FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 123000 A

Product name: AZA

Chemical active substance:

Azadirachtin, 10 g/L

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 06.2022

Version history

When	What
10/2020	Submission dossier from applicant
08/2021	Draft RR evaluated by RMS to commenting
06/2022	Final RR evaluated by RMS to commenting

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Tomato**	F	*Aleuroids, Thrips, Aphids*	Foliar Spray	Apply at pest presence BBCH 12-85	a) 2 b) 2	7-10	a) 3 b) 6	a) 0.03 b) 0.06	750-1000	3	DE: plant height until 50cm 2 L/ha in 600 M/ha, from 50 to 125cm 2.5 L/ha, over 125cm 3 L/ha in 1000 L/ha	
2	CEU	**Potato**	F	Collorado beetle *(Leptinotarsa decemlineata)*	Foliar Spray	Apply at pest presence BBCH 12-91	a) 2 b) 2	7-10	a) 2.5 b) 5	a) 0.025 b) 0.05	500-1000	3		
3	CEU	**Ornamentals**	F	*Aleuroids, Thrips, Aphids*	Foliar Spray	Apply at pest presence BBCH 12-89	a) 2 b) 2	7-10	a) 3 b) 6	a) 0.03 b) 0.06	750-1000	3		

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

** 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

Explanation for column 15 "Conclusion"

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of Azadirachtin concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	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: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					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		
-	NEU	Potato	F	Colorado beetle	Spray	During the vegetation period (independent from growth stage)	a) 1 b) 1	-	-	0.025	300-600	4	Treatment at beginning infestation : 5 days after hatching of young larvae
-	NEU CEU	Ornamentals on artificial soils	G	Spider mites	Spray	During the vegetation period (independent from growth stage)	a) 4 b) 4	7/10	-	0.01 – 0.03	600-1000	NA	Treatment at beginning of infestation

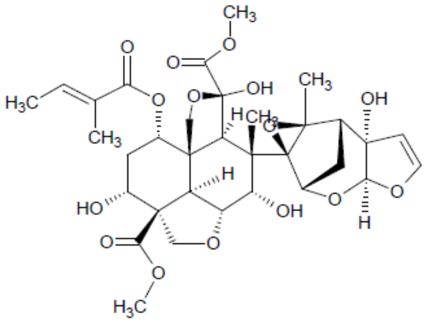
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

zRMS comments:
All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Azadirachtin potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Azadirachtin H*	678.69		Soil: 63% Water/Sediment: No data available	No assessment performed. No input parameters available. PEC_{gw}

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Azadirachtin A and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Azadirachtin A- laboratory studies

Azadirachtin A, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa****	**χ^2**	**Kinetic model**	**Evaluated on EU level y/ Reference**
LUFA 2.1	Sand	6.0	20	40 (29%)	3.3*	11.0	3.2	(0.997)	SFO	y/ EFSA Journal 2018;16(4):5234
LUFA 2.2	Loamy sand	5.8	20	40 (50%)	4.0*	13.4	4.0	(0.989)		
LUFA 2.3	Sandy loam	6.6	20	40 (39%)	2.0*	6.6	1.7	(0.955)		
LUFA 2.2	Loamy sand	5.6	20	40 (48%)	1.9*	6.5	1.9	(0.993)		
Soil B	Silty clay	8.0	25	40-50	25.6*	85.0	27.0***	(0.986)		
Soil C	Loam	5.9	25	40-50	10.6*	35.0	12.2***	(0.998)		
Clay	Clay	7.1	20	45 (45.93%)	3.3	11.1	1.8	7.9		
Loam	Loam	5.5	20	45 (59.42%)	2.7	8.9	2.7	5.5		
Sand	Sand	5.2	20	45 (27.27%)	8.3	27.7	8.3	14.0		
Sandy loam	Sandy loam	6.8	20	45 (32.47%)	2.4	8.1	2.0	8.0		
Geometric mean (n=10)							**4.0**			
pH-dependency:							no			

*** Recalculated SFO, original data from study referred to pseudo 1st order**
**** Normalized values using a Q_{10} = 2.58 (temperature correction factor) and soil moisture correction were done according to FOCUS guidance and with MWHC determined in the study**
***** Soil moisture correction was done according to FOCUS guidance and with default value for MWHC**

Table 8.3-2: Summary of aerobic degradation rates for Azadirachtin B - laboratory studies

Azadirachtin B, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa****	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	6.0	20	40 (29%)	6.0*	19.9	5.9	(0.96)	SFO	y/ EFSA Journal 2018;16(4):5234

Azadirachtin B, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa****	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Soil B	Silty clay	8.0	25	40-50	35.2*	110	37.3***	(0.99)	SFO	
Soil C	Loam	5.9	25	40-50	14.1*	101	16.2***	(0.93)	SFO	
Clay	Clay	7.1	20	45 (45.93%)	10.8	36.0	6.0	21.3	SFO	
Loam	Loam	5.5	20	45 (59.42%)	7.8	26.1	7.8	11.5	SFO	
Sand	Sand	5.2	20	45 (27.27%)	17.1/16.3	104.5/91.8	33.1***	4.6/4.9	FOMC/HS	
Sandy loam	Sandy loam	6.8	20	45 (32.47%)	8.9	29.7	7.4	9.8	SFO	
Geometric mean (n=7)							**12.2**			
pH-dependency:							no			

*** Recalculated SFO, original data from study referred to pseudo 1st order**
**** Normalised values using a Q_{10} = 2.58 (temperature correction factor) and soil moisture correction were done according to FOCUS guidance and with MWHC determined in the study**
***** Soil moisture correction was done according to FOCUS guidance and with default value for MWHC**
****** Different models have to be taken for the modelling DT_{50} and the persistence DT_{50}, FOMC cannot be taken for the modelling endpoint, because 10% of the initial concentration were not reached within the experimental period. DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-3: Summary of aerobic degradation rates for Azadiradione - laboratory studies

Azadiradione, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	18.3	60.7	10.1	8.6	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	11.8	39.1	11.8	6.2	SFO	
-	Sand	5.2	20	45 (27.27%)	19.0/ 18.7	122.1/ 103.4	36.5*	7.2/6.7	FOMC/HS	
-	Sandy loam	6.8	20	45 (32.47%)	7.5	25.1	6.2	11.6	SFO	
Geometric mean (n=4)							**12.8**			
pH-dependency:							no			

***different models have to be taken for the modelling DT_{50} and the persistence DT_{50}, FOMC cannot be taken for the modelling endpoint, because 10% of the initial concentration were not reached within the experimental period. DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-4: Summary of aerobic degradation rates for 12 Decarbomethoxy-azadirachtin - laboratory studies

12 Decarbomethoxy-azadirachtin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.o C**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	5.2/5.3	27.5/ 30.4	14.3*	4.0/3.5	FOMC/ DFOP	y/ EFSA Journal 2018;16(4) :5234
-	Loam	5.5	20	45 (59.42%)	4.1	13.5	4.1	17.6	SFO	
-	Sand	5.2	20	45 (27.27%)	16.0/ 15.7	119.3/ 103.1	40.4*	5.9/6.4	FOMC/HS	
-	Sandy loam	6.8	20	45 (32.47%)	4.1/3.8	24.0/ 27.0	6.0**	11.5/10.9	FOMC/ DFOP	
Geometric mean (n=4)							**10.9**			
pH-dependency:							no			

***different models have to be taken for the modelling DT_{50} and the persistence DT_{50}, FOMC cannot be taken for the modelling endpoint, because 10% of the initial concentration were not reached within the experimental period. DT_{50} of slow phase from DFOP or HS were used as modelling endpoint.**
**** different models have to be taken for the modelling DT_{50} and persistence DT_{50}, DT_{50} back calculated from FOMC DT_{90}/3.32 was used as modelling endpoint.**

Table 8.3-5: Summary of aerobic degradation rates for 3-Desacetylsalannin - laboratory studies

3-Desacetylsalannin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	29.6	98.3	16.4	7.1	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	12.8/12.5	102.7/83.0	30.9*	7.7/7.6	FOMC/DFOP	
-	Sand	5.2	20	45 (27.27%)	11.4	156.4	63.1**	11.8	HS	
-	Sandy loam	6.8	20	45 (32.47%)	12.0	40.0	10.0	14.6	SFO	
Geometric mean (n=4)							**23.8**			
pH-dependency:							no			

***different models have to be taken for the modelling DT_{50} and persistence DT_{50}, DT_{50} back calculated from FOMC DT_{90}/3.32 was used as modelling endpoint.**
**** DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-6: Summary of aerobic degradation rates for 6-Desacetylnimbin - laboratory studies

6-Desacetylnimbin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	25.4	84.2	14.1	3.3	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	19.9	66.0	19.9	9.5	SFO	
-	Sand	5.2	20	45 (27.27%)	19.1/ 18.6	140.8/ 112.1	40.3	5.7/4.6	FOMC/HS	
-	Sandy loam	6.8	20	45 (32.47%)	15.0	49.7	12.5	4.2	SFO	
Geometric mean (n=4)							**19.4**			
pH-dependency:							no			

***different models have to be taken for the modelling DT_{50} and the persistence DT_{50}, FOMC cannot be taken for the modelling endpoint, because 10% of the initial concentration were not reached within the experimental period. DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-7: Summary of aerobic degradation rates for 11-Epi-azadirachtin D - laboratory studies

11-Epi-azadirachtin D, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	6.9	23.1	3.8	7.4	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	5.3	17.7	5.3	9.6	SFO	
-	Sand	5.2	20	45 (27.27%)	11.0	36.6	11.0	3.3	SFO	
-	Sandy loam	6.8	20	45 (32.47%)	5.6	18.6	4.7	9.2	SFO	
Geometric mean (n=4)							**5.7**			
pH-dependency:							no			

Table 8.3-8: Summary of aerobic degradation rates for 14,15-Epoxy-azadiradione - laboratory studies

14,15-Epoxy-azadiradione, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	30.8	102.4	17.1	9.1	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	15.3	51.0	15.3	10.6	SFO	
-	Sand	5.2	20	45 (27.27%)	36.7	230.8	84.8*	11.7	HS	
-	Sandy	6.8	20	45 (32.47%)	14.9	49.3	12.4	11.5	SFO	

14,15-Epoxy-azadiradione, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
	loam									
Geometric mean (n=4)							**22.9**			
pH-dependency:							no			

***DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-9: Summary of aerobic degradation rates for Nimbin - laboratory studies

Nimbin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	30.7	102.1	17.0	6.0	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	23.0	76.4	23.0	11.6	SFO	
-	Sand	5.2	20	45 (27.27%)	22.9	102.7	34.4*	8.4	HS	
-	Sandy loam	6.8	20	45 (32.47%)	17.7	58.7	14.7	7.8	SFO	
Geometric mean (n=4)							**21.1**			
pH-dependency:							no			

***DT_{50} of slow phase from HS was used as modelling endpoint.**

Table 8.3-10: Summary of aerobic degradation rates for ohchinolide B - laboratory studies

ohchinolide B, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	1.7/1.7	10.2/11.4	1.7*	4.4/2.6	FOMC/DFOP	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	9.9	64.5	19.4*	4.1	FOMC	
-	Sand	5.2	20	45 (27.27%)	5.3/5.1	45.7/54.7	13.8*	4.5/3.3	FOMC/DFOP	
-	Sandy loam	6.8	20	45 (32.47%)	5.0/4.6	36.5/36.8	9.2*	7.5/6.0	FOMC/DFOP	
Geometric mean (n=4)							**8.0**			
pH-dependency:							no			

***different models have to be taken for the modelling DT_{50} and persistence DT_{50}, DT_{50} back calculated from FOMC DT_{90}/3.32 was used as modelling endpoint.**

Table 8.3-11: Summary of aerobic degradation rates for Salannin - laboratory studies

Salannin, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC % (% MWHC from study)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
-	Clay	7.1	20	45 (45.93%)	27.9	92.8	15.5	8.0	SFO	y/ EFSA Journal 2018;16(4):5234
-	Loam	5.5	20	45 (59.42%)	29.8	99.0	29.8	23.7	SFO	
-	Sand	5.2	20	45 (27.27%)	30.4	100.9	30.4	6.8	SFO	
-	Sandy loam	6.8	20	45 (32.47%)	20.7	68.6	17.2	14.7	SFO	
						Geometric mean (n=4)	**22.2**			
						pH-dependency:	no			

Table 8.3-12: Summary of aerobic degradation rates for metabolite Azadirachtin H* - laboratory studies, the Sala's 2013 data are from Azatin EC Polish and Dutch registration reports 2014 and 2015 respectively

Azadirachtin H*, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 / DT90 (d) (study re-calculated SFO)**	**DT50 (d) 20°C pF2/10kPa**	**f.f.**	**χ^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
LUFA 2.1	Sand	6.0	20	40	9.8*	9.6**	0.85	10.0	SFO	y/ EFSA Journal 2018;16(4):5234
Refesol 01-A	Loamy Sand	5.56		45	23.2	23.2	-	9.1		Sala, 2013
Refesol 03-G	Silt loam	4.52			8.7	8.7	-	4.1		Sala, 2013
					Geometric mean (n=3)	**12.4**				

*** Original data from study referred to kinetic model (consecutive first order)**
**** For moisture normalisation the maximum water holding capacity (MWHC) derived from the study and B=0.7 were used**

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No data available.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

As the maximum DT_{50} value of 36.7 days at 20 °C, pF 2 of Azadirachtin components derived from the laboratory studies does not exceed 60 days, a soil dissipation testing for these components is not required.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Due to the rapid degradation of Azadirachtin A components, a soil accumulation test is not required. However, this may need to be revised once information on the route of degradation is completed, since persistence in soil of some of the components is still unknown and the breakdown of the polycyclic structure (common to all the active components) has not been proven.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.5.1 Azadirachtin and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Azadirachtin A

Azadirachtin A									
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd**	**Kd-oc**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/ Reference**
Soil A*	Silty clay	1.86	8.1	2.26	121.5	3.13	168	0.87	y/ EFSA Journal 2018;16(4):5234 EFSA Journal 2011;9(3):1858
Soil B*	Silty clay	0.47	8.0	4.11	875.1	5.07	1079	0.93	
Soil C*	Loam	3.32	5.9	2.51	75.8	3.33	99	0.91	
Soil D*	Silt loam	1.36	6.8	1.02	75.1	2.43	179	0.73	
LUFA 2.1**	Sand	0.62	5.9	0.405***	65.4	-	-	1	
LUFA 2.2**	Loamy sand	2.32	5.6	0.479***	20.6	-	-	1	
LUFA 2.3**	Loamy sand	1.22	6.4	0.373***	30.6	-	-	1	
Geometric mean (n=7)					**82.01**	-	-	-	
Arithmetic mean (n=7)					-	-	-	0.92	
pH-dependency y/n					n				

*** Test material: Azadiractin A TEC**
**** Test material: NeemAzal**
***** Kd calculated as the mean of three individual data points, therefore only Koc were considered reliable in EFSA's 2011conclusion. For modelling these values should be associated to a 1/n = 1.**

Adsorption / desorption data obtained for Azadirachtin A may be extrapolated to Azadirachtin B.

Table 8.5-2: Summary of soil adsorption/desorption for Azadirachtin H (Fifi, A. 2013) from Azatin EC registered in Poland and The Netherlands in 2014 and 2015 respectively

Azadirachtin H									
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd**	**Kd-oc**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Reference**
Soil Type 2	Clay loam	3.55	8.02	1.0	27.4	0.61	17.18	1.015	Azatin EC registration reports, Fifi, A. 2013
Soil Type 5	Loamy sand	0.85	5.56	0.5	55.9	0.48	56.47	0.908	
Soil Type 6	Clay loam/clay	0.66	7.52	1.0	155.8	0.47	71.21	1.023	

Azadirachtin H									
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd**	**Kd-oc**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Reference**
Geometric mean (n=3)							**41.03**	-	
Arithmetic mean (n=3)							48.3	0.982	
pH-dependency y/n					n				

The potential mobility in soil of Azadirachtin components was estimated according to OECD Guideline No. 121 by means of High Performance Liquid Chromatography (HPLC) (Mori, 2013). This data can only be considered as tentative estimations subject to and error of about 0.5 logarithmic units. Data gap identified for fully reliable values:

Compound	Concentration [mg/L]	Retention times mean values (min)	Capacity Factor, k'	Log k'	Log Koc	Koc Tentative
12-decarbomethoxyazadirachtin	19.3	3.73	1.94	0.29	1.46	**28.8**
11-epi-azadirachtin D	20.2	4.03	2.17	0.34	1.64	**43.7**
azadirachtin B	20.1	4.29	2.38	0.38	1.79	**61.7**
azadirachtin A	18.1	4.35	2.42	0.38	1.82	**66.1**
6-desacetylnimbin	18.8	6.61	4.20	0.62	2.69	**490**
3-desacetylsalannin	19.1	6.60	4.19	0.62	2.69	**490**
nimbin	21.2	8.02	5.32	0.73	3.06	**1148**
ohchinolide B substance 8	20.6	8.47	5.67	0.75	3.16	**1445**
azadiradione	21.1	8.54	5.72	0.76	3.18	**1514**
salannin	19.3	8.59	5.76	0.76	3.19	**1549**
14,15-epoxyazadiradione	20.7	12.51	8.85	0.95	3.87	**7413**

8.5.2 Column leaching (KCP 9.1.2.1)

No study available, no study required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

No study available, no study required.

8.5.4 Field leaching studies (KCP 9.1.2.3)

No study available, no study required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 Azadirachtin and its metabolites

A guideline water/sediment study was not carried out, since radio-labelled components of Azadirachtin extract were not available. A cold hydrolysis study in natural water was provided instead with an extract containing 85.4 g/kg of Az A and 26 g/kg Az B (content of Az A is well below the specified content for the commercial extracts). In this study, investigating the behaviour of Azadirachtin TEC in river water samples of a single system, a rapid disappearance of Azadirachtin A from the water phase was found (DT_{50} = 13.7 d).

Additionally, an outdoor water sediment system with forest sediment has been provided.

Identification of metabolites has not been attempted.

Table 8.6-1: Summary of degradation in water/sediment of Azadirachtin A

Azadirachtin A Distribution (max. water/sediment x % after x days)								
Water/sediment system	**pH water/ sed.**	**T °C**	**$DegT_{50}$/ $DegT_{90}$ whole syst. (d)**	**$DissT_{50}$/$DissT_{90}$ water (d)**	**R^2**	**$DissT_{50}$/$DissT_{90}$ sed. (d)**	**Method of calcu-la-tion/kinetic**	**Evaluated on EU level y/n/ Reference**
Water system (river)	7.58/ n.d.	25	n.d.	8.82	0.997	n.d.	Pseudo 1st	y/ EFSA Journal 2018;16(4):5234
		25		9.3	0.9986		SFO	
		20		13.7*				
Outdoor water/sediment system (stream, forest)	6.32 / 6.21	n.d	n.d.	8-13	n.d.	2-3	n.d.	

*** recalculated DT_{50} value of one water metabolism study used for modelling in surface waters**

Table 8.6-2: Summary of degradation in water/sediment of Azadirachtin B

Azadirachtin B Distribution (max. water/sediment x % after x days)								
Water/sediment system	**pH water/ sed.**	**T °C**	**$DegT_{50}$/ $DegT_{90}$ whole syst. (d)**	**$DissT_{50}$/$DissT_{90}$ water (d)**	**R^2**	**$DissT_{50}$/$DissT_{90}$ sed. (d)**	**Method of calcu-la-tion/kinetic**	**Evaluated on EU level y/n/ Reference**
Water system (river)	7.58/ n.d.	25	n.d.	12.6	0.9835	n.d.	Pseudo 1st	y/ EFSA Journal 2018;16(4):5234
		20		19.51*	0.9986		SFO	

*** recalculated DT_{50} value of one water metabolism study used for modelling in surface waters**

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.7.2 Active substance and relevant metabolites

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1	2	3	
Crop	Tomato	Potato	Ornamentals	
			Grape vine**	a)Onion***
Application rate (g as/ha)	Azadirachtin A: 30.0	Azadirachtin A: 25.0	Azadirachtin A: 30.0	
Number of applications/interval	2/7			
Crop interception (%)	50	15	50	10
Application rate (g as/ha) rzeczywista	15	21.25	15	27
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)	20 cm (tillage)	5 cm (no tillage)	20 cm (tillage)

a) Worst-case for PECsoil calculation
**** Surrogate crop for bush ornamentals**
***** Surrogate crop for herbaceous and ornamental flowers**

Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT_{50} (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Azadirachtin A	720.7	-	**25.0 d** (Maximum, laboratory data, normalisation to 10 kPa or pF2 and 20°C with Q10 of 2.58)	EFSA Journal 2018;16(4):5234 EFSA Journal 2011;9(3):1858 Addendum 08 (confirmatory data) to the Additional Report of azadirachtin, 2017 Azatin EC dRR from Poland and The Netherlands 2014 and 2015 respectively
Azadirachtin H	687.7	63	23.2 d (Maximum, laboratory data, normalisation to 10 kPa or pF2 and 20°C with Q10 of 2.58)	
12 decarbometoxyazadirachtin*	662.7	8.3	-	
11 epi azadirachtin D*	676.6	16.6	-	
Azadirachtin B*	662.7	29.6	-	
3 desacetylsalanin*	554.7	21.3	-	
6 desacetylnimbin*	498.6	29.5	-	
Sub 8 (ohcbinolide)*	624.7	12.9	-	
Azadiradione*	450.6	67.2	-	
Nimbin*	540.6	37.9	-	
Salannin*	596.7	95.2	-	

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT_{50} (days)**	**Value in accordance to EU end-point y/n/ Reference**
14,15 epoxyazadiradione*	466.6	23.5	-	

***Only PECsoil $_{ini}$ will be calculated**

In order to calculate PEC_{soil} for the metabolites of Azadirachtin, a specific application rate adjusted for maximum amount of metabolite found in laboratory soil degradation studies and for molecular weight was derived.

In this context, specific application rate for each relevant metabolite is calculated based on the following equation:

$$\text{Application rate}_{metabolite} = (MW_{metabolite}/ MW_{parent}) \text{ x } (\% \text{ maximum occurrence}/100) \text{ x application rate}_{parent}$$

The corresponding application rates for the relevant metabolites are summarized in the table below.

Table 8.7-3: Corrected application rates for each relevant metabolite (worst-case)

Active substance	**Metabolite**	**Application rate of the parent (g/ha)**	**MW parent**	**MW metabolite**	**Maximum occurrence in soil (%)**	**Corrected application rate (g/ha)**
Azadirachtin	Azadirachtin H	2 x 30	720.7	687.7	63	18.9
	12 decarbometoxyazadirachtin			662.7	8.3	2,29
	11 epi azadirachtin D			676.6	16.6	4,68
	Azadirachtin B			662.7	29.6	8,17
	3 desacetylsalanin			554.7	21.3	4,92
	6 desacetylnimbin			498.6	29.5	6,12
	Sub 8 (ohcbinolide)			624.7	12.9	3,35
	Azadiradione			450.6	67.2	12,60
	Nimbin			540.6	37.9	8,53
	Salannin			596.7	95.2	23,65
	14,15 epoxyazadiradione			466.6	23.5	4,56

8.7.2.1 Azadirachtin A

Table 8.7-3: PEC_{soil} for Azadirachtin A on onion (worst-case)

PEC_{soil} (mg/kg)		Onions			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.036	-	0.066	-
Short term	24h	0.035	0.036	0.064	0.065
	2d	0.034	0.035	0.062	0.064
	4d	0.032	0.034	0.059	0.062
Long term	7d	0.030	0.033	0.054	0.060
	14d	0.024	0.030	0.045	0.054

	21d	0.020	0.027	0.037	0.050
	28d	0.017	0.025	0.030	0.046
	50d	0.009	0.019	0.016	0.036
	100d	0.002	0.012	0.004	0.022
Plateau concentration (20 cm) after year 10		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-4: PEC_{soil} for Azadirachtin H on onions (worst-case)

PEC_{soil} (mg/kg)		Onions			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.023	-	0.041	-
Short term	24h	0.022	0.022	0.040	0.040
	2d	0.021	0.022	0.039	0.040
	4d	0.020	0.021	0.036	0.039
Long term	7d	0.018	0.020	0.033	0.037
	14d	0.015	0.019	0.027	0.034
	21d	0.012	0.017	0.022	0.031
	28d	0.010	0.015	0.018	0.028
	50d	0.005	0.012	0.009	0.021
	100d	0.001	0.007	0.002	0.013
Plateau concentration (20 cm) after year 10		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-5: PEC_{soil} ini for Azadirachtin metabolites on onion (worst-case)

Metabolite	Applica-tion rate of the parent (g/ha)	MW parent	MW metabolite	Maximum occurrence in soil (%)	Corrected applica-tion rate (g/ha)	PEC_{soil} ini (mg/kg) (sin-gle/multiple)
12 decarbometoxyazadirachtin	2 x 30	720.7	662.7	8.3	2.29	0.003/0.005
11 epi azadirachtin D			676.6	16.6	4.68	0.006/0.011
Azadirachtin B			662.7	29.6	8.17	0.010/0.020
3 desacetylsalanin			554.7	21.3	4.92	0.006/0.012
6 desacetylnimbin			498.6	29.5	6.12	0.007/0.015
Sub 8 (ohchinolide)			624.7	12.9	3.35	0.004/0.008
Azadiradione			450.6	67.2	12.60	0.015/0.030
Nimbin			540.6	37.9	8.53	0.010/0.020
Salannin			596.7	95.2	23.65	0.028/0.057
14,15 epoxyazadiradione			466.6	23.5	4.56	0.005/0.011

8.7.2.2 PEC_{soil} of AZA

Since AZA is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S(mg/kg) = \frac{\text{Application rate (g/ha)} \times \text{(1-F)}}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3\text{)}}$$

Table 8.7-6: PEC_{soil} for AZA on onion (worst-case)

Active substance / Preparation	Application rate (g/ha)	Crop interception (%)	PEC_{act} (mg/kg)
Azadirachtin / AZA	2 x 2882.4*	10	6.918

***Based on a density of 0.9608 g/mL**

zRMS comments

PEC_{soil} calculations have been conducted with azadirachtin and its relevant metabolites using the EU agreed endpoints EFSA Journal 2018;16(4):5234.
Interception has been appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
The calculations of PECs cover proposed uses in GAP.
The results initial PEC soil of the active substances and tits metabolites in soil are appropriate to be used for the subsequent risk assessment.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1	2	3	
Crop	Tomato	Potato	Ornamentals	
			Grape vine*	Onion**
Application rate (g as/ha)	Azadirachtin A: 30.0	Azadirachtin A: 25.0	Azadirachtin A: 30.0	
Number of applications/interval (d)	2/7			
Crop interception (%)	50	15	50	10
Frequency of	Annual			

application	
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

*** Surrogate crop for bush ornamentals and tomato for PL**
**** Surrogate crop for herbaceous and ornamental flowers**

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)*			
	Tomato	Potato	Ornamentals	
			Grape vine	Onion
Châteaudun	14/05	03/05	10/04	09/05
Hamburg	-	15/05	07/05	09/05
Jokioinen	-	10/06	-	28/05
Kremsmünster	-	15/05	07/05	09/05
Okehampton	-	05/05	-	-
Piacenza	14/05	23/04	10/04	-
Porto	22/03	20/03	25/03	16/03
Sevilla	19/04	04/02	06/04	-
Thiva	14/04	05/03	23/03	24/04

***First application according to AppDate v 3.06 (28th June 2019)**

8.8.2.1 Azadirachtin and its metabolites

Only metabolite Azadirachtin H has been evaluated since the Kfoc values for the rest of metabolites are tentative.

Table 8.8-3: Input parameters related to active substance Azadirachtin A, components and metabolite for PEC_{gw} calculations

Compound	Azadirachtin A	Azadirachtin H	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	720.7	687.7	EFSA Journal 2018;16(4):5234 EFSA Journal 2011;9(3):1858 Addendum 08 (confirmatory data) to the Additional Report of azadirachtin,
Water solubility (mg/L):	2900 @ 20°C	1000 (default)	
Saturated vapour pressure (Pa):	1.90×10^{-20} (25°C) 9.88×10^{-21} (20ºC)*	0 (default at 20ºC)	
DT_{50} in soil (d)	4.0 (geomean, normalisation to 10	12.4 (geomean, normalisation to 10	

Compound	**Azadirachtin A**	**Azadirachtin H**	**Value in accordance with EU endpoint y/n/ Reference***
	kPa or pF2, 20 °C with Q_{10} of 2.58, n = 10)	kPa or pF2, 20 °C with Q_{10} of 2.58, n = 3)	2017 Azatin EC dRR from Poland and The Netherlands 2014 and 2015 respectively
K_{foc} / K_{fom} (mL/g)/	82.01 / 47.57(geomean, n = 7)	41.03 / 23.8 (geomean, n = 3)	
1/n	0.92 (arithmetic mean, n = 7)	0.982 (arithmetic mean, n = 3)	
Plant uptake factor	0		
Formation fraction	-	0.85 from Azadiractin A	

Table 8.8-4: PEC$_{gw}$ for Azadirachtin A and its metabolites on Tomato (with FOCUS PEARL v4.4.4/PELMO v5.5.3)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**			
		Azadirachtin A		**Azadirachtin H**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Tomato	Châteaudun	< 0.001	< 0.001	0.009	0.005
	Piacenza	< 0.001	< 0.001	0.003	0.007
	Porto	< 0.001	< 0.001	0.001	0.002
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	0.001	< 0.001

Table 8.8-5: PEC$_{gw}$ for Azadirachtin A and its metabolites on Potato (with FOCUS PEARL v4.4.4/PELMO v5.5.3)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**			
		Azadirachtin A		**Azadirachtin H**	
		PEARL	**PELMO**	**PEARL**	**PELMO**
Potato	Châteaudun	< 0.001	< 0.001	0.008	< 0.001
	Hamburg	< 0.001	< 0.001	0.028	0.008
	Jokioinen	< 0.001	< 0.001	0.016	0.008
	Kremsmünster	< 0.001	< 0.001	0.016	0.003
	Okehampton	< 0.001	< 0.001	0.023	0.004
	Piacenza	< 0.001	< 0.001	0.005	< 0.001
	Porto	< 0.001	< 0.001	0.002	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001

	Thiva	< 0.001	< 0.001	0.001	< 0.001

Table 8.8-6: PEC$_{gw}$ for Azadirachtin A and its metabolites on Vines (with FOCUS PEARL v4.4.4/PELMO v5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Azadirachtin A		Azadirachtin H	
		PEARL	PELMO	PEARL	PELMO
Vines	Châteaudun	< 0.001	< 0.001	0.010	0.015
	Hamburg	< 0.001	< 0.001	0.019	0.020
	Kremsmünster	< 0.001	< 0.001	0.011	0.021
	Piacenza	< 0.001	< 0.001	0.005	0.017
	Porto	< 0.001	< 0.001	0.002	0.006
	Sevilla	< 0.001	< 0.001	0.003	0.002
	Thiva	< 0.001	< 0.001	< 0.001	0.002

Table 8.8-5: PEC$_{gw}$ for Azadirachtin A and its metabolites on Onions (with FOCUS PEARL v4.4.4/PELMO v5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Azadirachtin A		Azadirachtin H	
		PEARL	PELMO	PEARL	PELMO
Onion	Châteaudun	< 0.001	< 0.001	0.004	0.004
	Hamburg	< 0.001	< 0.001	0.034	0.031
	Jokioinen	< 0.001	< 0.001	0.016	0.019
	Kremsmünster	< 0.001	< 0.001	0.017	0.016
	Porto	< 0.001	< 0.001	0.002	0.006
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001

Conclusion

The PECgw of Azadirachtin and its metabolite Azadirachtin H values were below 0.1 µg/L for all scenarios and crops. Therefore, use of AZA doesn’t pose an unacceptable risk for ground water and the relevance assessment of the metabolites is not necessary.

zRMS comments

Generally, the evaluator agrees with the groundwater modeling carried out by Applicant.
The input parameters used in calculation was established in the EU review of EFSA Journal 2018;16(4):5234 and Addendum 08 (confirmatory data) to the Additional Report of azadirachtin, 2017.
Interception has been appropriate to the proposed BBCH of crops (EFSA guidance was published, (2014;12(5):3662).
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT_{50} a values were used in modelling.

The PECgw of azadirachtin and its metabolite azadirachtin H values were below 0.1 µg/L for all scenarios and crops.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

8.9 Predicted Environmental Concentrations in surface water (PEC_{SW}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.9.2 Active substance, relevant metabolites and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	AZA			
Use No.	1	2	3	
Crop	Tomato	Potato	Ornamentals	
			Vines late application*	Onions (bulb vegetables**)
Application rate (kg as/ha)	Azadirachtin A: 0.03	Azadirachtin A: 0.025	Azadirachtin A: 0.03	
Number of applications/interval (d)	2/7			
Application window	Mar-May (relevant for STEP 1 and 2 only, minimal cover)			
Application method	Foliar spray			
CAM (Chemical application method)	CAM 2			
Soil depth (cm)	4 cm			
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v 5.0.0			

*** Worst case for surrogate crop for bushed ornamentals**
**** Surrogate crop for herbaceous and ornamental flowers**

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of AZA

Scenario	Application window used in modelling*			
	Tomato	Potato	Ornamentals	
			Vines late application (BBCH 12)	Bulb vegetables
D3	15/05**	15/05	18/04***	09/05
D4	28/05**	28/05	23/04***	09/05
D6 1st	14/04	13/04	08/02	21/05

Scenario	Application window used in modelling*			
D6 2nd	-	09/08	-	18/11
R1	09/05**	09/05	21/04	04/05
R2	22/03	20/03	25/03	16/03
R3	14/05	13/04	10/04	17/03
R4	24/04	-	20/03	17/03

***First application according to AppDate v3.06 (28th June 2019)**
****Dates for Potato as surrogate crop**
*****Dates for Apple as surrogate at BBCH 11 since there are no dates for BBCH 12**

8.9.2.1 Azadirachtin A and its metabolites

Only metabolite Azadirachtin H has been evaluated since the Kfoc values for the rest of metabolites are tentative.

For Ornamentals onions and vines for herbaceous and bushed crops respectively have been chosen as surrogate crops. For vines, the calculations have ben carried out taken the late application but using the dates at BBCH 12 as worst case. For Polish relevant scenarios D3 and D4 Apple as surrogate crop instead of vines has been used. The calculations were done setting the application to soil incorporation and finally the drift was change manually and was set for vines at late application.

Table 8.9-3: Input parameters related to active substance Azadirachtin A for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Azadirachtin A	Azadirachtin H*	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	720.7	687.7	EFSA Journal 2018;16(4):5234 EFSA Journal 2011;9(3):1858 Addendum 08 (confirmatory data) to the Additional Report of azadirachtin, 2017 Azatin EC dRR from Poland and The Netherlands 2014 and 2015 respectively
Saturated vapour pressure (Pa)	1.9×10^{-20} at 25°C	Not required for Steps 1+2	
Water solubility (mg/L)	2900 at 20°C	1000 (default)	
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	Not required for Steps 1+2	
Diffusion coefficient in air (m²/d)	0.43		
K_{foc} (mL/g)	82.01 (geomean, n = 7)	41.03 (geomean, n=3)	
Freundlich Exponent 1/n	0.92 (arithmetic mean, n = 7)	Not required for Steps 1+2	
Plant Uptake	0		
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)		
$DT_{50,soil}$ (d)	4.0 (geomean, n=10, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	12.4 d (geomean, n=3, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	
$DT_{50,water}$ (d)	13.7 (n=1, fisrt order; 20°C)	1000 (default)	
$DT_{50,sed}$ (d)	1000 (default)		
$DT_{50,whole\ system}$ (d)	13.7 (n=1, fisrt order; 20°C)		
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 85 Water / Sediment: 1×10^{-5}	

Compound	**Azadirachtin A**	**Azadirachtin H***	**Value in accordance to EU endpoint y/n/ Reference**
		(default) Total system: 1 x 10^{-5} (default)	
Formation fraction in soil:	-	0.85	

PEC$_{sw/sed}$

D3 and D4 scenarios for Step 3 in vines were calculated using Apple as surrogate applying manually the drift values for vines late applications.

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC$_{sw}$ and PEC$_{sed}$ for Azadirachtin A following single/multiple applications of AZA to Tomato (fruiting vegetables)

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**21 d- PEC$_{sw,twa}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 1	---	9.29/18.58	Drift	5.71/11.41	7.39/14.79
Step 2					
Southern Europe	March-May	1.56/82.08	Runoff / Erosion	1.00/1.32	1.28/1.69
Northern Europe		0.89/1.20		0.57/0.76	0.72/0.98
Step 3					
D3	ditch	0.157/0.137	Drift	0.009/0.015	0.036/0.040
D4	pond	0.006/0.007	Drift	0.004/0.005	0.006/0.010
D4	stream	0.134/0.115	Drift	0.001/0.001	0.006/0.006
D6	ditch	0.187/0.164	Drift	0.003/0.006	0.023/0.025
R1	pond	0.015/0.043	Runoff / Erosion	0.011/0.028	0.017/0.047
R1	stream	0.244/0.536	Runoff / Erosion	0.011/0.022	0.051/0.146
R2	stream	0.174/0.187	Runoff / Erosion	0.013/0.013	0.042/0.046
R3	stream	0.690/0.690	Runoff / Erosion	0.025/0.028	0.130/0.130
R4	stream	0.894/0.930	Runoff / Erosion	0.037/0.072	0.207/0.248

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC$_{sw}$ and PEC$_{sed}$ for Azadirachtin A following single/multiple applications of AZA to Potato

Scenario FOCUS	**Waterbody**	**Max PEC$_{sw}$ (µg/L)**	**Dominant entry route**	**21 d- PEC$_{sw,twa}$ (µg/L)**	**Max PEC$_{sed}$ (µg/kg)**
Step 1	---	7.74/15.48	Runoff / Erosion	4.75/9.51	6.16/12.32
Step 2					
Southern Europe	March-May	1.45/1.93	Runoff / Erosion	0.93/1.23	1.19/1.57

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Northern Europe		0.82/1.10		0.52/0.70	0.66/0.89
Step 3					
D3	ditch	0.131/0.114	Drift	0.007/0.013	0.030/0.034
D4	pond	0.005/0.006	Drift	0.004/0.004	0.005/0.008
D4	stream	0.112/0.096	Drift	<0.001/<0.001	0.005/0.005
D6 1st	ditch	0.146/0.182	Drift	0.021/0.023	0.057/0.068
D6 2nd	ditch	0.129/0.112	Drift	0.002/0.004	0.015/0.016
R1	pond	0.012/0.035	Runoff / Erosion	0.009/0.024	0.015/0.040
R1	stream	0.202/0.444	Runoff / Erosion	0.009/0.018	0.043/0.122
R2	stream	0.145/0.160	Runoff / Erosion	0.011/0.011	0.036/0.039
R3	stream	0.479/0.479	Runoff / Erosion	0.025/0.026	0.129/0.128

Table 8.9-6: **FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azadirachtin A following single/multiple applications of AZA to Vines late application (worst case for bushed ornamentals)**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	9.82/19.63	Drift	6.00/12.00	7.59/15.18
Step 2					
Sothern Europe	March-May	1.70/2.34	Runoff / Erosion	1.08/1.49	1.38/1.90
Northern Europe		1.16/1.64		0.73/1.04	0.93/1.32
Step 3					
D3	ditch	0.511/0.452	Drift	0.028/0.051	0.111/0.124
D4	pond	0.018/0.022	Drift	0.014/0.016	0.021/0.031
D4	stream	0.447/0.417	Drift	0.001/0.002	0.016/0.025
D6	ditch	0.506/0.458	Drift	0.013/0.060	0.072/0.155
R1	pond	0.018/0.029	Runoff / Erosion	0.014/0.021	0.019/0.033
R1	stream	0.374/0.330	Runoff / Erosion	0.003/0.004	0.030/0.027
R2	stream	0.497/0.439	Runoff / Erosion	0.002/0.003	0.023/0.023
R3	stream	0.529/0.468	Runoff / Erosion	0.027/0.033	0.116/0.115
R4	stream	0.374/0.330	Runoff / Erosion	0.003/0.005	0.030/0.030

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azadirachtin A following single/multiple applications of AZA to Bulb Vegetables (herbaceous ornamentals use)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	9.29/18.58	Drift	5.71/11.41	7.39/14.79
Step 2					
Southern Europe	March-May	1.83/2.43	Runoff / Erosion	1.17/1.55	1.50/1.98
Northern Europe		1.02/1.37		0.65/0.87	0.83/1.12
Step 3					
D3	ditch	0.190/0.166	Drift	0.010/0.019	0.043/0.048
D4	pond	0.007/0.010	Drift	0.005/0.007	0.007/0.011
D4	stream	0.146/0.126	Drift	<0.001/<0.001	0.005/0.004
D6 1st	ditch	0.191/0.170	Drift	0.022/0.051	0.061/0.090
D6 2nd	ditch	0.605/1.565	Drift	0.158/0.331	0.266/0.667
R1	pond	0.016/0.047	Runoff / Erosion	0.012/0.036	0.019/0.051
R1	stream	0.282/0.920	Runoff / Erosion	0.012/0.031	0.055/0.177
R2	stream	0.180/0.191	Runoff / Erosion	0.014/0.014	0.046/0.048
R3	stream	0.176/0.309	Runoff / Erosion	0.004/0.017	0.027/0.084
R4	stream	0.828/1.102	Runoff / Erosion	0.036/0.077	0.190/0.290

FOCUS Step 4

D3 and D4 scenarios for Step 4 in vines were calculated using Apple as surrogate applying manually the drift values for vines late applications from FOCUS Drift Calculator v1.1.

Table 8.9-8: Global maximum PEC_{sw} values for Azadirachtin A, following single/multiple applications of AZA to Tomato (fruiting vegetables) according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Azadirachtin				
Nozzle reduction	Vegetative strip (m)	None	5*	10	15**	20
	No spray buffer (m)	5	5	10	15	20
None	D6 ditch	0.051/0.043	-/-	-/-	-/-	-/-
	R1 stream	0.244/0.536	0.157/0.349	-/0.244	-/0.187	-/0.128
	R2 stream	0.174/0.187	0.113/0.120	-/-	-/-	-/-
	R3 stream	0.690/0.690	0.449/0.449	0.313/0.313	0.240/0.240	0.163/0.163
	R4 stream	0.894/0.930	0.583/0.605	0.407/0.421	0.312/0.323	0.213/0.220

***The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.**
****The values used for reduction in run-off volume and run-off flux was 0.7, and for erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.**

Table 8.9-9: Global maximum PEC_{sw} values for Azadirachtin A, following single/multiple applications of AZA to Potato according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Azadirachtin				
Nozzle reduction	Vegetative strip (m)	None	5*	10	15**	20
	No spray buffer (m)	5	5	10	15	20
None	D6 ditch	-/0.147	-/-	-/-	-/-	-/-
	R1 stream	0.202/0.444	0.131/0.290	-/0.202	-/0.155	-/-
	R3 stream	0.479/0.479	0.313/0.313	0.219/0.219	0.168/0.168	0.115/0.115

***The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.**
****The values used for reduction in run-off volume and run-off flux was 0.7, and for erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.**

Table 8.9-10: Global maximum PEC_{sw} values for Azadirachtin A, following single/multiple applications of AZA to Vines late application (worst case for bushed ornamentals use) according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 Azadirachtin				
Nozzle reduction	Vegetative strip (m)	None		5*	10	15**
	No spray buffer (m)	5	10	5	10	15
None	D3 ditch	0.309/0.272	0.112/0.098	-/-	-/-	-/-
50 %		0.154/0.136	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-
None	D4 stream	0.271/0.253	0.098/0.091	-/-	-/-	-/-
50 %		0.136/0.126	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-
None	D6 ditch	0.307/0.278	0.112/0.103	-/-	-/-	-/-
50 %		0.154/0.141	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-
None	R1 stream	0.272/0.240	0.099/0.086	-/-	-/-	-/-
50 %		0.136/0.120	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-
None	R2 stream	0.362/0.319	0.131/0.115	-/-	-/-	-/-
50 %		0.181/0.159	-/-	-/-	-/-	-/-
75 %		0.091/-	-/-	-/-	-/-	-/-
None	R3 stream	0.412/0.412	0.412/0.412	0.386/0.340	0.186/0.186	0.142/0.142

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Azadirachtin**				
Nozzle reduction	Vegetative strip (m)	None		5*	10	15**
	No spray buffer (m)	5	10	5	10	15
50 %		0.412/0.412	-/-	0.268/0.268	0.186/0.186	-/-
75 %		-/-	-/-	0.268/0.268	-/-	-/-
None	R4 stream	0.273/0.240	0.099/0.086	-/-	-/-	-/-
50 %		0.136/0.120	-/-	-/-	-/-	-/-
75 %		-/-	-/-	-/-	-/-	-/-

***The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.**
****The values used for reduction in run-off volume and run-off flux was 0.7, and for erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.**

Table 8.9-11: Global maximum PEC_{sw} values for Azadirachtin A, following single/multiple applications of AZA to Bulb Vegetables (<u>herbaceous ornamentals)</u> according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Azadirachtin**				
Nozzle reduction	Vegetative strip (m)	None	5*	10	15*	20
	No spray buffer (m)	5	5	10	15	20
None	D3 ditch	0.052/0.043	-/-	-/-	-/-	-/-
	D6 ditch	0.052/0.044	-/-	-/-	-/-	-/-
	D6 ditch	0.605/1.565	-/-	-/-	-/-	-/-
	R1 stream	0.282/0.920	0.173/0.599	0.116/0.417	-/0.320	-/0.218
	R2 stream	0.180/0.191	0.117/0.123	-/-	-/-	-/-
	R3 stream	0.092/0.309	-/0.202	-/0.141	-/-	-/-
	R4 stream	0.828/1.102	0.539/0.719	0.376/0.501	0.288/0.384	0.197/0.262

***The value used for reduction in run-off volume, run-off flux, erosion mass and erosion flux was 0.4, according to the Austrian Environmental Agency AGES.**
****The values used for reduction in run-off volume and run-off flux was 0.7, and for erosion mass and erosion flux was 0.9, according to the Austrian Environmental Agency AGES.**

Metabolites of Azadirachtin

As Southern Europe PECsw values are worst case for parent PECsw and PECsed calculations for metabolite have been done only for this zone.

Table 8.9-12: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Azadirachtin H following single/multiple applications to Tomato (fruiting vegetables)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.69/15.38	Drift	7.63/15.27	3.16/6.31
Step 2					
Southern Europe	March-May	1.84/3.09	Runoff / Erosion	1.83/3.07	0.76/1.27

Table 8.9-13: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Azadirachtin H following single/multiple applications to Potato

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	6.41/12.82	Drift	6.36/12.72	2.63/5.26
Step 2					
Southern Europe	March-May	1.74/2.92	Runoff / Erosion	1.73/2.90	0.71/1.20

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Azadirachtin H following single/multiple applications to Vines late application (worst case for bushed ornamentals use)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.69/15.38	Drift	7.63/15.27	3.16/6.31
Step 2					
Southern Europe	March-May	1.48/2.47	Runoff / Erosion	1.47/2.46	0.61/1.01

Table 8.9-15: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Azadirachtin H following single/multiple applications to Bulb Vegetables (herbaceous ornamentals use)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	7.69/15.38	Drift	7.63/15.27	3.16/6.31
Step 2					
Southern Europe	March-May	2.21/3.71	Runoff / Erosion	2.20/3.68	0.91/1.52

8.9.2.2 $PEC_{sw/sed}$ of AZA

The PEC_{SW} for AZA was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha)}{Water\ depth\,(cm) \times 10}$$

The maximal application of AZA is 2 x 3 L/ha, corresponding to 2 x 2882.4 g/ha (taking into account a density of 0.9608 g/ml) for tomato and ornamentals. The depth of the static water body was assumed to be 30 cm and the drift value was assumed to be equivalent to the intended uses. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-16.

Table 8.9-16: PEC_{sw} for AZA following single/multiple applications to field and vines crops

Crop	Distance (m)	Drift (%)	Max PEC_{sw} (µg/L)
Field crops	1 m	2.77 / 2.38	26.614 / 45.734
Vines late application (as worst case)	3 m	8.02 / 7.23	77.056 / 138.932

zRMS comments

Evaluator agrees with modelling carried out by Applicant.
Predicted concentrations of azadirachtin and its metabolites in surface water were calculated by the Applicant at Steps 1to 3 and 4 on the basis input parameters from EFSA Journal 2018;16(4):5234, EFSA Journal 2011;9(3):1858 and Addendum 08 (confirmatory data) to the Additional Report of azadirachtin, 2017.

The modelling approach according to the Austrian Environmental Agency AGES should be accepted at national level.
Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

PL: The calculations were performed for all relevant scenarios for Polish: D3, D4, R1.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1: Summary of atmospheric degradation and behaviour

Compound	Azadirachtin
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Azadirachtin A: 5.55 x 10^{-4}
Photochemical oxidative degradation in air	DT50 (h): 1.696 hours derived by the Atkinson model (version 1.91) OH (24h) concentration assumed = 0.5 x 10^{6} OH/cm^3
Volatilisation	Vapour pressure (Pa): 3.6 x 10^{-13} Pa (20°C, extrapolation) and 1.9 x 10^{-20} Pa (25°C, calculation) Henry's Law Constant (Pa.m3/mol): 10^{-14} – 10^{-19} Pa m^3 $mole^{-1}$
Metabolites	-

The vapour pressure at 20 °C of the active substance Azadirachtin A is < 10^{-5} Pa. Hence the active substance Azadirachtin A is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Azadirachtin A due to volatilization with subsequent deposition should not be considered.

zRMS comments
Accepted.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCP 8.01	-	2014	Azatin EC dRR Part B 5, Sothern Zone, Core Dossier, zRMs Italy, April 2014. Polish Mutual Recognition.	N	Public
KCP 8.02	Mitsui AgriScience international S.A./N.V.	2015	Azatin EC dRR Part B 5, Central Zone, Core Dossier, zRMs The Netherlands, October 2015	N	Public

Appendix 2 Detailed evaluation of the new Annex II studies

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)