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

NATIONAL ADDENDUM

Poland

Applicant: Sharda Cropchem España S.L.

Submission date: June 2022

MS Finalisation date: **06.2022**

Version history

When	**What**
06.2022	The assessment new PECsw/sed

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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

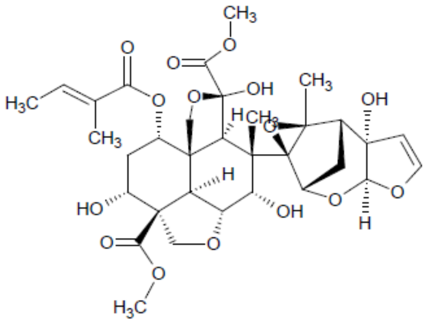
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: 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

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.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%)	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)**	**R²**	**$DissT_{50}$/$DissT_{90}$ 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)**	**R²**	**$DissT_{50}$/$DissT_{90}$ 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)

Please refer to the core dossier.

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

Please refer to the core dossier.

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 and SWAN v5.0.1			

*** 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
R1	09/05**	09/05	21/04	04/05

***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} (default) Total system: 1×10^{-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. Meanwhile, R1 in Fruiting Vegetables has been calculated using Potatoes.

NOTE: The Steps 1, 2 and 3 calculations were already done in the core dossier and for consistency have been reported here but only Polish relevant scenarios.

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
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

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
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
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

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 <u>bushed ornamentals</u>)**

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
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

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

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.

NOTE: The Steps 4 calculations were already done in the core dossier and for consistency have been reported here but only Polish relevant scenarios. Only VFSMOD calculations are new in the Addenda and the calculations will be submitted together.

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	R1 stream	0.244/0.536	0.157/0.349	-/0.244	-/0.187	-/0.128

***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 Tomato (fruiting vegetables) according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Azadirachtin**
Nozzle reduction	Vegetative strip (m)	5
	No spray buffer (m)	5
	R1 stream	-/0.056

Table 8.9-10: 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**
	No spray buffer (m)	5	5	10	15
None	R1 stream	0.202/0.444	0.131/0.290	-/0.202	-/0.155

***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 <u>Potato</u> according to the central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	**Scenario**	**VFSMOD STEP 4 Azadirachtin**
Nozzle reduction	Vegetative strip (m)	5
	No spray buffer (m)	5
	R1 stream	-/0.046

Table 8.9-12: Global maximum PEC_{sw} values for Azadirachtin A, following single/multiple applications of AZA to Vines late application (worst case for <u>bushed ornamentals use</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	
	No spray buffer (m)	5	10
None	D3 ditch	0.309/0.272	0.112/0.098
50 %		0.154/0.136	-/-
None	D4 stream	0.271/0.253	0.098/0.091
50 %		0.136/0.126	-/-
None	R1 stream	0.272/0.240	0.099/0.086
50 %		0.136/0.120	-/-

Table 8.9-13: 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	-/-	-/-	-/-	-/-
	R1 stream	0.282/0.920	0.173/0.599	0.116/0.417	-/0.320	-/0.218

***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 8.9-14: 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 VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Azadirachtin
Nozzle reduction	Vegetative strip (m)	5
	No spray buffer (m)	5
	R1 stream	0.045/0.051

zRMS comments

Evaluator agrees with modelling carried out by Applicant for all relevant scenarios for Polish: D3, D4, R1.
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.
According the Polish harmonization guidance the calculations in step 4w using VFSMOD modelling are acceptable. Therefore the PECsw/sed calculations performed in step 4 by Applicant were accepted .

Metabolites of Azadirachtin

Please refer to the core dossier.

8.9.2.2 $PEC_{sw/sed}$ of AZA

Please refer to the core dossier.

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

Please refer to the core dossier.

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)