

NeemAzal-T/S -current status of registration and maximum residue levels in the EU

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Abstract

The paper reflects the current situation of the registration status in the EU with special focus on Germany. Also the MRL for Azadirachtin A with respect to regulation 149/2008/EC are discussed.

Keywords: NeemAzal-T/S, Azadirachtin A registration, MRL.

Status of Registration

Azadirachtin A is the active ingredient of the plant protection product (ppp) NeemAzal-T/S, which gains its first registration as ppp in Germany in 1998 and was afterwards registered in many other countries world wide and became known as a safe biological insecticide with high efficacy.

In the frame of the implementation of the European plant protection directive 91/414/EC Azadirachtin was notified for the Annex I inclusion in 2002 by Trifolio-M. A dossier was submitted in 2005 to the Rapporteur Member State Germany.

In December 2008 the non-inclusion of Azadirachtin in Annex I of Reg. 91/414 has been published by the European Commission (decision No. C(2008) 7803). It was a result of the voluntary withdrawal of the dossier by Trifolio-M due to a new released EU Regulation at this time, which prohibited the submission of further data to the dossier to close identified data gaps. The non-inclusion was not based on any hazard properties of the product.

Trifolio-M has resubmitted the revised dossier in June 2009. The deadline for a decision on inclusion or non-inclusion by the EU is the 31st of December 2010.

For national registration two different procedures apply:

- Countries where the national registration is valid until 31st of December 2010 or longer, the current situation will have no impact on the national approval.
- Countries where registration will expire in December 2010, e.g. Germany, an application for re-registration will be submitted in time to maintain the marketability of NeemAzal-T/S beyond this date.

Table 1 gives an overview on some of the existing registrations of NeemAzal-T/S.

Table 1: EU and other countries with NeemAzal-T/S registrations

Country	valid until
Austria	31.12.2010
Belarus	06.06.2016
Belgium	applied
Bulgaria	applied
Cyprus	31.12.2010
Denmark	applied
Estonia	31.12.2010
France	applied
Germany	31.12.2010
Greece	expired

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Table 1 : Continuation

Country	valid until
Czech Republic	applied
Hungary	applied
Iran	18.11.2011
Italy	31.12.2010
Kenya	in progress
Latvia	14.10.2014
Lithuania	31.12.2010
Luxemburg	31.12.2010
Morocco	01.07.2019
The Netherlands	31.12.2010
Norway	applied
Romania	applied
Russia	applied
Saudi Arabia	16.07.2010
Serbia	sales approval
Slovenia	25.11.2012
Spain	31.12.2010
Sweden	applied
Switzerland	31.12.2015
Turkey	20.06.2010
United Kingdom	in progress

All submitted and intended registrations within the EU are or will be based on the new indications as presented in Table 2. In countries, where re-registration will become necessary (e.g. Germany), data for the extension of indications were already submitted.

Table 2: Indications as submitted in Germany

Host/Pest	Field	Field HaG*	Glass-house	Glass-house HaG*	Rooms, Offices, Balconies HaG*	waiting period [days]
Potato/Colorado Potato beetle	Existing	Existing				4
Pip-Fruit (exc. Pear)/ sucking, biting and leaf mining insects	New	New				14
Cherry/ sucking, biting and leaf mining insects	New (§18)	New				not def. (4/15)
Small Fruits (exc. Strawberry) sucking, biting and leaf mining insects	New	New				not def. (XF)
Ornamental (exc. Conifers) sucking, biting and leaf mining insects	Existing	Existing	Existing	Existing	Existing	XN
Ornamentals (exc. Conifers)/ Spider Mites	Existing	Existing	Existing	Existing	Existing	XN
Leafy Vegetables (exc. leek and chicorie)/ sucking, biting and leaf mining insects	Existing (§18)	New				7
Asparagus/ sucking, biting and leaf mining insects	Existing (§18)	New				XF
Fresh Herbs (exc. chives)/ sucking, biting and leaf mining insects	New	New	New	New	New	14 exemptions for Dill, Parsley, Sage
Plum/ sucking, biting and leaf mining insects	New	New				not def. (4/15)

Table 2: Continuation

Host/Pest	Field	Field HaG	Glass-house	Glass-house HaG	Rooms, Offices, Balconies HaG	waiting period [days]
Cabbage/ sucking, biting and leaf mining insects	New	New				3
Pulses/ sucking, biting and leaf mining insects	Existing (§18)	New	New	New	New	XF
Fruity Vegetables/ sucking, biting and leaf mining insects	New	New	New	New	New	1 – 3 (F) 3 (GH)
Pulses/ Spider Mites	New	New	New	New	New	XF
Fruity Vegetables/ Spider Mites	New	New	New	New	New	1 – 3 (F) 3 (GH)
Leafy Vegetables/ Spider Mites	New	New				7
Fores/ biting and leaf mining insects	Existing (§18)					XN
Ornamentals/ Sciarids				New	New	XN
Pip-Fruit (exc. Pears)/ Bugs	New					XF
Spices/ sucking, biting and leaf mining insects	New	New				14
Tea Herbs/ sucking, biting and leaf mining insects	New	New				14
Medicinal Herbs/ sucking, biting and leaf mining insects	New	New				14
Spices/ Spider Mites	New	New				14
Tea Herbs/ Spider Mites	New	New				14
Medicinal Herbs/ Spider Mites	New	New				14
Forest/Cockchafer (Imago)	New					XN
Tree Nursery/ sucking, biting and leaf mining insects	Existing (§18)					XN
Tree Nursery / Spider Mites	New					XN
Viticulture/ Cockchafer (Imago)	Existing (§18)					XF
Orchards/ Cockchafer (Imago)	New					XF
Viticulture/Vine Pest (only for propagation material)	Existing (§18)					XF

*HaG = home and garden

Azadirachtin A residues in/on fruits, vegetables and herbs

Azadirachtin A (AzA) is the analytical leading compound of the group of Azadirachtins, which is the active ingredient of the plant protection product NeemAzal-T/S. Analysis of the AzA-residues in/on foodstuff are an important issue in terms of consumer protection and registration. The current situation concerning the registration is that numerous data for a huge variety of crops were submitted as presented in table 3. For residue analysis the crops were generally treated 3 times in weekly intervals with a spray solution of 0.3 to 0.5% NeemAzal-T/S in water. First sampling were carried out after drying of the spray film unless otherwise stated (e.g. fennel seeds). Therefore the AzA content as given in Table 3 is the amount of residue directly after treatment. A good deal of the herbs were analysed in fresh and dry condition. The relatively high AzA content on the day of application is due to the loss of water during the drying process.

The MRL-values are taken from the Commission Regulation (EC) No 149/2008 which may be subject to changes in the years to come.

The waiting periods in the table are proposed by Trifolio-M and are based on the current MRL-values and the degradation of AzA in/on the crops. Finally the waiting periods will be established by the responsible registration authorities.

Table 3: Overview - AzA residues, MRL and waiting periods

	Crop	Crop growth stage at application	AzA content ¹⁾ [mg AzA / kg]	MRL ²⁾ [mg AzA / kg]	waiting period ³⁾ [d]
Fruits	Apple	BBCH 87-89	< LOQ	1	0
	Apple	BBCH 56-69	< LOQ		
	Cherry	BBCH 81-87	0.26	1	0
	Orange, peel and pulp	BBCH 87-98	peel: 0.055	0.5	0
			pulp: < LOQ	0.5	0
	Peach	BBCH 83-86	0.049	1	0
	Strawberry	BBCH 84-87	0.032	1	0
Vegetables	Cabbage	BBCH 48-49	0.020	1	0
	Cucumber, field	BBCH 75-76	< LOQ	1	0
	Cucumber, greenhouse	BBCH 69-89	< 0.020		
	Head lettuce	height: 25 cm	0.13	1	0
	Potato	BBCH 40-70	< LOQ	1	0
	Spinach	BBCH 11-49	0.94	1	1
	Sweet pepper	BBCH 72-76	0.17	1	0
Herbs	Tomato, field	ripe fruit; BBCH 82-84	< 0.043 from study with 10fold application rate	1	0
	Tomato, greenhouse	fruit producing	< LOQ		
	Basil	height: 40-45 cm	0.43	1	0
	Dill, fresh	BBCH 45-49	0.7	1	1
	Dill, dried		1.38		
	Fennel seeds	BBCH 92	< LOQ at harvest	0.01	0
	Lemon balm, dried	BBCH 49	4.60	1	3
	Lemon balm, fresh		0.81		
	Parsley, dried, field	height: 25 cm	6.84	1	3
	Parsley, fresh, greenhouse	46-49; height: 15 cm	3.06	1	? ⁴⁾
	Parsley, fresh, field	height: 25 cm	1.39	1	1
	Sage	height: 35 cm	1.04	1	7
	Savory, fresh	not stated	1.43	1	1
Savory, dried	5.39				

1) mean AzA content; 2) MRL according to regulation No 149/2008; 3) proposal by Trifolio-M GmbH; 4) results on degradation on/in parsley differ variably

Conclusion

NeemAzal-T/S is an effective and efficient plant protection agent which can be applied against a huge variety of crops and pest. Further advantage is the fast degradation of its leading compound Azadirachtin A.