

REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: GLOB1811F

Product name: RASPUT

Chemical active substance:

Boscalid, 500 g/kg

Poland – Art. 33

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: June 2021

MS Finalisation date: 18/03/2022

Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period

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6 Mammalian Toxicology (KCP 7)

Review Comments:

This application was submitted by Globachem NV for approval of Rasput (GLOB1811F) a water dispersible granule (WG) containing 500 g/kg boscalid for use as a fungicide in oilseed rape in Poland.

Boscalid was included on Annex I of Directive 91/414/EEC on 1 of August 2008 under Inclusion Directive 2008/44/EC.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.


6.1 Summary

Table 6.1-1: Information on GLOB1811F *

Product name and code	GLOB1811F / RASPUT
Formulation type	Water dispersible granule [Code: WG]
Active substance(s) (incl. content)	Boscalid; 500 g/kg
Function	Fungicide
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 GLOB1811F can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

Hazard classes, categories	1A
Hazard pictograms or Code(s) for hazard pictogram(s)	
Signal word	Warning
Hazard statement(s)	H317 May cause an allergic skin reaction
Precautionary statement(s)	P272, P280, P333 + P313, P363
Additional labelling phrases	Contains 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one. May produce an allergic reaction. [EUH208] To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, GLOB1811F does not warrant classification for human health.

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GLOB1811F

	Result	PPE / Risk mitigation measures
Operators	Acceptable	No PPE required Work wear (arms, body and legs covered) is recommended during M/L and A
Workers	Acceptable	No PPE required Work wear (arms, body and legs covered) is recommended during M/L and A
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. safen- er/synergist (L/ha)) critical gap for operator, work- er, resident or bystander expo- sure based on [Exposure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion tech- nique ***	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	Max. appli- cation rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1,2	Oilseed rape (Winter & Spring) BBCH 55-69	F	Foliar Spray	2 (14d)	0.25	100- 400	-	Maximum 2 applications of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A	A	A	A
3	Oilseed rape (Winter & Spring) BBCH 20-59	F	Foliar Spray	2 (14d)	0.25	100- 400	-	Maximum 2 applications of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A	A	A	A

* 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.

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)

	Boscalid
Common Name	Boscalid
CAS-No.	188425-85-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Not classified
Additional C&L proposal	Contains 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one. May produce an allergic reaction. [EUH208] To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
Agreed EU endpoints	
AOEL systemic	0.1 mg/kg bw/d (corrected for 44% oral absorption)
Reference	EFSA, 2008
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report for Boscalid	None

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GLOB1811F is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB1811F

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	Study not necessary	Yes No / Supplementary	None	Theoretical calculations (see part C)
LD ₅₀ dermal, rat	Study not	Yes No /	None	Theoretical

	necessary	Supplementary		calculations (see part C)
LC ₅₀ inhalation, rat	Study not necessary	Yes /No/ Supplementary	None	Theoretical calculations (see part C)
Skin irritation	Study not necessary	Yes /No/ Supplementary	None	Theoretical calculations (see part C)
Eye irritation	Study not necessary	Yes /No/ Supplementary	None	Theoretical calculations (see part C)
Skin sensitisation	Study not necessary	Yes /No/ Supplementary	None	Theoretical calculations (see part C)
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GLOB1811F

	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 non-active substance(s) (relevant for classification of product)	5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-4-isothiazolin-3-one*	Skin Sens. 1A	MSDS**	Classification not warranted (content in PPP < SCL) May produce an allergic reaction. [EUH208] Elicitation not warranted (content in PPP < 0.1 x SCL)
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS. in Part C

** Material safety data sheet by the applicant

The justification for not classifying of GLOB1811F can be found in part C, Point 3.1.

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substance Boscalid in GLOB1811F are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GLOB1811F

	Boscalid	
	Value	Reference
Concentrate	10%	EFSA Journal 2017; 15(6):4873
Dilution	50%	EFSA Journal 2017; 15(6):4873

6.5.1 Justification for proposed values - Boscalid

No data on dermal absorption for Boscalid in GLOB1811F 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 Boscalid

	Value	Justification for value	Acceptability of justification
Concentrate	10%	EFSA Journal 2017; 15(6):4873 Dependent of the amount of active substance in the formulation, if it surpasses a threshold value and on the formulation type.	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption: a default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed(c) or solid-formulated(d).
Dilution	50%	EFSA Journal 2017; 15(6):4873	According to EFSA Journal 2017;15(6):4873 Guidance on Dermal Absorption: a default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed(c) or solid-formulated(d).

(c): Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (=SC).

(d): Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

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	GLOB1811F
Formulation type	WG
Category	Fungicide
Active substance(s) (incl. content)	Boscalid 500 g a.s./kg PPP
AOEL systemic	0.1 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	44%
Dermal absorption	Concentrate: 10% Dilution: 50% (default values based on EFSA Journal 2017; 15(6):4873 guidelines)

6.6.1 Selection of critical use(s) and justification

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

Justification

There is only one intended use.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of GLOB1811F according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Oilseeds – max. 0.5 kg PPP/ha (max. 0.25 kg a.s./ha)
Model(s)	AOEM model based on 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)

		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors			
Application rate		2 x 0.25 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential	lt: 0.0534	53.4
		<u>acute: 0.3041</u>	-
	Work wear (arms, body and legs covered)	lt: 0.0332	33.2
		<u>acute: 0.2057</u>	-

The evaluator agrees with the risk assessment provided by the applicant on outdoor operator exposure for application to oilseed rape indicated as critical uses in Table 6.6-2. According to EFSA AOEM calculations, it can be concluded that the risk of operator exposure during mixing & loading and tractor-mounted application on field for oilseed rape is acceptable under conditions of intended uses and also without PPE. However, the use of work wear during mixing/loading and application is recommended (% of systemic AOEL = 33.2). No risk assessment for acute exposure is foreseen since no AAOELs were set.

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(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB1811F according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Oilseeds (max. 2 x 0.25 kg a.s./ha)
Model	AOEM model based on 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)

		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.25 kg a.s./ha	
Body weight: 60 kg	Potential	0.2693	269.3%
	Work wear (arms, body and legs covered)	0.0302	30.2%
	Work wear (arms, body and legs covered) + gloves	-	-

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Refinement of the generic Dislodgeable Foliar Residues (DFR) was not necessary since the risk to workers was acceptable based on the standard values.

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 mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

The evaluator agrees with estimation of worker exposure after entry into a previously treated area or handling a crop treated with GLOB1811F according to the critical use. However, some refinements are proposed below. According to EFSA AOEM calculations, it can be concluded that the risk of worker exposure during re-entry activities in field on oilseed rape is acceptable when work wear is worn.

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 exposure to Boscalid. The outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Oilseeds (max. 2 x 0.25 kg a.s./ha)
Model	AOEM model based on 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)

		Boscalid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 30days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days			
Number of applications and application rate		2 x 0.25 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0336	33.6
	Vapour (75 th perc.)	0.0011	1.1
	Deposits (75 th perc.)	0.0033	3.3
	Re-entry (75 th perc.)	0.0364	36.4
	Sum (mean)	0.0510	50.1 51.0
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0080	8.0
	Vapour (75 th perc.)	0.0002	0.2
	Deposits (75 th perc.)	0.0015	1.5
	Re-entry (75 th perc.)	0.0202	20.2

	Sum (mean)	0.0212	21.2
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The evaluator agrees with the applicant that exposure assessment for residents also covers bystander exposure, since no AAOEL was set. The risk assessment provided by the applicant considering the resident exposure for application in oilseed rape indicated as critical uses in Table 6.6-2 is appropriate. According to EFSA AOEM calculations, it can be concluded that the risk of long term exposure for resident after in field product application to oilseeds rape is acceptable.

6.6.4.2 Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Boscalid 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

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

Appendix 2 Detailed evaluation of the studies relied upon

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Operator exposure for Boscalid outdoor spray applications					
Application rate of active substance	0.25	kg a.s./ha	I_AppRate		
Assumed area treated	50	ha/day	d_AreaTreated		
Amount of active substance applied	12.5	kg a.s./day	I_AmountAS		
Dermal absorption of the product	10.00%		I_AbsorpProduct		
Dermal absorption of in-use dilution	50.00%		I_AbsorpInuse		
Formulation type	Wettable granules, soluble granules				
Indoor or Outdoor application	Outdoor				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				
Season	not relevant				
Outdoor (Wettable granules, soluble granules) Downward spraying (vehicle-mounted)					
Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	9163	44681	AOEM	
	Body	7290	33474	AOEM	
	Head	81	1119	AOEM	
	Protected hands (gloves)	86	393	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	174	778	AOEM	
	Protected head (hood and face shield)	1	63	AOEM	
	Inhalation	79	276	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		
Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	1854	14573	AOEM	
	Body	1037	5344	AOEM	
	Head	49	148	AOEM	
	Protected hands (gloves)	167	4475	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	28	70	AOEM	
	Inhalation	4	12	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	Yes		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)	3.2060915	1.9904037	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0534349	0.0331734	
% of RVNAS	53.43%	33.17%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	18.2478134	12.3410788	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.3041302	0.2056846	
% of RVAAS	#DELING.DOOR.0!	#DELING.DOOR.0!	

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Worker exposure from residues on foliage for raspud			
Crop type	Oilseeds		
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	0.25 kg a.s./ha	<i>i_AppRate</i>	
Number of applications	2	<i>i_AppNo</i>	
Interval between multiple applications	14 days	<i>i_AppInt</i>	
Half-life of active substance	30 days	<i>d_HalfLifeAS</i>	
Multiple application factor	1.7	<i>d_MAF</i>	
Dermal absorption of the product	10.00%	<i>i_AbsorpProduct</i>	
Dermal absorption of the in-use dilution	50.00%	<i>i_AbsorpInuse</i>	
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.75 µg a.s./cm ²	<i>d_DFR</i>	
Working hours	2 hr	<i>d_WorkHr</i>	
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr	<i>d_DermTcUCV</i>	
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr	<i>d_DermTcCV1</i>	
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment	<i>d_DermTcCV2</i>	
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³	<i>d_InhalTcAut</i>	
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³	<i>d_InhalTcCut</i>	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³	<i>d_InhalTcSort</i>	

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	16.1590746	1.8098163	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.2693179	0.0301636		
% of RVNAS	269.32%	30.16%		

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

Resident exposure for rasput				
Croptype	Oilseeds			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			L_AppEquip
Formulation type	Wettable granules, soluble granules			L_FormVal
Buffer strip	2-3 m			L_Buffer
Application rate of the product	0.25 kg a.s./ha			L_AppRate
Concentration of active substance (in-use dilution for liquid applications)	2.5 g a.s./l			d_ConcAS
Dermal absorption of product	10.00%			L_AbsorpProduct
Dermal absorption of in-use dilution	50.00%			L_AbsorpInuse
Oral absorption	44.00%			L_AbsorpOrallhouse
Dislodgeable foliar residue (L_AppRate*L_DFR)	0.75 µg a.s./cm²			d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10- Pa			L_Volat
Concentration in air	3Pa			d_AirCon
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			d_ReExpDur
Exposure duration inhalation	24 hours			d_ReExpDurInhal
Exposure duration entry into treated crops	0.25 hours			d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%			d_ClothAF
Breathing rate adult	0.23 m³/day/kg			d_BreathRAD
Breathing rate child (1-3 year old)	1.07 m³/day/kg			d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%			
Drift percentage on surface (mean)	4.10%			
Turf transferable residues percentage	5.00%			d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour			d_ReTCAAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour			d_ReTCCCh
Saliva extraction percentage	50.00%			d_SalExt
Surface area of hands mouthed	20 cm²			d_AreahM
Frequency of hand to mouth activity	9.5 events/hour			d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²			d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%			d_DFRP
Transfer coefficient for entry into treated crops (75th percentile) -	7500 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) -	2250 cm²/h			d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h			d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h			d_TcEntryCh

1. Total					
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)	0.3357250	0.0107000	0.0329097	0.3635792	0.5096134
Total systemic exposure per kg body weight (a.s./kg/day)	0.0335725	0.0010700	0.0032910	0.0363579	0.0509613
% of RVNAS	33.57%	1.07%	3.29%	36.36%	50.96%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.4820000	0.0138000	0.0880777	1.2119306	1.2735826
Total systemic exposure per kg body weight (a.s./kg/day)	0.0080333	0.0002300	0.0014680	0.0201988	0.0212264
% of RVNAS	8.03%	0.23%	1.47%	20.20%	21.23%

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.