerons, aleurodes, thrips et mineuses en tomates, poivrons et aubergines et en cultures ornementales en pleins champs. Pucerons et Chenilles phytophages ou foreuses sur les arbres à pépins, pucerons sur pêches, nectarines, abricots, et pucerons, aleurodes, thrips et mineuses en tomates, poivrons, aubergines, concombres, courgettes, cornichons et en cultures ornementales sous serre.

Mener des tests préalables pour vérifier la sensibilité des variétés.

### Dose et période d'application

Usage N°	Usage	Dose	Nb Max Trait.	D.A.R.
12603105	Pommier * Traitement des parties aériennes * chenilles phytophages	Max. 3 L/ha	3	-
12603150	Pommier * Traitement des parties aériennes * pucerons (autres que lanigère)	Max. 3 L/ha	3	-
12553122	Pêcher * Traitement des parties aériennes * pucerons	Max. 3 L/ha	3	3 j
16953113	Tomates * Traitement des parties aériennes * chenilles phytophages	Max. 3 L/ha	3	3 j
16953104	Tomates * Traitement des parties aériennes * pucerons	Max. 3 L/ha	3	3 j
16953110	Tomates * Traitement des parties aériennes * thrips	Max. 3 L/ha	3	3 j
16953101	Tomates * Traitement des parties aériennes * aleurodes	Max. 3 L/ha	3	3 j
16953106	Tomates * Traitement des parties aériennes * mouches	Max. 3 L/ha	3	3 j
16323107	Concombre * Traitement des parties aériennes * thrips	Max. 3 L/ha	3	3 j
16323106	Concombre*Traitement des parties aériennes* pucerons	Max. 3 L/ha	3	3 j
16323105	Concombre*Traitement des parties aériennes* chenilles phytophages	Max. 3 L/ha	3	3 j
16323103	Concombre*Traitement des parties aériennes* aleurodes	Max. 3 L/ha	3	3 j
16323104	Concombre*Traitement des parties aériennes* mouches	Max. 3 L/ha	3	3 j
17403102	Cultures florales et plantes vertes * Trait. des parties aériennes * aleurodes	Max. 3 L/ha	3	-
17403108	Cultures florales et plantes vertes * Trait. des parties aériennes * chenilles phytophages	Max. 3 L/ha	3	-
17403104	Cultures florales et plantes vertes * Trait. des parties aériennes * pucerons	Max. 3 L/ha	3	-

17403106	Cultures florales et plantes vertes * Trait. des parties aériennes * thrips	Max. 3 L/ha	3	-
17403107	Cultures florales et plantes vertes* Trait. des parties aériennes * mouches	Max. 3 L/ha	3	-

Intervalle entre traitements : 7 jours. Volume de bouillie recommandé : 500-1500 L/ha pour les fruits à pépins, pêches, abricots et nectarines, 250-1500 L /ha pour les tomates, poivrons, aubergines, et cultures ornementales, et 800-1500 L/ha for les concombres, courgettes et cornichons.

#### Sélectivité

NeemAzal-T/S a été testé sur de nombreuses plantes cultivées en extérieur ou sous abris, il montre généralement un niveau de sélectivité satisfaisant. Cependant, la pratique indique que la sélectivité de NeemAzal-T/S dépend de l'espèce et de la variété cultivée.

Chez des espèces présentant normalement un bon niveau de tolérance, certaines variétés ont montré des signes de phytotoxicité (voir ci-dessous). A cause de la variabilité des conditions d'une saison à l'autre et de la multiplicité des espèces et des variétés, des cas de phytotoxicité ne peuvent être exclus sur des plantes qui normalement n'en présentent aucun.

En conséquence, aucun avis définitif et global ne peut être fourni sur la sélectivité de NeemAzal-T/S. En prenant en compte ce point d'attention, nous estimons qu'il n'y a pas de risque lors de l'application. Avant une première utilisation, il est recommandé de procéder à des tests de sélectivité avec quelques plantes ou quelques feuilles à plusieurs stades phénologiques, 3 à 5 jours avant le traitement sur grande parcelle.

Les informations relatives aux potentiels problèmes de phytotoxicité de NeemAzal-T/S sont issues de la pratique. Elles ne sont pas exhaustives et sont communiquées uniquement à titre indicatif.

Sur poirier, les variétés suivantes montrent :

**D'éventuelles brûlures** : Conference, Bristol Cross, Alexander Lukas, HW606, Illinois 13B83 Maxine, Winterdechant, Trévoix, Lectier, Pierre Corneille, Comice, Guyot.

**Pas de symptôme de phytotoxicité constaté** : Williams, Gute Luise, Bosc's Butterbirne, Packam's, Concorde, Gellerts, Harrow Sweet, Harrow Delight, Abate Fetel, Nordhauser Winterforelle, Giffards, Butterbirne.

En cultures ornementales, les espèces et les variétés suivantes montrent :

**Une sélectivité satisfaisante sur feuilles et bourgeons** : *Antirrhinum majus*, *Acalypha hispida*, *Argyranthemum frutescens*, *Astericus*, *Begonia-Hybrids*, *Bidens ferulifolius*, *Brachycome*, *Chrysanthemum* (Merced, Bronze Arola, Kory), *Celosia cristata*, *Convolvulus sabatius*, *Coreopsis* (Mädchenauge), *Dendranthema grandiflorum*, *D. indicum*, *Diascia*, *Euryops chrysanthemoides*, *Fuchsia*, F-Hybrids, *Gazania splendens*, *Gerbera jamesonii*, *Gerbera* sp. (Hydroponics - Azur, Bandola, Bounty, Chateau, Dino, Explosive, Figoury, Goldi, Golden Serena, Harley, Kaliki, Kayla, Kimsey, Lucky, Luna, Lyrix, Mistique, New Look, Opium, Optima, Red Ruby, Taifun, Tamara), *Glechoma*, *Helichrysum petiolare*, *Hibiscus* 5 cv's, *Kalanchoe* (Boston), *Lantana-Camara-Hybriden*, *Lobelia*, *L. speciosa*, *Manettia bicolor*, *Mentha*, *Dianthus* (Aristo), *Calceolaria*, *Pelargonium*, *Petunia*, *Pilea microphylla*, *Rosen* (Komet), *Rudbeckia*, *Sanvitalia procumbens*, *Scaevola*, *Sutera*, *Tagetes* (yellow), *Torenia fournieri*, *Verbena* (Tapien blau, Sunvop (P).

**Sélectivité sur feuille satisfaisante** : *Ageratum houstonianum*, *Alonsoa*, *Alyssum*, *Amaranthus*, *Calceolaria-Hybriden*, *Callistephus chinensis*, *Calocephalus brownii*, *Centaurea*, *Cestrum*, *Clarkia*, *Cleome*, *Coleus*, *Cosmos*, *Cuphea*, *Cynara scolymus*, *Dahlia*, *Dianthus barbatus*, *Dimorphoteca*, *Eucalyptus*, *Eustoma grandiflorum*, *Ficus*, *Felicia*, *Gazania*, *Gnaphalium*, *Helianthus*, *Heliotropium arborescens*, *Iresine lindenii*, *I. herbstii*, *Kochia*, *Lavatera*, *Limonium*, *Lotus*, *Lysimachia*, *Melampodium paludosum*, *Mesembryanthemum crystallinum*, *Nicotiana*, *Nigellia*, *Pennisetum*, *Pennstemon*, *Plectranthus fruticosus*, *Polygonum*, *Portulaca*, *Primula*, *Ricinus*, *Roses* (Hydroponics – 6 cv's, Ambiance, Avelance, Beauty Bijoyer, Bulls Eyes, Esperance, First Red, 01-344 van Terra Nigra, Passion, Poison, Rossi, Roxette, Sabine, Swing, Utopia), *Salvia farinacea*, *Saintpaulia* (Miho io), *Senecio*, *Serenoa*, *Streptocarpus*, *Tanacetum*, *Tithonia*, *Trachelium*, *Veronica*, *Zinnia*.

**Phytotoxicité sur bourgeons selon les espèces** : *Begonia semperflorens*, *B. elatior-Hybrids*, *Chrysanthemum* (Deep Luv), *Euphorbia pulcherrima* (Peter Star, Cortez), *Gerbera* (Pretty Red, Sigma, Luciana, Hydroponics – Chateau,

Emperor, Goldspark, Icefolly, Leila, Margarita, Mario, Napoli, Olilia, Optima, Purity, Red Explosion, Rusty, Ruby Red, Santos, Serena, Tino, Vigour, Dream, Kimsey, Siby), *Impatiens*-Neu-Guinea-Hybrids, *Impatiens walleriana*, *Isotoma Pratia fluviatillis* (Blue Star Creeper), *Pelargonium-Peltatum*-Hybrids, *P.-Zonale*-Hybrids, *Solanum rantonnetti*, *Saintpaulia* (Miho io), *Tagetes*, *Tulbaghia violacea* (Tricolos Society), *Verbena* (several varieties).

**Phytotoxicité sur feuilles** (enroulement, déformation) : *Abutilon*-Hybrids, *Begonia elatior*-Hybrids, *Callistemon cirinus* (Dwarf Bottle Brush), *Cestrum*, *Clytostoma callistegioides* (Lavender Trumpet Vine), *Dahlia*-hybrid (Dwarf Dahlia), *Datura*, *Euphorbia pulcherrima*, *Impatiens*-Neu-Guinea-Hybrids, *Impatiens walleriana*, *Gypsophila paniculata* (Baby's Breath), *Liriope spicata* (Silver Dragon Lilyturf), *Magnolia stellata* (Royal Star), *Passiflora*, *Solanum rantonnetti*, *Rosa* (Alina, Arabia, Baronesse, Black Magic, Funky Jazz Ducat, Eveline, Lola, Noblesse Papa Meilland, Saphir, Roulette, White Noblesse, Hydroponics – First Red, Lenny, Poison, Prima Donna, Red Berlin).

NeemAzal-T/S est un insecticide à base de la substance active Azadirachtin (variante NeemAzal®), un extrait naturel issu des semis de l'arbre *Azadirachta indica*. Quelques heures après le traitement avec NeemAzal-T/S, les insectes cessent de s'alimenter et perdent leur activité. NeemAzal-T/S n'est pas un insecticide de contact, aussi les insectes ne meurent pas immédiatement, mais le développement larvaire est stoppé et les cycles de multiplication sont interrompus.

Selon l'IRAC, Azadirachtin est classé comme « une substance sans mode d'action connu ». Ainsi, le risque d'apparition de résistance est-il réduit. Il peut donc s'intégrer dans des stratégies combinant d'autres insecticides.

Compatibilité avec les auxiliaires:

NeemAzal-T/S est considéré sans effet sur les carabes (*Poecilus cupreus*). Il a un faible impact sur *Phytoseiulus persimilis*, *Typhlodromus pyri* (acarien prédateur) et *Encarsia formosa*, *Aphidius rhopalosiphi* (guêpe parasitoïde). Il est classé toxique pour les populations de *Amblyseius cucumeris* (acarien prédateur), *Coccinella septempunctata* (coccinelle), *Chrysoperla carnea* (chrysope) and *Epipyrrhus balteatus* (syrphe).

Conditions de stockage et d'élimination des déchets :

Stocker dans un endroit frais et sec. Un stockage en dessous de 10°C peut conduire à la formation d'un précipité. Celui-ci peut se solubiliser sous agitation par réchauffement (environ 20°-30°C), sans affecter l'efficacité du produit.

Après utilisation, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides par un service de collecte spécifique. Réemploi de l'emballage interdit. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée à la collecte et à l'élimination de produits dangereux. En cas d'urgence appeler le 15 ou le centre anti-poison.

Consulter la Fiche de Données de Sécurité disponible sur simple demande.

Insecticide

Autorisation numéro :

Conforme au règlement 1107/2009

Substance active : Azadirachtin (variante NeemAzal); concentration correspondant à 1% (10 g/kg) d'Azadirachtin A (composé analytique principal)

**Content: 5 liter**

Concentré emulsionable

Lot n°

**Date de fabrication**

Date d'expiration : 2 ans après la date de production.

**Détenteur de l'homologation :**

Andermatt France  
166 Boulevard du Montparnasse  
75014 Paris  
France

### Appendix 3 – Letters of Access



**ANSES-DPR-UGAmm**  
**To: Applicant Department**  
14 rue Pierre et Marie Curie  
94701 MAISON ALFORT CEDEX  
FRANCE

**Letter of access to support the application of "NeemAzal T/S" for  
Andermatt France (application n° 2015-0036)**

8<sup>th</sup> of July, 2015.

Dear Madam/Sir,

Ref. : 2015/509/NE

For "NeemAzal T/S" a 1% w/w azadirachtin based product to be registered in France for professional use again pests in greenhouses (as stated in GAB table) Andermatt France, 166 Boulevard de Montparnasse, 75014 Paris, France, requires access to protected studies used for the biological dossier and done by Bayer CropScience.

Bayer S.A.S  
Environmental Science  
16 rue Jean-Marie Leclair  
CS 90106  
F-69266 Lyon Cedex 09  
  
Tel. +33 (0)4 72 85 48 25  
Fax +33 (0)4 72 85 47 75  
Dominique.Renault@bayer.com

Andermatt France will be the approval holder and the marketing company for this product.

Bayer S.A.S  
Société par actions simplifiée  
au capital de 113 084 535 €  
  
Siège social :  
16, rue Jean-Marie Leclair  
F-69009 LYON  
  
562 038 893 RCS Lyon  
562 038 893 00656  
FR 29 562 038 893

Andermatt France is a customer of Trifolio who is a customer of Bayer S.A.S, Environmental Science Division.

We, Bayer SAS, Environmental Science, a division of Bayer CropScience hereby authorise the ANSES-DPR-UGAmm, to access the Bayer S.A.S, Environmental Science/Bayer Cropscience protected studies attached to this letter and contained in a CD ROM to support the application by Andermatt France.

This letter of access is only applicable to the above mentioned product and above mentioned uses. Access is granted to the above approval holder alone and is not transferable or subassignable.

.../...



Page 2

This letter of access is not transferable to any other company or legal entity based in, or, out of the French territory for the support of any other formulation or uses. This letter of access is exclusively granted Andermatt France for French territory. It doesn't allow Andermatt France to submit any other product or uses based on "NeemAzal T/S" registration. Therefore, any other formulation or uses submitted for registration must be supported by a new letter of access

This letter does not give Andermatt France neither Trifolio nor any other company permission to see or receive copies of any material submitted by Bayer S.A.S, Environmental Science/Bayer Cropscience including all documents contained in the attached CD Rom.

This authorisation is valid only for such duration as there is a valid agreement:

- ✓ between Andermatt France and Trifolio and
- ✓ between Trifolio and Bayer S.A.S, Environmental Science.

Therefore it may be revoked at any time.

Yours faithfully,



**Dominique RENAULT**  
Global Regulatory Manager



Nufarm Deutschland GmbH  
Im Mediapark 4e  
50670 Köln

Albert van den Ende  
Registrierung Deutschland

To whom it may concern,

Nufarm Deutschland GmbH, Im Media park 4e, 50670 Köln, Germany, being:

- registrant for NeemAzal-T/S (N12455) in NL
- legal successor to Asepta B.V., Delft, Netherlands with regards to the NeemAzal-T/S dossier in the Netherlands

grants

Andermatt France, 166 Boulevard du Montparnasse, 75014 Paris, France.

the right to use the studies as mentioned in the Annex for registration purposes in:

- France

Many thanks.

Best regards,

Albert van den Ende

Registration Manager

Geschäftsführer:  
Dr. Niels Pörksen

Sitz der Gesellschaft: Köln  
Amtsgericht Köln: HRB 48079

**Grow a better tomorrow.**



**CBC (Europe) S.r.l.**  
Società unipersonale  
Via E. Majorana, 2  
20834 Nova Milanese (MB) ITALY  
Capitale sociale Euro 7.000.000 i.v.  
C.F./P.IVA e Reg. Imprese MB n.07867200961

Nova Milanese, July 9<sup>th</sup> 2015

**TO WHOM IT MAY CONCERN**

**Letter of Access to the Biological data package of product NEEMAZAL-T/S,  
containing *Azadirachtin* as active ingredient.**

Dear Madam,  
Dear Sir,

We, the undersigned **CBC (Europe) S.r.l.** (formerly known as **INTRACHEM BIO ITALIA S.p.A.**; hereinafter referred to as "CBC"), located at via E. Majorana 2, 20834 Nova Milanese (MB), Italy, hereby grant to **ANDERMATT FRANCE SAS** (hereinafter referred to as "ANDERMATT FRANCE"), located at 166 Boulevard du Montparnasse, 75014 Paris, France, full access to all field trial studies and data (refer to "Exhibit A") generated for the plant protection product **NEEMAZAL-T/S** and included into the Draft Registration Report prepared exclusively for product registration process in France.

This letter of access is only applicable to the above mentioned product and above mentioned uses. This access is not granted to the register of other products that might appear in the individual trial reports.

The right of access is solely granted in favour of ANDERMATT FRANCE and is neither transferable nor assignable to any other entity or person, without prior written consent of CBC, for the support of any other formulation or uses; it doesn't allow ANDERMATT FRANCE to submit any other product or uses based on "NeemAzal T/S" registration. Therefore, any other formulation or uses submitted for registration must be supported by a new letter of access

CBC's data ownership need to be indicated into any documents submitted to competent Authorities for registration of the Product.

CBC also retains the right to unilaterally revoke this letter at any time at its own discretion.

Yours faithfully,

  
**CBC (Europe) S.r.l.**  
S. Franceschini



Sede operativa  
Via XXV Aprile, 44 - 24050 Grassobbio (BG)  
tel: +39 035 335313 fax: +39 035 335334  
infobiogard@cbceurope.it - www.biogard.it

Area tecnica  
Via Calcinaro, 2085 - 47023 Cesena (FC)  
tel: +39 0547 630336 fax: +39 0547 632685  
tecnicobiogard@cbceurope.it

Sede principale  
Via E. Majorana, 2 - 20834 Nova Milanese (MB)  
tel: +39 0362365079 fax: +39 0362 41273  
sales@cbceurope.it



*Agrichem S.A.*  
Plaza Castilla 3 14<sup>a</sup> – 28046 Madrid  
Tel. 91 3149888 Fax 91 3149887  
e-mail: [info@agrichembio.com](mailto:info@agrichembio.com) / [pedro@agrichembio.com](mailto:pedro@agrichembio.com)

Date: 20<sup>th</sup> of July, 2015

**Letter of Access to the Dossier regarding the formulated product NeemAzal-T/S**

To whom it may concern:

The company **AGRICHEM, S.A.** (hereinafter referred to as "AGRICHEM"), with its registered seat at Plaza de Castilla, 3 – 14 A, 28046 Madrid, Spain, does hereby declare that we are owner of a set of field trials (refer to Exhibit A) on the efficacy of the formulated product **NEEMAZAL-T/S**, which is manufactured by the company TRIFOLIO-M GmbH (hereinafter referred as TRIFOLIO), located at Dr. Hans Wilhelmi-Weg 1, D-35633 Lahnau, Germany.

We, AGRICHEM, as the owner of the results and reports of field trials on the above mentioned formulated product, hereby authorise the distribution partner of TRIFOLIO in France, the company **ANDERMATT FRANCE**, located at 166 Boulevard du Montparnasse, 75014 Paris, France, to get access to the results and reports of the trials for registration purposes of the formulated product registration in France.

This access is not granted to the registration of other products that might appear in the individual trial reports.

The right of access is solely granted in favour of **ANDERMATT FRANCE** and is neither transferable nor assignable to any other entity or person, without prior written consent of AGRICHEM.

This Letter of Access shall in no event be construed as granting any property rights to **ANDERMATT FRANCE** whatsoever (including but not limited to intellectual property rights) in the Dossier.

AGRICHEM is not required to provide or to file any additional data under this Letter of Access.

Sincerely yours,

**AGRICHEM, S.A.**

Juan José Guerra Benito

General Manager

inscrito en el Registro Mercantil de Madrid, Tomo 4.095, folio 3133 de la sección 3º del libro de sociedades, folio 193, hoja B-1.709, inscripción 13.07.1998.



Trifolio-M GmbH - Dr.-Hans-Wilhelmi-Weg 1 · D-35633 Lahnau

Dr. Kerstin Jung

Phone: +49 6441 209 77 27

Fax: +49 6441 209 77 50

Mail: kerstin.jung@trifolio-m.de

**TO WHOM IT MAY CONCERN**

**Letter of Access**

Trifolio-M GmbH, located at Dr.-Hans-Wilhelmi-Weg 1, D-35633 Lahnau, Germany, being:

- the manufacturer of the active substance **Azadirachtin** (variant NeemAzal® technical), which was included into Annex I of Directive 91/414 (Commission Implementing Directive 2011/44/EU (13 April 2011)) and is now included in the list of approved active substances according to Commission Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) No 540/2011), following entry into force of Commission Regulation (EC) No. 1107/2009, having repealed Directive 91/414/EEC,
- supplier and manufacturer of the end user product, named **NeemAzal®-T/S**
- notifier of the active substance **Azadirachtin**, and also the owner, either outright or jointly, of the data subject to protection pursuant to Article 13 of Directive 91/414/EEC as noted therein,

grants **Andermatt France**, 166 Boulevard du Montparnasse, 75014 Paris, France the right to cite, refer to and rely on all the documents and studies belonging to the data package of Azadirachtin only for the registration of NeemAzal®-T/S in France.

This Letter of Access does not authorize **Andermatt France** or any other third party to have direct access to the data (whole or part, nor original or copy) or to make use of it for any further authorisation.

This access is only valid for the present data listed above at this date. It does not include access to data which might be submitted by Trifolio-M in future.

Lahnau, 23/07/2015

  
**Trifolio-M GmbH**

Dr.-Hans-Wilhelmi-Weg 1  
D-35633 Lahnau

Ina Kleeberg

Representative of the Management

Trifolio-M GmbH  
Dr.-Hans-Wilhelmi-Weg 1  
D-35633 Lahnau  
Germany

Fon: +49 (0) 6441 20 977 0  
Fax: +49 (0) 6441 20 977 50  
E-Mail: info@trifolio-m.de  
Web: www.trifolio-m.de

Amtsgericht: Wetzlar HRB 881  
GL.: Dr. Hubertus Kleeberg,  
Jenny Kleeberg  
Vat-No: DE112635527

Volksbank Heuchelheim eG  
IBAN: DE17 5136 1021 0203 6133 30  
SWIFT: GENODES1HHE

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

Azadirachtin

Letter of Access  
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TO WHOM IT MAY CONCERN

LETTER OF ACCESS

**MITSUI AgriScience International S.A./N.V.**, located in Boulevard de la Woluwe, 60, 1200 Brussels, Belgium (hereinafter referred to as “Mitsui”),

**Trifolio-M GmbH**, located in **Dr.-Hans-Wilhelmi-Weg 1, D-35633 Lahnaus, Germany**, (hereinafter referred to as “Trifolio”),

and

**Oxon Italia S.p.A.**, located in Via Sempione 195, I-20016 Pero (Milan), Italy (hereinafter referred to as “Oxon”),

**WHEREAS**, Mitsui, Trifolio, and Sipcam S.p.A. - located in Via Sempione 195, I-20016 Pero (Milan), Italy - submitted the two dossiers for the EU Review of the active substance Azadirachtin under Commission Regulations 1112/2002/EC and 2229/2004/EC, as well as the joint dossier for the re-submission of this active substance according to the accelerated procedure of Commission regulation (EC) 33/2008 (Article 13); *and*

**WHEREAS**, the active substance Azadirachtin was included in Annex I of Directive 91/414/EEC with Directive n° 2011/44/EU published on April 13, 2011; *and*

**WHEREAS**, Mitsui, Trifolio, and Sipcam S.p.A. submitted the confirmatory data after the EU approval of this active substance, as required by Commission Implementing Directive 2011/44/EU of 13 April 2011 and subsequent Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011; *and*

**WHEREAS**, Oxon has purchased Sipcam S.p.A. share of Azadirachtin dossier, as stated in the attached document (Attachment 1);

it is **AGREED** among Mitsui, Trifolio, and Oxon that the following data:

- the data submitted before the Annex 1 inclusion of Azadirachtin and covered by the letter of authorisation among Mitsui, Trifolio, and Sipcam S.p.A. of November 3, 2011 (enclosed as Attachment 2); *and*
- the confirmatory data submitted by Mitsui, Trifolio, and Sipcam S.p.A. after the EU approval of Azadirachtin, as required by Commission Implementing Directive 2011/44/EU of 13 April 2011 and subsequent Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011;

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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can be used by Mitsui, Trifolio, and Oxon to support in all European Member States registrations of formulated plant protection products containing the active ingredient Azadirachtin.

This Letter of Access enables each of the three companies to issue Letters of Access (LoA) to the above mentioned data to support third-parties' registrations within Europe of formulated products based on Azadirachtin supplied by the issuing company. Third parties entitled by this Letter of Access do not have the right to issue a Letter of Access to other parties by themselves, granting access to the dossier.

This Letter of Access does not authorize any other person other than the Member States to have direct access to the said data.

This authorization does not affect any agreements among Mitsui, Trifolio, and Oxon as to data compensation.

**For Mitsui AgriScience  
International S.A./N.V.**

Signature :



Name:

\_\_\_\_\_  
Toru TANAKA  
Managing Director

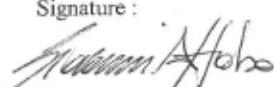
Position: Mitsui AgriScience  
International S.A./N.V.

Date :

23. 06. 2014

**For Oxon Italia S.p.A.**

Signature :



Name:

\_\_\_\_\_  
GIOVANNI AFFABRI

Position:

MANAGING DIRECTOR

Date : June 16<sup>th</sup>, 2014

**For Trifolio-M GmbH**

Signature :



Name:

\_\_\_\_\_  
Jenny Kleesberg

Position:

Managing Director

Date : 01.07.14

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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**Attachment 1**

**Oxon Italia S.p.A. and Sipcam S.p.A. – statement on study ownership**



Statement on study ownership

SIPCAM S.p.A., located in via Sempione 195, 20016 Pero (MI) Italy, and OXON Italia S.p.A., located in via Sempione 195, 20016 Pero (MI) Italy, hereby declare that the property of all the studies concerning the active ingredient Azadirachtin previously owned by SIPCAM S.p.A. ("studies") has been transferred for its share to OXON Italia S.p.A.

OXON Italia S.p.A. is entitled to make use of or refer to any of these studies without any restriction.

Pero, 1st January 2014

S.I.P.C.A.M. S.p.A.

Oxon Italia S.p.A.

SIPCAM S.p.A.

Direzione e Uffici:  
Via Sempione, 195  
20016 Pero (MI) Italia  
Tel. +39 02 35 376 408  
Fax +39 02 33 00 275  
www.sipcam.oxon.com  
sipcamox@oxonitalia.it

Stabilimenti:  
Via Vittorio Veneto, 81  
26057 Salvaro sul Lambro (LO)  
Italy  
Tel. +39 0371 5981  
Fax +39 0371 71428

Via San Colombano 81/A  
26090 Ledro (LO)  
Italy  
Tel. +39 0371 5971  
Fax +39 0371 499954

Sede Legale:  
Via Camuccia, 8  
20123 Milano Italia  
Codice Fiscale n.00777400152  
Società per Azioni  
Capitale Sociale  
€ 6.939.000,00 – I.v.

Registro Imprese di Milano n. c  
Codice Fiscale n.00777400152  
R.E.A. Milano n. 343850  
C.F./P.IVA IT 00777400152



OXON ITALIA S.p.A.

Direzione e Uffici:  
Via Sempione, 195  
20016 Pero (MI) Italia  
Tel. +39 02 35 378-1  
Fax +39 02 33 00 275  
www.oxonitalia.it  
montana@oxonitalia.it

Stabilimenti:

Via Sempione, 125  
20016 Pero (MI)  
Italy  
Tel. +39 02 35 378-1  
Fax +39 02 33 00 275

Sede Legale:

Via Del Corpicchio, 8  
20123 Milano Italia  
Società per Azioni  
Capitale Sociale  
€ 12.655.779,00

Registro Imprese di Milano n. c

Codice Fiscale n. 0384500152  
R.E.A. Milano n. 404631  
C.F./P.IVA IT 00645900152



Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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**Attachment 2**

**Letter of Authorisation among Mitsui, Trifolio, and Sipcam S.p.A. – November 3, 2011**

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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Sipcam S.p.A., Trifolio-M GmbH

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TO WHOM IT MAY CONCERN

LETTER OF ACCESS

We,

MITSUI AgriScience International S.A./N.V., located in Boulevard de la Woluwe, 60,  
1200 Brussels, Belgium,

Sipcam S.p.A., located in Via Sempione 195, I-20016 Pero (Milan), Italy,

and

Trifolio-M GmbH, located in Dr.-Hans-Wilhelmi-Weg 1, D-35633 Lahna, Germany,

owners of the two dossiers submitted for the EU Review of the active substance Azadirachtin under Commission Regulations 1112/2002/EC and 2229/2004/EC, in the following named Azadirachtin Dossier Defence Group ("ADDG"), have agreed on presenting a joint dossier for the re-submission of this active substance according to the accelerated procedure of Commission regulation (EC) 33/2008 (Article 13). Annex I inclusion of Azadirachtin was voted positively by the Standing Committee on Food Chain and Animal Health on March 11<sup>th</sup> 2011. Directive of inclusion n° 2011/44/EU has been published on April 13, 2011.

It is agreed between MITSUI AgriScience, Sipcam S.p.A. and Trifolio-M GmbH that the following data:

- the data within the above mentioned joint dossier presented for the resubmission of Azadirachtin as included in the letter of authorisation between the three companies of June 26<sup>th</sup>, 2009 (enclosed as Appendix 1 to the present LoA); and
- the data mentioned in the letter of authorization of Sipcam S.p.A. and Mitsui AgriScience International S.A./N.V to Trifolio-M GmbH dated June 16<sup>th</sup>, 2005, enclosed as Appendix 2 to the present LoA; and
- the data mentioned in the letter of authorization of Trifolio GmbH to Sipcam S.p.A. and Mitsui AgriScience International S.A./N.V dated June 13, 2005, enclosed as Appendix 3 to the present LoA;

can be used by MITSUI AgriScience International S.A./N.V., Sipcam S.p.A., and Trifolio-M GmbH, to support in all European Member States national registrations of formulated plant protection products based on Azadirachtin following its inclusion into Annex I of Dir. 91/414/EEC. Moreover, this letter of authorization enables each of the three companies to issue Letters of Access (LoA) to the above mentioned data to support third-parties' national registrations within Europe of formulated products based on Azadirachtin supplied by the issuing company. Third parties entitled by this Letter of Access do not have the right to issue a Letter of Access to other parties by themselves, granting access to the dossier.

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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Mitsui AgriScience International,  
Sipcam S.p.A., Trifolio-M GmbH

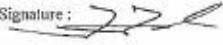
Azadirachtin

Letter of Access  
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This Letter of Access does not authorize any other person other than the Member States to have direct access to the said data.

This authorization does not affect any agreements among the members of the ADDG as to data compensation.

For Mitsui AgriScience  
International S.A./N.V.

Signature:   
Name: *Toshi Tanaka*  
Position: *MANAGING DIRECTOR*  
Date: *11 OCT. 2011*

For Sipcam S.p.A.

Signature:   
Name: *Giovanni D'Adda*  
Position: *MANAGING DIRECTOR*  
Date: *14 OCT 2011*

For Trifolio-M GmbH

Signature:   
Name: *Hubertus Klostberg*  
Position: *Man. Dir.*  
Date: *3/11/11*

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Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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Mitsui AgriScience International,  
Sipcam S.p.A., Trifolio-M GmbH

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## Appendix 1

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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Mitsui AgriScience International,  
Sipcam S.p.A., Trifolio-M GmbH

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TO WHOM IT MAY CONCERN

LETTER OF ACCESS

We, MITSUI AgriScience International S.A./B.V., located in Boulevard de la Woluwe,  
60, 1200 Brussels, Belgium,

Sipcam S.p.A., located in Via Sempione 195, I-20016 Pero (Milan), Italy,  
and

Trifolio-M GmbH, located in Dr.-Hans-Wilhelmi-Weg 1, D-35633 Lahnau, Germany,  
owners of the two dossiers submitted for the EU Review of the active substance Azadirachtin  
under Commission Regulations 1112/2002/EC and 2229/2004/EC, in the following named  
Azadirachtin Dossier Defence Group ("ADDG"), have agreed on presenting a joint dossier for  
the re-submission of this active substance according to the accelerated procedure of  
Commission regulation (EC) 33/2008 (Article 13). The eligibility to present a joint dossier  
was confirmed by the European Commission (Directorate E3) by letter dated 11.12.2008.

We hereby authorise the European Commission, represented by the Rapporteur Member State  
Germany, to assess the data within this joint dossier for the inclusion of the active substance  
Azadirachtin with the specifications as stated in that dossier.

Moreover, this letter of authorisation enables also all other European Member State  
authorities to assess the complete above mentioned data, within the joint dossier submitted for  
the notification of Azadirachtin, to support the national registrations by MITSUI AgriScience  
International S.A./B.V., Sipcam S.p.A., and Trifolio-M GmbH, of formulated products  
based on Azadirachtin, before and after its inclusion into Annex I of Dir. 91/414/EEC.

This Letter of Access does not authorize any other person other than the Rapporteur Member  
State, the Member States and the authorities of the European Commission to have direct  
access to the said data.

This authorization does not affect any agreements among the members of the ADDG as to  
data compensation. Further, this authorization is not to be extended or transferred to any other  
applicant.

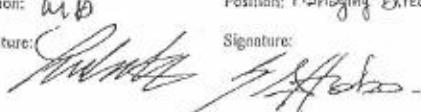
For Mitsui AgriScience  
International

Date : June 26'09

Name: TRICUBORI

Position: MD

Signature:



For Sipcam S.p.A.

Date : June 10<sup>th</sup> 2009

Name: Dr. Giovanni Affola

Position: Managing Director

Signature:

For Trifolio-M GmbH

Date: June 10<sup>th</sup> 2009

Name: Dr. Hubertus Kleeberg

Position: General Manager

Signature:



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Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

Azadirachtin

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Mitsui AgriScience International,  
Sipcam S.p.A., Trifolio-M GmbH

Azadirachtin

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## Appendix 2

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

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Sipcam S.p.A. /  
MITSUI AgriScience International

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TO WHOM IT MAY CONCERN  
LETTER OF AUTHORIZATION

We, Sipcam SpA, located in Via Sempione 195, I-20016 Pero (MI), Italy, represented by  
Mr. Giovanni Affaba

and

Mitsui AgriScience International S.A./B.V. located in Boulevard de la Woluwe,  
Woluwe 60, 1200 Brussels Belgium, represented by Mr. Hideo Sudo,

owners of the data for the joint dossier presented to the EC notification for Azadirachtin, SIP-  
IT (Sipcam SpA, Italy) and MAS-BE (Mitsui AgriScience International S.A./B.V., Belgium)  
under the Commission regulation (EC) 2229/2004,

hereby authorise the European Commission, represented by the Rapporteur Member State  
Germany, to assess the following data within the dossier submitted for the notification of  
Azadirachtin:

1. The data and studies referring to Annex II, Point 6.3: "Residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed or where residues from soil can be taken up" and Annex III, Point 8.3: "Supplementary residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed" for the uses in apples, tomatoes and ornamentals
2. The data and studies referring to Annex II, Point 7: "Fate and behaviour in the environment" and Annex III, Point 9: "Fate and behaviour in the environment"
3. Other data as listed in Annex I attached to this agreement

This is to support the notification TRF-DE (Trifolio-M, Germany) under the Commission  
regulation (EC) 2229/2004 for Azadirachtin.

Moreover, this letter of authorisation enables also all other European Member State  
authorities to assess the above mentioned data within the dossier submitted for the notification  
of Azadirachtin, to support the national registration by Trifolio-M of formulated products  
based on Azadirachtin, before and after its inclusion in the Annex I of Dir. 91/414/EEC.

Location: Brussels  
Date : June 13<sup>th</sup>, 2005  
Name: Hideo Sudo  
For Company: Mitsui AgriScience  
International SA  
Signature :



Location: MI/Italy  
Date : June 16<sup>th</sup>, 2005  
Name: GIOVANNI AFFABA  
For Company: Sipcam SpA  
Signature :



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Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

Azadirachtin

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Mitsui AgriScience International,  
Sipcam S.p.A., Trifolio-M GmbH

Azadirachtin

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## Appendix 3

Mitsui AgriScience International S.A./N.V.,  
Trifolio-M GmbH, Oxon Italia S.p.A.

Azadirachtin

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Trifolio-M GmbH

Azadirachtin  
(variant NeemAza)

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TO WHOM IT MAY CONCERN

LETTER OF AUTHORIZATION

We, Trifolio-M, located in Sonnenstraße 22, D-35633 Lahnau, Germany, represented by  
Mr. Hubertus Kleeberg

owner of the data for the dossier presented to the EC notification for Azadirachtin, TRF-DE  
(Trifolio-M, Germany) under the Commission regulation (EC) 2229/2004,

hereby authorise the European Commission, represented by the Rapporteur Member State  
Germany, to assess the following data within the dossier submitted for the notification of  
Azadirachtin:

1. The data and studies referring to Annex II, Point 6.3: "Residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed or where residues from soil can be taken up" and Annex III, Point 8.3: "Supplementary residue trials (supervised field trials) for crops or plant products used as food or feed on which use is proposed" for the uses in apples, tomatoes and ornamentals
2. The data and studies referring to Annex II, Point 7: "Fate and behaviour in the environment" and Annex III, Point 9: "Fate and behaviour in the environment"
3. Other data as listed in Annex I attached to this agreement

This letter of Authorization is to support the joint notification of SIP-IT (Sipcam SpA, Italy) and MAS-BE (Mitsui AgriScience International S.A./B.V., Belgium) under the Commission regulation (EC) 2229/2004 for Azadirachtin.

This letter of authorisation enables all other European Member State authorities to assess the above mentioned data within the dossier submitted for the notification of Azadirachtin, to support the national registration by Sipcam SpA and MAS-BE of formulated products based on Azadirachtin, before and after its inclusion in the Annex I of Dir. 91/414/EEC.

Location: *LAHNNAU*  
Date: *13/6/05*  
Name: *H. KLEEBERG, N.*  
For Company: *TRIFOLIO-M GMBH*  
Signature: *H. Kleeberg*  
*35633 Lahnau*