FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

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: 07/2021

Version history

When	What
July 2021	ZRMs evaluated dRR submitted by Applicant.

Table of Contents

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 123000 A / AZA*

Product name and code	AZA / SHA 123000 A
Formulation type	Emulsifiable Concentrate [Code: EC]
Active substance(s) (incl. content)	Azadirachtin; 10 g/L
Function	Insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of Azadirachtin 1% EC can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for SHA 123000 A / AZA according to Regulation (EC) No 1272/2008

Hazard class(es), categories	–
Hazard pictograms or Code(s) for hazard pictogram(s)	–
Signal word	–
Hazard statement(s)	–
Precautionary statement(s)	P101, P102
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 123000 A / AZA

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) during mixing/loading and application
Workers	Acceptable	Work wear (arms, body and legs covered)
Residents	Acceptable	None
Bystanders	Acceptable	None

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.
A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	**Crops and situation (e.g. growth stage of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ******	**Application**		**Application rate**		**PHI (d)**	**Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]**	**Acceptability of exposure assessment**			
			Method / Kind (incl. application technique ***)**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**Max. application rate kg as/ha**	**Water L/ha min / max**			**Operator**	**Worker**	**Residents**	**Bystander**
1	Tomato (BBCH 12-85)	F	Spraying, LCTM	2 ; 2	0.03	750-1000	3	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
2	Potato (BBCH 12-91)	F	Spraying, LCTM	2 ; 2	0.025	500-1000	3					
3	Ornamentals (BBCH 12-89)	F	Spraying, LCTM	2 ; 2	0.03	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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

No Data gaps .

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Azadirachtin
Common Name	Azadirachtin (no ISO common name allocated)
CAS-No.	11141-17-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) **ECHA Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of Azadirachta 2018**	Not classified

	Azadirachtin
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d
Reference	EFSA Journal 2018;16(4):5234 and SANCO/10311/2011, 11 March 2011, Rev.2 19 May 2020
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report for Azadirachtin (SANCO/10311/2011 final)	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SHA 123000 A / AZA is given in the following tables.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SHA 123000 A / AZA

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral	> 5000 mg/kg bw	Yes	None	calculated
LD_{50} dermal	> 2000 mg/kg bw	Yes	None	calculated
LC_{50} inhalation	> 5 mg/L air	Yes	None	calculated
Skin irritation	Non-irritant	Yes	None	calculated
Eye irritation	Non-irritant	Yes	None	calculated
Skin sensitisation	Non-sensitising	Yes	None	calculated
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 123000 A / AZA

	Substance (concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Azadirachtin (1% (w/w))	Not classified	Reg. 1272/2008	None
Toxicological properties of non-active substance(s) (relevant for classification of product)	–	–	–	–
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.
** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

No ground water assessment on metabolites is available.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 123000 A / AZA are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 123000 A / AZA

	Azadirachtin	
	Value	**Reference**
Concentrate	70% (default)	EFSA Journal 2017;15(6):4873
Dilution	70% (default)	EFSA Journal 2017;15(6):4873

6.5.1 Justification for proposed values - Azadirachtin

No data on dermal absorption for Azadirachtin in SHA 123000 A / AZA is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Azadirachtin

	Value	**Justification for value**	**Acceptability of justification**
Concentrate	70%	< 5 % of a.s Azadirachtin in formulation	Acceptable
Dilution	70%	Default values (EFSA Journal 2017;15(6):4873) for EC formulation (emulsifiable concentrate)	Acceptable

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	AZA / SHA 123000 A
Formulation type	EC
Category	Insecticide
Active substance(s) (incl. content)	**Azadirachtin** 10 g/L
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 70 % (Default) Dilution: 70 % (Default)

6.6.1 Selection of critical use(s) and justification

The critical GAPs used for the exposure assessment of the plant protection product are shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

No justification is needed since all the intended uses are considered as critical GAPs.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure model used for estimation of operator exposure to the active substances during application of SHA 123000 A / AZA according to the critical uses is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical uses	Tomato (max. 3 L product/ha) Potato (max. 2.5 L product/ha) Ornamentals (max. 3 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Azadirachtin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops **(tomato, use No. 1)**			
Application rate		0.03 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1378	138
	Work wear (arms, body and legs covered) M/L and A	0.0815	**82**
Tractor mounted boom spray application outdoors to low crops **(potato, use No. 2)**			
Application rate		0.025 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.1202	120
	Work wear (arms, body and legs covered) M/L and A	0.0707	**71**
Tractor mounted boom spray application outdoors to low crops **(ornamentals, use No. 3)**			
Application rate		0.03 kg a.s./ha	
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg	Potential exposure	0.0541	**54**
	Work wear (arms, body and legs covered) M/L and A	0.0286	**29**

According to the AOEM model, calculations, it can be concluded that the risk for the operator using AZA is acceptable without PPE only with standard working clothing (long sleeved shirt and trousers) during mixing/loading and application.

6.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 123000 A / AZA according to the critical uses. Outcome of the estimation is presented inTable 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical uses	Tomato (max. 3 L product/ha) Potato (max. 2.5 L product/ha) Ornamentals (max. 3 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-5: Estimated worker exposure (longer term exposure)

		Azadirachtin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tomato, use No. 1 Reaching, picking Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.03 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0902	**90**
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0389	**39**
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	0.0090	**9**
Potato, use No. 2 Inspection, irrigation Outdoor Work rate: 2 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.025 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm²/person/h	0.0405	**40**
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0045	**5**
	Work wear (arms, body and legs covered) and gloves TC: not available	-	-
Ornamentals, use No. 3 Cutting, sorting, bundling, carrying Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.03 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm²/person/h	0.2176	218
	Work wear (arms, body and legs covered) TC: 5000 cm²/person/h	0.0777	**78**
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm²/person/h	0.0218	**22**

It is concluded that there is no unacceptable risk is anticipated for the worker re-entering the treated crops tomato and potato and no unacceptable risk for workers with suitable work wear (arms, body and legs covered) after application on ornamentals.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Not required.

6.6.3.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-6 shows the exposure model used for estimation of resident and bystander exposure to Azadirachtin. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical uses	Tomato (max. 3 L product/ha) Potato (max. 2.5 L product/ha) Ornamentals (max. 3 L product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-7: Estimated resident exposure (longer term exposure)

		Azadirachtin	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops **(tomato, use No. 1)** Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.03 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0007	0.75
	Vapour (75th perc.)	0.0011	1.07
	Deposits (75th perc.)	0.0006	0.61

		Azadirachtin	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
	Re-entry (75th perc.)	0.0066	6.56
	Sum (mean)	0.0072	7.16
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.18
	Vapour (75th perc.)	0.0002	0.23
	Deposits (75th perc.)	0.0003	0.26
	Re-entry (75th perc.)	0.0036	3.64
	Sum (mean)	0.0034	3.41
Tractor mounted boom spray application outdoors to low crops **(potato, use No. 2)** Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.025 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0009	0.94
	Vapour (75th perc.)	0.0011	1.07
	Deposits (75th perc.)	0.0005	0.51
	Re-entry (75th perc.)	0.0055	5.47
	Sum (mean)	0.0063	6.32
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.22
	Vapour (75th perc.)	0.0002	0.23
	Deposits (75th perc.)	0.0002	0.22
	Re-entry (75th perc.)	0.0030	3.04
	Sum (mean)	0.0029	**2.92**
Tractor mounted boom spray application outdoors to low crops **(ornamentals, use No. 3)** Buffer zone: 2-3(m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		2 × 0.03 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.0007	0.75
	Vapour (75th perc.)	0.0011	1.07
	Deposits (75th perc.)	0.0006	0.61
	Re-entry (75th perc.)	0.0066	6.56
	Sum (mean)	0.0072	7.16
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.0002	0.18
	Vapour (75th perc.)	0.0002	0.23
	Deposits (75th perc.)	0.0003	0.26
	Re-entry (75th perc.)	0.0036	3.64
	Sum (mean)	0.0034	**3.41**

The performed exposure (longer term) estimation bystander / resident (child & adult) is acceptable under the conditions of the intended use of SHA 123000 A / AZA and bufor zone 2-3 m

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Azadirachtin will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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
-	-	-	-	-	-

The following tables are to be completed by MS

List of data submitted by the applicant and not 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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	N/A

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	**The product does not contain any coformulant which would be classified oral toxically so SHA 123000 A / AZA was estimated to be 8680 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified**

Acute toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the coformulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any coformulant which would be classified oral toxically so SHA 123000 A / AZA was estimated to be over 2000 mg/kg.

Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	**The product does not contain any coformulant which would be classified dermal toxically so SHA 123000 A / AZA was estimated to be over 2000 mg/kg.** **Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified**

Acute toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the coformulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any coformulant which would be classified dermal toxically so SHA 123000 A / AZA was estimated to be over 2000 mg/kg.

Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	**The product does not contain any coformulant which would be classified inhalation toxically so SHA 123000 A / AZA was estimated to be over 5 mg/L.** **Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified.**

Acute toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any coformulant which would be classified inhalation toxically so SHA 123000 A / AZA was estimated to be over 5 mg/L.

Therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	**The product does not contain any co-formulant which would be classified as skin irritant (H315), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified**

Toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any co-formulant which would be classified as skin irritant (H315), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	**The product does not contain any co-formulant which would be classified as eye irritant (H319), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified**

Toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any co-formulant which would be classified as eye irritant (H319), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	**The product does not contain any co-formulant which would be classified as skin sensitizer (H317), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is not classified**

Toxicity studies for SHA 123000 A / AZA were **not** evaluated as part of the EU review of a Azadirachtin. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of SHA 123000 A / AZA can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product does not contain any co-formulant which would be classified as skin sensitizer (H317), therefore, according to the Regulation EC No. 1272/2008, SHA 123000 A / AZA is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

Not relevant.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 25 % (concentrate) and 70% (diluted) of may be applied for products that are organic solvent-based [(a)] or other [(b)]

[(a)] Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil-based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).

[(b)] Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesticide (PS), experimental solution of active substances in solvent (AI).

Considering < 5 % of a.s Azadirachtin in formulation, dermal absorption value of 70% (concentrate) and 70% (diluted) are used for exposure calculations.

A 2.11 Other/Special Studies

No further data submitted in the framework of this application.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Azadirachtin

Table A 1: Input parameters and estimation of longer term operator exposure towards azadirachtin considered for the estimation of operator exposure on tomato (use No. 1)

Operator exposure for Azadirachtin 1% EC outdoor spray applications

Application rate of active substance	0.03	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	1.5	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	70.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	6636	24403	AOEM	
	Body	4744	81029	AOEM	
	Head	78	427	AOEM	
	Protected hands (gloves)	45	297	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	34	219	AOEM	
	Protected head (hood and face shield)	1	24	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	222	3084	AOEM	
	Body	124	641	AOEM	
	Head	6	18	AOEM	
	Protected hands (gloves)	53	3494	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	3	8	AOEM	
	Inhalation	1	4	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	8.2727404	4.8913488
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1378790	0.0815225
% of RVNAS	137.88%	81.52%

Table A 2: Input parameters and estimation of longer term operator exposure towards azadirachtin considered for the estimation of operator exposure on potato (use No. 2)

Operator exposure for Azadirachtin 1% EC outdoor spray applications

Application rate of active substance	0.025	kg a.s./ha	*i_AppRate*
Assumed area treated	50	ha/day	*d_AreaTreated*
Amount of active substance applied	1.25	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	70.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	5767	21173	AOEM	
	Body	4173	76848	AOEM	
	Head	65	356	AOEM	
	Protected hands (gloves)	40	248	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	29	183	AOEM	
	Protected head (hood and face shield)	1	20	AOEM	
	Inhalation	4	29	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	185	2699	AOEM	
	Body	104	534	AOEM	
	Head	5	15	AOEM	
	Protected hands (gloves)	48	3421	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	3	7	AOEM	
	Inhalation	1	3	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	7.2144409	4.2430243
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.1202407	0.0707171
% of RVNAS	120.24%	70.72%

Table A 3: Input parameters and estimation of longer term operator exposure towards azadirachtin considered for the estimation of operator exposure on ornamentals (use No. 3)

Operator exposure for Azadirachtin 1% EC outdoor spray applications

Application rate of active substance	0.03	kg a.s./ha	*i_AppRate*
Assumed area treated	10	ha/day	*d_AreaTreated*
Amount of active substance applied	0.3	kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	70.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	70.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Season	not relevant		

OutdoorSoluble concentrates, emulsifiable concentrate, etc.Downward sprayingVehicle-mounted

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	1922	6969	AOEM	
	Body	1530	50766	AOEM	
	Head	16	85	AOEM	
	Protected hands (gloves)	16	59	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8	44	AOEM	
	Protected head (hood and face shield)	0	5	AOEM	
	Inhalation	3	28	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	486	1552	AOEM	This scenario assumes that small area equipment is used
	Body	667	845	AOEM	
	Head	4	47	AOEM	
	Protected hands (gloves)	11	19	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	8	10	AOEM	
	Inhalation	3	20	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	3.2431835	1.7166602
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0540531	0.0286110
% of RVNAS	54.05%	28.61%

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Azadirachtin

Table A 4: Input parameters and estimation of longer term worker exposure towards azadirachtin on tomato (use No. 1) according to EFSA guidance

Worker exposure from residues on foliage for Azadirachtin 1% EC		
Crop type	Fruiting vegetables	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Reaching, picking	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.03	kg a.s./ha
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1.9	
Dermal absorption of the product	70.00%	
Dermal absorption of the in-use dilution	70.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.09	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	5800	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	2500	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	580	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5.4098702	2.3318406	0.5409870
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0901645	0.0388640	0.0090165
% of RVNAS	90.16%	38.86%	9.02%

Table A 5: Input parameters and estimation of longer term worker exposure towards azadirachtin on potato (use No. 2) according to EFSA guidance

Worker exposure from residues on foliage for Azadirachtin 1% EC		
Crop type	Root and tuber vegetables	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Inspection, irrigation	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.025	kg a.s./ha
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1.9	
Dermal absorption of the product	70.00%	
Dermal absorption of the in-use dilution	70.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.075	µg a.s./cm^2
Working hours	2	hr
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	2.4290006	0.2720481	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0404833	0.0045341	
% of RVNAS	40.48%	4.53%	

Table A 6: Input parameters and estimation of longer term worker exposure towards azadirachtin on ornamentals (use No. 3) according to EFSA guidance

Worker exposure from residues on foliage for Azadirachtin 1% EC		
Crop type	Ornamentals	
Indoor or outdoor	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Worker's task	Cutting, sorting, bundling, carrying	
Main body parts in contact with foliage	Hand and body	
Application rate of active substance	0.03	kg a.s./ha
Number of applications	2	
Interval between multiple applications	7	days
Half-life of active substance	30	days
Multiple application factor	1.9	
Dermal absorption of the product	70.00%	
Dermal absorption of the in-use dilution	70.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.09	µg a.s./cm^2
Working hours	8	hr
Dermal transfer coefficient - Total potential exposure	14000	cm^2/hr
Dermal transfer coefficient - arms, body and legs covered	5000	cm^2/hr
Dermal transfer coefficient - hands, arms, body and legs covered	1400	cm^2/hr
Inhalation transfer coefficient for automated applications	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10^(-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10^(-3)

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	13.0583075	4.6636812	1.3058307
Total systemic exposure per kg body weight (mg/kg bw/day)	0.2176385	0.0777280	0.0217638
% of RVNAS	217.64%	77.73%	21.76%

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Azadirachtin

Table A 7: Input parameters considered for the estimation of longer term resident exposure on tomato (use No. 1)

Resident exposure for Azadirachtin 1% EC		
Croptype	Fruiting vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0.03	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.04	g a.s./l
Dermal absorption of product	70.00%	
Dermal absorption of in-use dilution	70.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.09	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0.25	hours
Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m^3/day/kg
Breathing rate child (1-3 year old)	1.07	m^3/day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 8: Estimation of longer term resident exposure towards Azadirachtin according to EFSA guidance on tomato (use No. 1)

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0075167	0.0107000	0.0061094	0.0655830	0.0716041
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007517	0.0010700	0.0006109	0.0065583	0.0071604
% of RVNAS	0.75%	1.07%	0.61%	6.56%	7.16%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0107952	0.0138000	0.0158876	0.2186101	0.2048649
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0001799	0.0002300	0.0002648	0.0036435	0.0034144
% of RVNAS	0.18%	0.23%	0.26%	3.64%	3.41%

Table A 9: Input parameters considered for the estimation of longer term resident exposure on potato (use No. 2)

Resident exposure for Azadirachtin 1% EC		
Croptype	Root and tuber vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0.025	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.05	g a.s./l
Dermal absorption of product	70.00%	
Dermal absorption of in-use dilution	70.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.075	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0.25	hours
Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m^3/day/kg
Breathing rate child (1-3 year old)	1.07	m^3/day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 10: Estimation of longer term resident exposure towards Azadirachtin according to EFSA guidance on potato (use No. 2)

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0093959	0.0107000	0.0050912	0.0546525	0.0631782
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0009396	0.0010700	0.0005091	0.0054653	0.0063178
% of RVNAS	0.94%	1.07%	0.51%	5.47%	6.32%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0134940	0.0138000	0.0132397	0.1821750	0.1751573
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0002249	0.0002300	0.0002207	0.0030363	0.0029193
% of RVNAS	0.22%	0.23%	0.22%	3.04%	2.92%

Table A 11: Input parameters considered for the estimation of longer term resident exposure on ornamentals (use No. 3)

Resident exposure for Azadirachtin 1% EC		
Croptype	Ornamentals	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.	
Buffer strip	2-3	m
Application rate of the product	0.03	kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0.04	g a.s./l
Dermal absorption of product	70.00%	
Dermal absorption of in-use dilution	70.00%	
Oral absorption	100.00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.09	µg a.s./cm^2
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa
Concentration in air	0.001	mg/m^3
Resident dermal spray drift exposure 75th percentile - adult	0.47	ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0.327	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0.00010	ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0.00022	ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0.22318	ml spray dilution/person
Resident dermal spray drift exposure mean - child	0.18	ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0.00009	ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0.00017	ml spray dilution/person
Exposure duration dermal	2	hours
Exposure duration inhalation	24	hours
Exposure duration entry into treated crops	0.25	hours
Light clothing adjustment factor	18.0%	
Breathing rate adult	0.23	m^3/day/kg
Breathing rate child (1-3 year old)	1.07	m^3/day/kg
Drift percentage on surface (75th percentile)	5.60%	
Drift percentage on surface (mean)	4.10%	
Turf transferable residues percentage	5.00%	
Transfer coeff. of surface deposits-adult	7300	cm^2/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm^2/hour
Saliva extraction percentage	50.00%	
Surface area of hands mouthed	20	cm^2
Frequency of hand to mouth activity	9.5	events/hour
Ingestion rate for mouthing of grass per day	25	cm^2
Dislodgeable residues percentage transferability for object to mouth	20.00%	
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500	cm^2/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250	cm^2/h
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm^2/h
Transfer coefficient for entry into treated crops (mean) - child	1794	cm^2/h

Table A 12: Estimation of longer term resident exposure towards Azadirachtin according to EFSA guidance on ornamentals (use No. 3)

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0075167	0.0107000	0.0061094	0.0655830	0.0716041
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0007517	0.0010700	0.0006109	0.0065583	0.0071604
% of RVNAS	0.75%	1.07%	0.61%	6.56%	7.16%

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0107952	0.0138000	0.0158876	0.2186101	0.2048649
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0001799	0.0002300	0.0002648	0.0036435	0.0034144
% of RVNAS	0.18%	0.23%	0.26%	3.64%	3.41%

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.