

REGISTRATION REPORT

Part A

Risk Management

Product name: NEEMAZAL-T/S JARDIN

Active substance:

Azadirachtin A: 9.8 g/L

COUNTRY: FRANCE

Interzonal

Zonal Rapporteur Member State: France

**NATIONAL ASSESSMENT FRANCE
(marketing authorisation)**

Applicant: Trifolio-M GmbH

Date: 2018-08-14

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PART A – Risk Management

The company Trifolio-M GmbH has requested marketing authorisation in France for the product NEEMAZAL-T/S JARDIN, 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 JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NEEMAZAL-T/S JARDIN 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 JARDIN.

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 Trifolio-M GmbH's application to market NEEMAZAL-T/S JARDIN in France as an insecticide (product uses described under point 2.3) for non-professional use. 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”)¹ – the highest application rates over the European Union. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4th May 2017² provides that:

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

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009³, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ is to supply “minor” crops with registered plant

¹ SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

² Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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

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

protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Last, The French Order of 30 December 2010⁷, defines the classification of “home and garden” product that can be used in France.

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 JARDIN, 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

Product name	NEEMAZAL-T/S JARDIN
Authorisation number	Not applicable
Function	Insecticide
Applicant	Trifolio-M GmbH
Composition	9.8 g/L azadirachtin A
Formulation type (code)	Emulsifiable concentrate (EC)
Requested packaging	N/A : not registered in France

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-
Health hazards	Reproductive toxicity, Hazard Category 2
Environmental hazards	Hazardous to the aquatic environment, Chronic, Hazard Category 2
Hazard pictograms	
Signal word	Warning

⁷ Arrêté du 30/12/10 interdisant l'emploi de certains produits phytopharmaceutiques par des utilisateurs non professionnels

Hazard statements	H361d	Suspected of damaging fertility or the unborn child
	H411	Toxic to aquatic life with long lasting effects
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

- EUH208: Contains azadirachtin. May produce allergic reactions.

The classification of the product (H361d) is not suitable for “home and garden” use in France, than no authorisation can be granted

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

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

N/A : not registered in France

2.2.4 Other phrases linked to the preparation

N/A : not registered in France

2.3 Product uses

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

When the conclusion is “not acceptable” or “not finalised”, 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: 2018-08-14

PPP (product name/code): **NEEMAZAL-T/S JARDIN**
Active substance: azadirachtin
Applicant: **Trifolio-M GmbH**
Zone(s): interzonal ^(d)
Verified by MS: yes
Field of use: insecticide

Formulation type: **EC** ^(a, b)
Conc. of as: **9.8 g/L** ^(c)
Professional use: ☐
Non professional use: ☒

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, 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, 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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
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	Not acceptable (classification)
	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	Not acceptable (classification)
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	Not acceptable (classification)
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	Not acceptable (classification)
4	France	Ornamentals	F	White flies, leafminers, aphids, thrips	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 L/ha	Not acceptable (classification)

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, 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			
					equipment: any conventional spray equipment									
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)														
5	France	Tomato, Pepper, Aubergine	G	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	Not acceptable (classification)
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	7-10	a) 3 b) 9	a) 0.03 b) 0.09	800- 1500	3	Product rate 2-3 L/ha	Not acceptable (classification)
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	7-10	a) 3 b) 9	a) 0.03 b) 0.09	250- 1500	NA	Product rate 2-3 L/ha	Not acceptable (classification)

* 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.

**Remarks
columns:**

- | | |
|---|---|
| <p>1 Numeration necessary to allow references</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>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)</p> <p>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</p> <p>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.</p> <p>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.</p> | <p>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</p> <p>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product</p> <p>10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>13 PHI - minimum pre-harvest interval</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions</p> |
|---|---|

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 JARDIN 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 PET 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 12 months of storage at ambient temperature, the content in azadirachtin A is still higher than 90 %. Consequently a stability of 12 months in PET packaging can be accepted. The formulation must not be stored more than 12 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: azadirachtin			
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		
Dermal absorption	Based on physico-chemicals properties of active substance (experts judgments, DAR azadirachtin):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)
	Dermal absorption endpoints %	10	10

3.1.3.1 Acute Toxicity

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

3.1.3.2 Operator Exposure

Critical use patterns (worst cases) are summarized below.

Crop	F/G ⁸	Equipment	Application rate (L product/ha)	Spray dilution	Model
Vegetables (risk envelop)	G	Manual-knapsack	3 L/ha (3 mL/10 m ²) (30 g azadirachtin A/ha)	250 L/ha	EFSA model
Ornamentals	G	Manual-knapsack	3 L/ha (3 mL/10 m ²) (30 g azadirachtin A/ha)	250 L/ha	EFSA model
Vegetables (risk envelop)	F	Manual-knapsack	3 L/ha (3 mL/10 m ²) (30 g azadirachtin A/ha)	250 L/ha	EFSA model
Orchards	F	Manual-knapsack	3 L/ha (3 mL/10 m ²) (30 g azadirachtin A/ha)	500 L/ha	EFSA model
Ornamentals	F	Manual-knapsack	3 L/ha (3 mL/10 m ²) (30 g azadirachtin A/ha)	250 L/ha	EFSA model

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

		Azadirachtin A	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Manual-Knapsack Downward spraying – Fruiting vegetables Application rate: 0.03 kg a.s./ha			
EFSA (75 th percentile) Body weight: 60 kg	potential	0.1687	169
	work wear M/L and A	0.0342	34
Manual-Knapsack Upward spraying – Fruiting vegetables Application rate: 0.03 kg a.s./ha			
EFSA (75 th percentile) Body weight: 60 kg	potential	0.0772	77
	work wear M/L and A	0.0184	18
Manual-Knapsack Downward spraying – Ornamentals Application rate: 0.03 kg a.s./ha			
EFSA (75 th percentile) Body weight: 60 kg	potential	0.1687	169
	work wear M/L and A	0.0342	34
Manual-Knapsack Upward spraying – Ornamentals Application rate: 0.03 kg a.s./ha			
EFSA (75 th percentile) Body weight: 60 kg	potential	0.0772	77
	work wear M/L and A	0.0184	18
Manual-knapsack Upward spraying – Pome fruit Application rate: 0.03 kg a.s./ha			
EFSA (75 th percentile) Body weight: 60 kg	potential	0.0772	77
	work wear M/L and A	0.0184	18

Operator exposure estimations using the EFSA model indicate that the predicted operator exposure upon application of NEEMAZAL-T/S JARDIN according to the GAP remains well below the AOEL for azadirachtin without personal protective equipment when is an upward application.

Nevertheless, operator exposure estimations using the EFSA model indicate that the predicted operator exposure upon application of NEEMAZAL-T/S JARDIN according to the GAP is above the AOEL for azadirachtin without personal protective equipment when is a downward application.

⁸ Open field or glasshouse

3.1.3.3 Bystander Exposure

For non-professional users, it is considered that the assessment for bystanders is covered by that for the operator.

3.1.3.4 Worker Exposure

NEEMAZAL-T/S JARDIN is intended to be used by non-professional users during home garden application. Thus, the worker is also the user of the product. It will be necessary to ensure complete drying of the treated area or of treated plants before handling them.

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.

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-T/S JARDIN

Crop	PHI for GLOB275 F proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GLOB275 F 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, the risk exposure for all intended uses cannot be finalized. However, the risk assessment provided by the applicant for azadirachtin A and its metabolite azadirachtin H* was reviewed by zRMS.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment by azadirachtin A is expected for all the intended uses.

Assessment for field uses

For a use by non-professional users, the exposure of soil compartment was considered negligible.

PEC_{sw} values based on the basic drift values (BBA) derived for azadirachtin A and its metabolite azadirachtin H* can be used for the ecotoxicological risk assessment.

PEC_{gw} 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 .

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 PEC_{sw} 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, the risk exposure for all intended uses cannot be finalized. However, the risk assessment provided by the applicant for azadirachtin A and its metabolite azadirachtin H* was reviewed by zRMS.

Assessment for field uses

As NEEMAZAL-T/S JARDIN is intended to be used by non-professional users, the exposure of mammals, 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 negligible.

Based on the guidance documents, the risks for birds are acceptable considering the intended field uses of NEEMAZAL-T/S JARDIN.

For aquatic organisms, the risks can be considered acceptable with the following mitigation measures: to protect aquatic organisms, do not apply the product at least 5 meters away from any surface water bodies (well, pond, stream, river ...) for the uses on pome fruit, peach and ornamentals.

Assessment for greenhouse uses

As NEEMAZAL-T/S JARDIN is intended to be used by non-professional users, the exposure of non-target terrestrial organisms to azadirachtin A and its metabolite azadirachtin H* is considered negligible.

Based on the guidance documents, the risks for aquatic organisms are acceptable considering the intended greenhouse uses of NEEMAZAL-T/S JARDIN.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of NEEMAZAL-T/S JARDIN is considered acceptable for all the claimed uses, with the exception of the use on moths of pome fruits. Given the lack of data, the evaluation for this use cannot be finalized.
- The phytotoxicity level of NEEMAZAL-T/S JARDIN 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 JARDIN on a few plants of the same variety and at the same growth stage before using NEEMAZAL-T/S JARDIN on a wide area.
- The risks of negative impact on 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

The proposed packaging are unable to ensure a minimum exposure of the non-professional user.

In addition, the product NEEMAZAL-T/S JARDIN is classified H361d that is not acceptable for a product intended to be used by non-professional users in France.

In conclusion, the product is not compliant with the French regulations relating to the use by non-professional users.

Taking into account the above assessment, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

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

N/A : not registered in France.

3.4.2 Post-authorisation data requirements

N/A : not registered in France.

3.4.3 Label amendments

N/A : not registered in France.

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

Vu l'arrêté du 30 décembre 2010 interdisant l'emploi de certains produits phytopharmaceutiques par des utilisateurs non professionnels,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **NEEMAZAL-T/S JARDIN***

de la société TRIFOLIO-M GmbH

enregistrée sous le n°2016-1073

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

Considérant que la classification - toxique pour la reproduction catégorie 2 (H361d) - du produit ne permet pas, en vertu de l'article 1 de l'arrêté du 30 décembre 2010 susvisé, la délivrance d'une autorisation pour un emploi par des utilisateurs non professionnels,

Considérant par ailleurs, qu'en l'absence de données sur le devenir dans l'environnement de la substance active azadirachtine, l'évaluation des risques pour l'environnement liée à l'utilisation du produit ne peut être finalisée,

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

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



Informations générales sur le produit		
Nom du produit	NEEMAZAL-T/S JARDIN	
Type de produit	Produit de revente	
Titulaire	TRIFOLIO-M GmbH Dr.-Hans-Wilhelmi-Weg 1 35633 LAHNAU ALLEMAGNE	
Formulation	Concentré émulsionnable (EC)	
Contenant	9,8 g/L - azadirachtine A	
Produit de référence	Nom commercial	NEEMAZAL-T/S
	N° AMM	2140090
Numéro d'intrant	300-2016.01	
Numéro d'AMM	-	
Fonction	Insecticide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort, le

14 AOUT 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)

NEEMAZAL-T/S JARDIN
AMM n°-

Page 2 sur 3



ANNEXE I : Classification du produit

Classification du produit	
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.	

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

NeemAzal®-T/S Jardin

Insecticide

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

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

Emploi autorisé dans les jardins.

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

Ne pas utiliser pour lutter contre d'autres insectes ni à des doses supérieures que ceux mentionnés sur l'étiquette.

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. Éviter 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

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 Jardin 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 Jardin 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 Jardin 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 Jardin s'emploie à une dose variant de 2-3 mL/10 m², dans un volume de bouillie de 0,25 à 1,5 L/10 m². Veiller à assurer une couverture complète de la végétation.

Appliquez NeemAzal-T/S Jardin 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.

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 mL/10m ²	3	-
12603150	Pommier * Traitement des parties aériennes * pucerons (autres que lanigère)	Max. 3 mL/10m ²	3	-
12553122	Pêcher * Traitement des parties aériennes * pucerons	Max. 3 mL/10m ²	3	3 j
16953113	Tomates * Traitement des parties aériennes * chenilles phytophages	Max. 3 mL/10m ²	3	3 j
16953104	Tomates * Traitement des parties aériennes * pucerons	Max. 3 mL/10m ²	3	3 j
16953110	Tomates * Traitement des parties aériennes * thrips	Max. 3 mL/10m ²	3	3 j
16953101	Tomates * Traitement des parties aériennes * aleurodes	Max. 3 mL/10m ²	3	3 j
16953106	Tomates * Traitement des parties aériennes * mouches	Max. 3 mL/10m ²	3	3 j
17403102	Cultures florales et plantes vertes * Trait. des parties aériennes * aleurodes	Max. 3 mL/10m ²	3	-
17403108	Cultures florales et plantes vertes * Trait. des parties aériennes * chenilles phytophages	Max. 3 mL/10m ²	3	-
17403104	Cultures florales et plantes vertes * Trait. des parties aériennes * pucerons	Max. 3 mL/10m ²	3	-
17403106	Cultures florales et plantes vertes * Trait. des parties	Max. 3 mL/10m ²	3	-

	aériennes * thrips			
17403107	Cultures florales et plantes vertes* Trait. des parties aériennes * mouches	Max. 3 mL/10m ²	3	-

Intervalle entre traitements : 7 jours. Volume de bouillie recommandé : 0,50-1,5 L/10 m² pour les fruits à pépins, pêches, abricots et nectarines, 0,25-1,5 L /10 m² pour les tomates, poivrons, aubergines, et cultures ornementales.

Sélectivité

NeemAzal-T/S Jardin 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 Jardin 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 Jardin. 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 Jardin** 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 : *Conférence, Bristol Cross, Alexander Lukas, HW606, Illinois 13B83 Maxine, Winterdechant, Trévoux, 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, Sutura, Tagetes (yellow), Torenia fournieri, Verbena (Tapien blau, Sunvop (P)).*

Sélectivité sur feuille satisfaisante : *Agerathum houstonianum, Alonsoa, Alyssum, Amaranthus, Calceolaria-Hybriden, Callistephus chinensis, Calocephalus brownii, Centaurea, Cestrum, Clarkia, Cleome, Coleus, Cosmos, Cuphea, Cynara scolymus, Dahlia, Dianthus barbatus, Dimorphoteka, Eucalyptus, Eustoma grandiflorum, Ficus, Felicia, Gazania, Gnaphalium, Helianthus, Heliotropium arborescens, Iresine lindenii, I. herbstii, Kochia, Lavatera, Limonium, Lotus, Lysimachia, Melampodium paludosum, Mesembryanthemum crystallinum, Nicotiana, Nigella, Pennisetum, Penstemon, Plectranthus fruticosus, Polygonum, Portulaca, Primula, Ricinus, Roses (Hydroponics - 6 cv's, Ambiance, Avelance, Beauty Bijoger, 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, G´oldspark, Icefolly, Leila, Margarita, Mario, Napoli, Olilia, Optima, Purity, Red Explosion, Rosty, Ruby Red, Santos, Serena, Timo, Vigoury, 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 vioacea (Tricolos Society), Verbena (several varieties).

Phytotoxicité sur feuilles (enroulement, déformation) : *Abutilon*-Hybrids, *Begonia elatior*-Hybrids, *Callistemon citrinus* (**Dwarf Botle Brush**), *Cestrum*, *Clytostoma callistegiodes* (**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 Jardin 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 Jardin, les insectes cessent de s’alimenter et perdent leur activité. NeemAzal-T/S Jardin 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 Jardin 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 rhopalosiphii* (guêpe parasitoïde). Il est classé toxique pour les populations d’*Amblyseius cucumeris* (acarien prédateur), *Coccinella septempunctata* (coccinelle), *Chrysoperla carnea* (chrysope) and *Episyrphus balteatus* (syrphe).

Conditions de stockage et d’élimination des déchets :

Stocké 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: 100 mL

Concentré émulsionnable

Lot n°

Date de fabrication

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

Détenteur de l'homologation :

Trifolio-M GmbH

Dr.-Hans-Wilhelmi-Weg 1

D-35633 Lahnau

Allemagne

Appendix 3 – Letters of Access



Agrichem S.A.
Plaza Castilla 3 14^a – 28046 Madrid
Tel.: 91 3149888 Fax: 91 3149887
e-mail: info@agrichembio.com / pedidos@agrichembio.com



Date: 22nd of December, 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**, 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 **TRIFOLIO-M GmbH**, located at Dr. Hans Wilhelmi-Weg 1, D-35633 Lahnau, Germany, to get access to the results and reports of the trials for registration purposes of the formulated product registration **NeemAzal-T/S Jardin** in France for the home and gardening sector.

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 **TRIFOLIO-M GmbH** 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 **TRIFOLIO-M GmbH** 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

Inscrita en el Registro Mercantil de Madrid, Tomo 4.095, folio 3.321 de la sec. 3ª del libro de sociedades, folio 183, hoja 31.782, inscripción 1ª C/P A-26429775



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

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

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