

# FINAL REGISTRATION REPORT

## Part B

### Section 6

#### Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 7273 A

Product name(s): CASINO ROYALE

Chemical active substances:

Boscalid, 267 g/kg

Pyraclostrobin, 67 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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When	What
February 2021	Updated by Applicant
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January 2022	Final Registration Report after the commenting period

## Table of Contents

<b>6</b>	<b>Mammalian Toxicology (KCP 7) .....</b>	<b>5</b>
6.1	Summary .....	5
6.2	Toxicological Information on Active Substance(s) .....	8
6.3	Toxicological Evaluation of Plant Protection Product.....	9
6.4	Toxicological Evaluation of Groundwater Metabolites.....	10
6.5	Dermal Absorption (KCP 7.3) .....	10
6.5.1	Justification for proposed values – Pyraclostrobin .....	10
6.5.2	Justification for proposed values – Boscalid .....	11
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	11
6.6.1	Selection of critical use(s) and justification.....	12
6.6.2	Operator exposure (KCP 7.2.1) .....	12
6.6.2.1	Estimation of operator exposure .....	12
6.6.2.2	Measurement of operator exposure.....	15
6.6.3	Worker exposure (KCP 7.2.3) .....	15
6.6.3.1	Estimation of worker exposure .....	15
6.6.3.2	Refinement of generic DFR value (KCP 7.2).....	20
6.6.3.3	Measurement of worker exposure.....	23
6.6.4	Resident and bystander exposure (KCP 7.2.2) .....	23
6.6.4.1	Estimation of resident and bystander exposure .....	23
6.6.4.2	Measurement of resident and/or bystander exposure.....	25
6.6.5	Combined exposure .....	26
6.6.5.1	Exposure assessment of pyraclostrobin and boscalid in .....	26
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>32</b>
<b>Appendix 2</b>	<b>Detailed evaluation of the studies relied upon.....</b>	<b>34</b>
A 2.1	Statement on bridging possibilities.....	34
A 2.2	Acute oral toxicity (KCP 7.1.1) .....	34
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2) .....	34
A 2.4	Acute inhalation toxicity (KCP 7.1.3) .....	34
A 2.5	Skin irritation (KCP 7.1.4).....	35
A 2.6	Eye irritation (KCP 7.1.5) .....	35
A 2.7	Skin sensitisation (KCP 7.1.6).....	36
A 2.8	Supplementary studies for combinations of plant protection products (KCP 7.1.7) .....	36
A 2.9	Data on co-formulants (KCP 7.4) .....	36
A 2.9.1	Material safety data sheet for each co-formulant.....	36
A 2.9.2	Available toxicological data for each co-formulant.....	36
A 2.10	Studies on dermal absorption (KCP 7.3) .....	36
A 2.11	Other/Special Studies .....	39

<b>Appendix 3</b>	<b>Exposure calculations .....</b>	<b>40</b>
A 3.1	Operator exposure calculations (KCP 7.2.1.1) .....	40
A 3.1.1	Calculations for Pyraclostrobin.....	40
A 3.1.2	Calculations for Boscalid .....	40
A 3.2	Worker exposure calculations (KCP 7.2.3.1) .....	46
A 3.2.1	Calculations for Pyraclostrobin.....	52
A 3.2.2	Calculations for Boscalid .....	52
A 3.3	Resident and bystander exposure calculations (KCP 7.2.2.1) .....	57
A 3.3.1	Calculations for Pyraclostrobin.....	61
A 3.3.2	Calculations for Boscalid .....	64
<b>Appendix 4</b>	<b>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) .....</b>	<b>67</b>

## 6 Mammalian Toxicology (KCP 7)

### 6.1 Summary

**Table 6.1-1: Information on CASINO ROYALE\***

Product name and code	CASINO ROYALE / SHA 7273 A, Pyraclostrobin 6.7% + Boscalid 26.7% WG
Formulation type	Water dispersible granules [Code: WG]
Active substance(s) (incl. content)	Boscalid; 267 g/kg Pyraclostrobin; 67 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 CASINO ROYALE 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 CASINO ROYALE according to Regulation (EC) No 1272/2008**

Hazard class(es), categories	<del>Not classified</del> Eye Irrit. 2
Hazard pictograms or Code(s) for hazard pictogram(s)	<del>None</del> GHS07
Signal word	<del>None</del> Warning
Hazard statement(s)	<del>None</del> H319: Causes serious eye irritation.
Precautionary statement(s)	<p>WARNING SECTION OF THE LABEL (first page):</p> <p>P280: Wear eye protection/face protection.</p> <p>P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Other section of the label:</p> <p>P270 – Do not eat, drink or smoke when using this product.</p> <p>P264 – Wash hands thoroughly after handling.</p> <p>And P280 as follows:</p> <p>OPERATOR:</p> <p>„Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed</p> <p>1/ In case of uses in <b>sugarbeets, tomatos, strawberries, ornamentals</b>:</p> <p>“Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą czasie wykonywania zabiegu. W przypadku oprysku pomidorów w szklarniach stosować dodatkowo ochronę dróg oddechowych (min. maska FFP2).”</p> <p>“Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and work wear during application. Use additional respiratory protection (minimum FFP2 mask) when spraying tomatoes in greenhouses”</p> <p>2/ In case of use in <b>cherries</b>:</p> <p>“Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”</p> <p>“Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application.</p> <p>WORKER:</p> <p>„Stosować rękawice ochronne i odzież roboczą (koszula z długim rękawem i długie spodnie) oraz nie wchodzić na teren poddany zabiegowi wcześniej niż:</p> <ul style="list-style-type: none"> <li>• po wyschnięciu preparatu na powierzchni roślin w przypadku uprawy: buraka cukrowego, marchwi, buraka, selera, pasternaku, pietruszki naciowej, rzod-kwi, chrzanu, brukwi, rzepy, korzenia cykorii, cebuli szalotki, topinamburu, salsefii, pomidora, cebuli, kapusty, bakłażana;</li> <li>• 2 dni po wykonaniu oprysku w przypadku uprawy: truskawki, maliny, porzeczki;</li> <li>• 2 dni po wykonaniu oprysku w przypadku uprawy: pomidor (szklarnia);</li> <li>• 6 dni po wykonaniu oprysku w przypadku uprawy: roślin ozdobnych;</li> <li>• 7 dni po wykonaniu oprysku w przypadku uprawy wiśni.</li> </ul> <p>Wear protective gloves, work wear (covered arms, body and legs) and do not enter the area treated with SHA 7273A:</p> <ul style="list-style-type: none"> <li>• until spray deposit on plant surfaces has dried in sugerbeet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes/rutabagas, turnip, chicory roots, shallot, Jerusalem artichokes, salsifies, tomato, onion, cabbage, aubergines/eggplants;</li> <li>• for 2 days in raspberry, blackcurrant, redcurrant, white currant;</li> </ul>

	<ul style="list-style-type: none"> <li>for 2 days in tomato (indoor);</li> <li>for 6 days in ornamentals;</li> <li>for 7 days in cherries.</li> </ul> <p>Section “First Aid”:</p> <p>P101: If medical advice is needed, have product container or label at hand.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313: If eye irritation persists: Get medical advice/ attention.</p>
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 CASINO ROYALE**

	Result	PPE / Risk mitigation measures
Operators	Acceptable	<p>Classification: eye/face protection.</p> <p>Exposure:</p> <p>Work wear (arms, body and legs covered) M/L, gloves are recommended – sugarbeet, tomato, strawberry, ornamentals</p> <p>Work wear (arms, body and legs covered) M/L+gloves M/L and A – cherry</p> <p>Work wear (arms, body and legs covered) M/L, gloves are recommended – greenhouses</p>
Workers	Acceptable	<p>Work wear (arms, body and legs covered) – sugarbeet</p> <p>Work wear (arms, body and legs covered) and gloves – tomato</p> <p>Work wear (arms, body and legs covered) and gloves and Re-entry period of 2 days – starwberry</p> <p>Work wear (arms, body and legs covered)– ornamentals – indoor and outdoor</p> <p>Work wear (arms, body and legs covered) and gloves – tomato and Re-entry period of 2 days – indoor</p> <p>Work wear (arms, body and legs covered) and gloves and Re-entry period of 15 days – cherry. Bearing in minds that PHI value exceeds the assessed safy re-entry period, the proposed length of re-entry period is 7 days.</p>
Residents & Bystander	Acceptable	None

No unacceptable risk for operator, worker, bystanders and residents 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. appli- cation technique ***)	Max. num- ber (min. interval between applications)  a) per use b) per crop/ season	Max. applica- tion rate kg as/ha  a)Pyraclostrobin b)Boscalid	Water L/ha  min / max			Operator	Worker	Residents	Bystander
1	<b>Sugarbeet</b> (Carrot, Beetroot, Celery root, Parsnip, Parsley, Radish, Horseradish,Swedes/rutabagas, Turnip, Chicory roots, Shallot, Jerusalem artichokes, Salsifies	F	Spraying, LCTM	a) 2 (8-10) b) 2 (8-10)	a) 0.100 b) 0.400	300- 600	14					
2	<b>Tomato</b> (Onion, Cabbage, Auber- gines/eggplants,	F	Spraying, LCTM	a) 3 (8-10) b) 3 (8-10)	a) 0.100 b) 0.400	300- 600	-					
3	<b>Tomato</b> (Aubergines/eggplants)	G	Spraying, LCTM	a) 2(5) b) 2 (5)	a) 0.134 b) 0.534	1000	3					
4	<b>Strawberry,</b> (Raspberry, Blackcurrant, Redcurrant, White currant)	F	Spraying, LCTM	a) 2 (5) b) 2 (5)	a) 0.1206 b) 0.4806	500- 800	3					
5	<b>Ornamentals</b>	F,G	Spraying, LCTM	a) 2 (7) b) 2 (7)	a) 0.0121 b) 0.0481	100	-					
6	<b>Cherry</b>	F	Spraying, HCTM	a) 2 (5) b) 2 (5)	a) 0.067 b) 0.267	500	7					

\* 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"

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

## 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)**

	<b>Pyraclostrobin</b>	<b>Boscalid</b>
Common Name	Pyraclostrobin	Boscalid
CAS-No.	175013-18-0	188425-85-6



	<b>Pyraclostrobin</b>	<b>Boscalid</b>
<b>Classification and proposed labelling</b>		
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes, categories: Skin Irrit. 2, Acute Tox. 3 Codes for hazard pictograms: GHS06, GHS07 Signal word: Danger Hazard statements: H315, H331	Not classified
Additional C&L proposal	-	-
<b>Agreed EU endpoints</b>		
AOEL systemic	0.015 mg/kg bw/d (corrected for 50 % oral absorption)	0.1 mg/kg bw/d (corrected for 44% oral absorption)
Reference	SANCO/1420/2001-Final	SANCO/3919 /2007-rev. 5
<b>Conditions to take into account/critical areas of concern with regard to toxicology</b>		
According to SANCO/1420/2001-Final and SANCO/3919 /2007-rev. 5 for Pyraclostrobin and Boscalid, respectively	None	The operator safety

### 6.3 Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of CASINO ROYALE are derived from the classification of the active compound and co-formulants. When considering the properties of all co-formulants and toxicity study CASINO ROYALE is not classified.

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

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat	-	Yes	None	Estimation based on the composition of the product (additivity formula)
LD <sub>50</sub> dermal, rat	-	Yes	None	Estimation based on the composition of the product (additivity formula)
LC <sub>50</sub> inhalation	> 5mg/L air	Yes	None	Estimation based on the composition of the product (additivity formula)
Skin irritation, rabbits	Not-irritant	Yes	None	Estimation based on the composition of the product (additivity formula)
Eye irritation, rabbits	irritant	Yes	Eye Irrit. 2, H319	Estimation based on the composition of the product (additivity formula)
Skin sensitisation, mouse	Non-sensitising	Yes	None	Estimation based on the composition of the product (additivity formula)
Supplementary studies for	No data – not	-		

combinations of plant protection products	required			
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**Table 6.3-2: Additional toxicological information relevant for classification/labelling of CASINO ROYALE**

	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)	Pyraclostrobin (6.7% (w/w))	H315, H331	Reg. 1272/2008	Not classified
	Boscalid (26.7% (w/w))	None	Reg. 1272/2008	Not classified
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

Comment of ZRMS:	Because the process of the renewal of the approval hasn't been finished yet, the assessment of the toxicological relevance of pyraclostrobin metabolites is still underway, in accordance with EU procedures. However, the PEC <sub>gw</sub> for all metabolites do not exceed the level of 0.1 µg/L.
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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 substances in **SHA 7273 A/ CASINO ROYALE** are presented in the following table.

**Table 6.5-1: Dermal absorption rates for active substances in CASINO ROYALE**

	Pyraclostrobin		Boscalid	
	Value	Reference	Value	Reference
Concentrate	4.6%	<i>In vitro</i> human skin	4.6%	<i>In vitro</i> human skin
Dilution	23%	<i>In vitro</i> human skin	23%	<i>In vitro</i> human skin

### 6.5.1 Justification for proposed values – Pyraclostrobin

Comment of ZRMS	The study presented by the applicant (Ashwinkumar V Meru, 2020) is acceptable. The use of joint measurement result for Pyraclostrobin and Boscalid is assumed to represent the worst case scenario. Consequently, the ZRMS agrees to use the values of 4.6 and 23 % for concentrate and in-use dilution, respectively, for pyraclostrobin.
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Proposed dermal absorption rates for Pyraclostrobin are based on dermal absorption studies on the comparable a formulation SHA 7273 A/ CASINO ROYALE (Pyraclostrobin 6.7% + Boscalid 26.7% WG). The study results are summarised in the following table. Full summaries of studies on the dermal absorption of SHA 7273 A/ CASINO ROYALE (Pyraclostrobin 6.7% + Boscalid 26.7% WG) that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2

**Table 6.5-2: Dermal absorption rates for Pyraclostrobin**

	Value	Justification for value	Acceptability of justification
Concentrate	4.6%	<i>In vitro</i> human skin	yes
Dilution	23%	<i>In vitro</i> human skin	yes

## 6.5.2 Justification for proposed values – Boscalid

Comment of ZRMS	The study presented by the applicant (Ashwinkumar V Meru, 2020) is acceptable. The use of joint measurement result for Pyraclostrobin and Boscalid is assumed to represent the worst case scenario. Consequently, the ZRMS agrees to use the values of 4.6 and 23 % for concentrate and in-use dilution, respectively, for boscalid.
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Proposed dermal absorption rates for Boscalid are based on dermal absorption studies on the comparable a formulation SHA 7273 A/ CASINO ROYALE (Pyraclostrobin 6.7% + Boscalid 26.7% WG). The study results are summarised in the following table. Full summaries of studies on the dermal absorption of SHA 7273 A/ CASINO ROYALE (Pyraclostrobin 6.7% + Boscalid 26.7% WG) that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2

**Table 6.5-3: Dermal absorption rates for Boscalid**

	Value	Justification for value	Acceptability of justification
Concentrate	4.6%	<i>In vitro</i> human skin	Yes
Dilution	23%	<i>In vitro</i> human skin	Yes

## 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	CASINO ROYALE / SHA 7273 A, Pyraclostrobin 6.7% + Boscalid 26.7% WG	
Formulation type	WG	
Category	Fungicide	
Active substance(s) (incl. content)	<b>Pyraclostrobin</b> 67 g/kg	<b>Boscalid</b> 267 g/kg
AOEL systemic	0.015 mg/kg bw/d	0.1 mg/kg bw/d
Inhalation absorption	100%	100%
Oral absorption	100 50%	100 44%
Dermal absorption	Concentrate: 4.6% Dilution: 23%	Concentrate: 4.6% Dilution: 23%

### 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 is given in Part B, Section 0.

#### Justification

The use No 1 on sugarbeet is the one which has the most elevated number of applications (2 applications of 1.5 L product/ha, with 8 days interval).

The use No 2 on tomatoes is the one which has the most elevated number of applications (3 applications of 1.5 L product/ha, with 8 days interval).

The use No 3 on strawberry is the one which has the most elevated number of applications (2 applications of 1.8 L product/ha, with 5 days interval).

### 6.6.2 Operator exposure (KCP 7.2.1)

#### 6.6.2.1 Estimation of operator exposure

Comment of ZRMS	<p>Critical uses of SHA 7273A / Casino Royale have been selected correctly. However, the input parameters used to calculate operator exposure towards pyraclostrobin and boscalid contain wrong oral absorption values which should amount to 50 and 44%, respectively.</p> <p>Nevertheless, the use of new oral absorption values does not change the results of operator exposure significantly. Thus, the estimation presented by the Applicant are accepted.</p> <p><b>Conclusions:</b></p> <p>The results of the estimations presented by the Applicant indicate that the exposure of an <b>unprotected operator</b> (no PPE) to pyraclostrobin and boscalid contained in the product SHA 7273A / Casino Royale does not cause an <b>unacceptable risk</b>, i.e. the values are significantly below the value of AOEL for the active substances, <u>for all intended uses presented in the GAP Table except of the use in cherries</u>.</p> <p>Additionally, the results performed based on Dutch greenhouse model indicate that protective gloves and coverall must be worn to maintain the exposure value below AOEL for the active substances.</p> <p>In case of the use of SHA 7273A / Casino Royale <u>in cherries</u> the <b>acceptable exposure</b> of an operator to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale is expected only if the operator <b>in equipped with work wear and protective gloves during M&amp;L and application</b>.</p> <p>However, taking into account the classification of the product (Eye Irrit. 2, H319), it is recommended to include on the label a note on the need of the use of eye/face protection and protective gloves in all intended uses (in the section regarding the precautions for people using the formulation).</p> <p>Taking into account the information presented above, the following sentence is recommended by the evaluator to be placed in the label:</p> <p>1/ In case of uses in sugarbeets, tomatoes, strawberries ornamentals: "Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz odzież roboczą w czasie wykonywania zabiegu. <b>W przypadku oprysku pomidorów w szklarniach stosować dodatkowo ochronę dróg oddechowych (min. maska FFP2).</b>"</p> <p>"Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and work wear during application. <b>Use additional respiratory protection (minimum FFP2 mask) when spraying tomatoes in greenhouses"</b></p>
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	<p>2/ In case of use in cherries:  <i>“Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.”</i>  <i>“Wear protective gloves, eye/face protection and work wear (coverall) and protective gloves and work wear during application.”</i></p>
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A summary of the exposure models used for estimation of operator exposure to the active substances during application of CASINO ROYALE 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	<p>Sugarbeet (max 2 x 1.5 L product/ha)          Tomatoes (max. 3 x 1.5 L product/ha)          Strawberry (max. 2 x 1.8 L product/ha)          Ornamentals (max. 2 x <b>0.18</b> L product/ha)          Cherry (max. 2 x 1.0 L product/ha)</p>
Model	<p>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          ECPA Greenhouse model</p>

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

		Pyraclostrobin		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (sugarbeet and tomato use)					
Application rate		0.1 kg a.s./ha		0.4 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0119805	80	0.0375892	38
	Work wear (arms, body and legs covered) M/L	0.0075588	50	0.0238310	24
Tractor mounted boom spray application outdoors to low crops (strawberry use)					
Application rate		0.1206 kg a.s./ha		0.4806 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0139268	93	0.0439373	44
	Work wear (arms, body and legs covered) M/L	0.0087843	59	0.0278977	28
Tractor mounted boom spray application outdoors to low crops (ornamentals use)					
Application rate		0.1201 kg a.s./ha		0.4801 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile) Body weight: 60 kg	Without RPE/PPE	0.0207505	138	0.0784057	78
	Work wear (arms, body and legs covered) M/L	0.0095833	64	0.0352079	35
Tractor mounted boom spray application outdoors to high crops (cherry use)					
Application rate		0.067 kg a.s./ha		0.267 kg a.s./ha	
<b>Spray application</b> (AOEM; 75 <sup>th</sup> percentile)	Without RPE/PPE	0.0352438	235	0.1318770	132

75 <sup>th</sup> percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L + gloves M/L and A	0.0047833	32	0.0161464	17
Tomato–Manual Spraying in greenhouses					
Application rate		0.134 kg a.s./ha		0.534 kg a.s./ha	
<b>Spray application</b> (ECPA Greenhouse model) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L	0.00439	29	0.01748	18
Ornamentals –Manual Spraying in greenhouses					
Application rate		0.0121 kg a.s./ha		0.0481 kg a.s./ha	
<b>Spray application</b> (ECPA Greenhouse model) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L	0.00039	2.6	0.00157	1.6

### Conclusion

According to the AOEM model, calculations, it can be concluded that the risk for the operator using CASINO ROYALE is acceptable without use of personal protective equipment for low crops.

According to the AOEM model, calculations, it can be concluded that the risk for the operator using CASINO ROYALE is acceptable without use of personal protective equipment for high crops.

According to ECPA Greenhouse model, calculations, it can be concluded that the risk for the operator using CASINO ROYALE is acceptable without use of personal protective equipment.

New calculations have been conducted considering Dutch Greenhouse model. Detailed calculations are in Appendix 3.

		Pyraclostrobin		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tomato–Manual Spraying in greenhouses					
Application rate		0.134 kg a.s./ha		0.534 kg a.s./ha	
Spray application (Dutch Greenhouse model) Body weight: 70 kg	Work wear (arms, body and legs covered) M/L + gloves M/L and A+ powered full-face filtering devices with filtertype 2	0.6298	60	2.5098	36
Ornamentals –Manual Spraying in greenhouses					
Application rate		0.0121 kg a.s./ha		0.0481 kg a.s./ha	
Spray application (Dutch Greenhouse model) Body weight: 70 kg	Work wear (arms, body and legs covered) M/L	0.5687	54	2.2607	32

### Conclusion

Operator exposure in glasshouse applications to tomato and ornamentals is acceptable with the use of gloves and working clothing (long sleeved shirt and trousers) during mixing/loading and application.

**Implication for labelling:** Wear protective gloves 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

Comment of ZRMS	<p>Critical uses of SHA 7273A / Casino Royale have been selected correctly. However, the input parameters used to calculate worker exposure towards pyraclostrobin and boscalid contain wrong oral absorption values which should amount to 50 and 44%, respectively. Nevertheless, the use of new oral absorption values does not change the results of worker exposure significantly. Thus, the estimations presented by the Applicant are accepted.</p> <p><b>Conclusions:</b></p> <p>The results of the estimations presented by the Applicant indicate that the worker exposure to pyraclostrobin and boscalid contained in the product SHA 7273A / Casino Royale causes <b>acceptable risk</b> in case of use in:</p> <ul style="list-style-type: none"> <li>- sugarbeet if work wear is used,</li> <li>- tomatos if work wear and gloves are used,</li> <li>- strawberries if work wear and gloves are used and the re-entry period amounts to 2 days,</li> <li>- ornamentals if work wear and gloves are used and the re-entry period amounts to 6 days,</li> <li>- cherries if work wear and gloves are used and the re-entry period amounts to 15 days.</li> </ul> <p>Taking into account the results of exposure estimations (AOEL model) to pyraclostrobin and boscalid contained in the product SHA 7273A / Casino Royale, as well as hygienic rules, a worker should be equipped with <b>work wear (long trousers, long-sleeve shirt) and protective gloves</b>.</p> <p>Bearing in mind PHI values for intended crops and the results of exposure assessment, it is forbidden to re-enter treated area for inspection and/or picking:</p> <ul style="list-style-type: none"> <li>- until spray deposit on plant surfaces has dried in case of SHA 7273A use <b>in sugarbeet and tomatos</b></li> <li>- for 2 days in case of SHA 7273A use <b>in strawberries</b></li> <li>- for 6 days in case of SHA 7273A use <b>in ornamentals</b></li> <li>- for 7 days in case of SHA 7273A use <b>in cherries</b></li> </ul> <p>A precautionary phrase referring to the worker should be included in the label:</p> <p><b>WORKER:</b></p> <p><i>„Stosować rękawice ochronne i odzież roboczą (koszula z długim rękawem i długie spodnie) oraz nie wchodzić na teren poddany zabiegowi wcześniej niż:</i></p> <ul style="list-style-type: none"> <li>- <i>po wyschnięciu preparatu na powierzchni roślin w przypadku uprawy: buraka cukrowego, marchwi, buraka, selera, pasternaku, pietruszki naciowej, rzodkwi, chrzanu, brukwi, rzepy, korzenia cykorii, cebuli szalotki, topinamburu, salsefii, pomidora, cebuli, kapusty, bakłażana;</i></li> <li>- <i>2 dni po wykonaniu oprysku w przypadku uprawy: truskawki, maliny, porzeczki;</i></li> <li>- <i>2 dni po wykonaniu oprysku w przypadku uprawy: pomidor (szklarnia);</i></li> <li>- <i>6 dni po wykonaniu oprysku w przypadku uprawy: roślin ozdobnych;</i></li> </ul>
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	<p>- 7 dni po wykonaniu oprysku w przypadku uprawy wiśni.</p> <p>Wear protective gloves, work wear (covered arms, body and legs) and do not enter the area treated with SHA 7273A:</p> <ul style="list-style-type: none"> <li>- until spray deposit on plant surfaces has dried in sugerbeet, carrot, beetroot, celery root, parsnip, parsley, radish, horseradish, swedes/rutabagas, turnip, chicory roots, shallot, Jerusalem artichokes, salsifies, tomato, onion, cabbage, aubergines/eggplants;</li> <li>- for 2 days in raspberry, blackcurrant, redcurrant, white currant;</li> <li>- for 2 days in tomato (indoor);</li> <li>- for 6 days in ornamentals;</li> <li>- for 7 days in cherries.</li> </ul>
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### 6.6.3.2

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 CASINO ROYALE according to the critical uses. Outcome of the estimation is presented in Table 6.6-5 (longer term exposure). Detailed calculations are in Appendix 3.

**Table 6.6-4: Exposure models for intended uses**

Critical uses	<p>Sugarbeet (max 2 x 1.5 L product/ha)</p> <p>Tomatoes (max. 3 x 1.5 L product/ha)</p> <p>Strawberry (max. 2 x 1.8 L product/ha)</p> <p>Ornamentals (max. 2 x 0.18 L product/ha)</p> <p>Cherry (max. 2 x 1.0 L product/ha)</p>
Model	<p>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</p> <p>calculator version: 30/03/2015</p>

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



		Pyraclostrobin		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Sugarbeet/Inspection, irrigation/Outdoor</b> Work rate: 2 hours/day, DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 8 days					
Number of applications and application rate		2 x 0.1 kg a.s./ha		2 x 0.4 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.0526481	351	0.2105924	211
	Work wear (arms, body and legs covered) TC: 1400 cm <sup>2</sup> /person/h	0.0058966	39	0.0235863	24
<b>Tomatoes/Reaching, picking/Outdoor</b> Work rate: 8 hours/day, DT <sub>50</sub> : 4.52 days for Pyraclostrobin and 7.67 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 8 days					
Number of applications and application rate		3 x 0.1 kg a.s./ha		3 x 0.4 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.0735946	491	0.3672947	367
	Work wear (arms, body and legs covered) TC: 2500 cm <sup>2</sup> /person/h	0.0317218	211	0.1583167	158
	Work wear (arms, body and legs covered) and gloves TC: 580 cm <sup>2</sup> /person/h	0.0073595	49	0.0367295	37

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even with suitable protective clothing (gloves).

<b>Strawberry/Reaching, picking/Outdoor</b> Work rate: 8 hours/day, DT50: 3.51 days for Pyraclostrobin and 5.96 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.1206 kg a.s./ha		2 x 0.4806 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.0883264	589	0.3998179	400
	Work wear (arms, body and legs covered) TC: 3000 cm <sup>2</sup> /person/h	0.0456861	305	0.2068024	207
	Work wear (arms, body and legs covered) and gloves TC: 750 cm <sup>2</sup> /person/h	0.0114215	76	0.0517006	52
<b>Proposal of Re-entry period of 2 days</b> <b>Strawberry/Reaching, picking/Outdoor</b> Work rate: 8 hours/day, DT50: 3.51 days for Pyraclostrobin and 5.96 days for Boscalid Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.1206 kg a.s./ha DFR: 1.98 µg/cm <sup>2</sup> /kg a.s./ha		2 x 0.4806 kg a.s./ha DFR: 2.32 µg/cm <sup>2</sup> /kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.0582954	389	0.3091925	309
	Work wear (arms, body and legs covered) TC: 3000 cm <sup>2</sup> /person/h	0.0301528	201	0.1599272	160
	Work wear (arms, body and legs covered) and gloves TC: 750 cm <sup>2</sup> /person/h	0.0075352	50	0.0399818	40

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves) for harvesting activities when for re-entering Strawberry treated with CASINO ROYALE when a time period of 2 days after application is respected. 2 days is PHI and therefore is acceptable

<b>Ornamentals/Cutting, sorting, bundling, carrying/Outdoor</b> Work rate: 8 hours/day, DT50: <b>30 days</b> DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 7 days					
Number of applications and application rate		2 x <b>0.0121</b> kg a.s./ha		2 x <b>0.0481</b> kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm <sup>2</sup> /person/h	<b>0.0290036</b>	<b>193</b>	<b>0.1152953</b>	<b>115</b>
	Work wear (arms, body and legs covered) TC: 5000 cm <sup>2</sup> /person/h	<b>0.0104621</b>	<b>70</b>	<b>0.0415892</b>	<b>42</b>
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm <sup>2</sup> /person/h	<b>0.0030456</b>	<b>20</b>	<b>0.0121067</b>	<b>12</b>

**It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing.**

<b>Cherry</b> /Searching, reaching, picking/Outdoor Work rate: 8 hours/day, DT50: 8.61 days for Pyraclostrobin and 14.62 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.067 kg a.s./ha		2 x 0.267 kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	0.2314223	1543	0.9887339	989
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.0462845	309	0.1977468	198
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.0231422	154	0.0988734	99
<b>Proposal of Re-entry period of 15 days</b> <b>Cherry</b> /Searching, reaching, picking/Outdoor Work rate: 8 hours/day, DT50: 8.61 days for Pyraclostrobin and 14.62 days for Boscalid Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.067 kg a.s./ha DFR: 0.90 µg/cm <sup>2</sup> /kg a.s./ha		2 x 0.267 kg a.s./ha DFR: 1.47 µg/cm <sup>2</sup> /kg a.s./ha	
Body weight: 60 kg	Potential TC: 22500 cm <sup>2</sup> /person/h	0.0694267	463	0.4844796	484
	Work wear (arms, body and legs covered) TC: 4500 cm <sup>2</sup> /person/h	0.0138853	93	0.0968959	97
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm <sup>2</sup> /person/h	0.0069427	46	0.0484480	49

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves) for harvesting activities when for re-entering **cherry** treated with CASINO ROYALE when a time period of 15 days after application is respected.

New calculations have been conducted considering Indoor applications. Detailed calculations are in Appendix 3.

**Table 6.6-6: Estimated worker exposure (longer term exposure)- Indoor application**

		Pyraclostrobin		Boscalid	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
<b>Ornamentals/Cutting, sorting, bundling, carrying/ Indoor</b> Work rate: 8 hours/day, DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.0121 kg a.s./ha		2 x 0.0481 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm <sup>2</sup> /person/h	0.0290036	193	0.1152953	115
	Work wear (arms, body and legs covered) TC: 5000 cm <sup>2</sup> /person/h	0.0104621	70	0.0415892	42
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm <sup>2</sup> /person/h	0.0030456	20	0.0121067	12
<b>Re-entry period of 2 days</b> <b>Tomatoes/Reaching, picking/Indoor</b> Work rate: 8 hours/day, DT <sub>50</sub> : 4.52 days for Pyraclostrobin and 7.67 days for Boscalid DFR: 2.15 µg/cm <sup>2</sup> /kg a.s./ha for Pyraclostrobin and 2.56 µg/cm <sup>2</sup> /kg a.s./ha for Boscalid Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.134 kg a.s./ha		2 x 0.534 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm <sup>2</sup> /person/h	0.0750468	500	0.3979032	398
	Work wear (arms, body and legs covered) TC: 2500 cm <sup>2</sup> /person/h	0.0323478	216	0.1715100	172
	Work wear (arms, body and legs covered) and gloves TC: 580 cm <sup>2</sup> /person/h	0.0075047	50	0.0397903	40

#### Ornamentals

It is concluded that no unacceptable risk is anticipated for the worker re-entering the treated crop even without suitable protective clothing.

#### Tomatoes

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing and with personal protective equipment (gloves) for harvesting activities when for re-entering tomato treated with CASINO ROYALE when a time period of 2 days after application is respected.

### 6.6.3.3 Refinement of generic DFR value (KCP 7.2)

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm<sup>2</sup> (30 mg a.s./m<sup>2</sup>).

#### Refinement

##### Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period of 2 days for strawberry and 15 days

for cherry.

Body weight 60 kg.

DT<sub>50</sub>:

Pyraclostrobin:

For this calculation DT50 value of 4.52 days, 3.51 days, 3.95 days and 8.51 days is considered according to “Fantke et al 2014 Half-lives for pesticide dissipation from plantses 500434p” and “Fantke et al 2014 supplementary”.

$$HL_{ref. Pyraclostrobin} = \alpha + \beta_{Pyraclostrobin} = 0.595 + 0 = 0.595.$$

$$HL_{tomato/ Pyraclostrobin, 20^{\circ}C} = \log HL_{ref. Pyraclostrobin} + \beta_{tomato} = 0.595 + 0.06 = 0.655$$

$$HL_{strawberry/ Pyraclostrobin, 20^{\circ}C} = \log HL_{ref. Pyraclostrobin} + \beta_{strawberry} = 0.595 - 0.05 = 0.545$$

$$HL_{cherry/ Pyraclostrobin, 20^{\circ}C} = \log HL_{ref. Pyraclostrobin} + \beta_{cherry} = 0.595 + 0.34 = 0.935$$

Half-life correction from plant correction parameter estimate range  $10^{0.655} = 4.52$  days for tomato,  $10^{0.545} = 3.51$  days for strawberry and  $10^{0.935} = 8.61$  days for cherry.

Boscalid:

For this calculation DT50 value of 7.67 days, 5.96 days, 6.71 days and 14.62 days is considered according to “Fantke et al 2014 Half-lives for pesticide dissipation from plantses 500434p” and “Fantke et al 2014 supplementary”.

$$HL_{ref. Boscalid} = \alpha + \beta_{Boscalid} = 0.595 + 0.23 = 0.825.$$

$$HL_{tomato/ Boscalid 20^{\circ}C} = \log HL_{ref. Boscalid} + \beta_{tomato} = 0.825 + 0.06 = 0.885$$

$$HL_{strawberry/ Boscalid, 20^{\circ}C} = \log HL_{ref. Boscalid} + \beta_{strawberry} = 0.825 - 0.05 = 0.775$$

$$HL_{cherry/ Boscalid, 20^{\circ}C} = \log HL_{ref. Boscalid} + \beta_{cherry} = 0.825 + 0.34 = 1.164$$

Half-life correction from plant correction parameter estimate range  $10^{0.885} = 7.67$  days for tomato,  $10^{0.775} = 5.96$  days for strawberry and  $10^{1.164} = 14.62$  days for cherry.

DFR<sub>t</sub> is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k, t}$$

Where:

DFR<sub>T</sub> Dislodgeable foliar residue at the time of re-entry (µg/cm<sup>2</sup>)

DFR<sub>0</sub> Dislodgeable foliar residue just after application (µg/cm<sup>2</sup>)

k Degradation constant (days<sup>-1</sup>), calculated from the half life time:

$$k = \ln(2)/DT_{50},$$

DT<sub>50</sub> Foliar half-life time (days)

t Re-entry interval (days)

Dislodgeable foliar residue just after application is calculated as:

$$DFR_0 = DFR_{def} \times MAF$$

Where:

DFR<sub>def</sub> default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm<sup>2</sup> per kg s.a/ha)

MAF<sub>m</sub> (multiple application factor for mean residue data for *n* application) is:

$$MAF = (1 - e^{-nki}) / (1 - e^{-ki})$$

where:

n is the number of applications

k is the rate constant for foliar dissipation  $k = \ln(2)/DT_{50}$ ,

i is the interval between applications (days)

#### Pyraclostrobin:

##### **Therefore for 2 days of re-entry interval:**

For strawberry, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.40. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.40 = 4.20 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.20 \mu\text{g}/\text{cm}^2 \times 0.659 = 2.77 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 2.77 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 1.98 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

##### **Therefore for 15 days of re-entry interval:**

For cherry, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.67. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.67 = 5.01 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.01 \mu\text{g}/\text{cm}^2 \times 0.299 = 1.50 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 1.50 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 0.90 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

#### **Re-entry period of 2 days for Tomato indoor uses:**

For tomato, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.50. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.5 = 4.5 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.5 \mu\text{g}/\text{cm}^2 \times 0.717 = 3.23 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 3.23 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 2.15 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

#### Boscalid:

##### **Therefore for 2 days of re-entry interval:**

For strawberry, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.60. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.60 = 4.80 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.80 \mu\text{g}/\text{cm}^2 \times 0.773 = 3.71 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 3.71 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 2.32 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

##### **Therefore for 15 days of re-entry interval:**

For cherry, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.80. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.80 = 5.40 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 5.40 \mu\text{g}/\text{cm}^2 \times 0.488 = 2.64 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 2.64 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 1.47 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

#### **Re-entry period of 2 days for Tomato indoor uses:**

For tomato, a number of 2 applications (n) and a 5 day interval (i) between applications is considered (worst case scenario) and MAF is 1.6. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.6 = 4.8 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

$$DFR_T = DFR_0 \times e^{-k \cdot t} = 4.8 \mu\text{g}/\text{cm}^2 \times 0.854 = 4.10 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def ref} \times MAF = 4.10 \mu\text{g}/\text{cm}^2 \quad \text{the } DFR_{def ref} = 2.56 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

#### 6.6.3.4 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.

#### 6.6.4 Resident and bystander exposure (KCP 7.2.2)

##### 6.6.4.1 Estimation of resident and bystander exposure

Comments of zRMS:	<p>Critical uses of SHA 7273A / Casino Royale have been selected correctly. However, the input parameters used to calculate resident/bystander exposure towards pyraclostrobin and boscalid contain wrong oral absorption values which should amount to 50 and 44%, respectively. Nevertheless, the use of new oral absorption values does not change the results of worker exposure significantly. Thus, the estimation presented by the Applicant are accepted.</p> <p>The reference values acutely toxic active substance (RVAAS) for pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale are not allocated. Consequently, it is assumed that the estimations of bystander exposure are covered by the calculations of resident exposure towards both active substances.</p> <p><b>Conclusions:</b></p> <p>The results of the estimations indicate that the exposure of a resident (both child and adult) to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale is below the value of AOEL.</p> <p>The <b>incidental short-time exposure of bystander and resident (children and adult)</b> to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale <b>causes no risk</b> to human health if the product is used in accordance to the intended uses listed in the GAP Table.</p>
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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 6.6-7 shows the exposure model used for estimation of resident and bystander exposure to Pyraclostrobin and Boscalid. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure) and Table 6.6-8 (acute bystander exposure). Detailed calculations are in Appendix 3.

**Table 6.6-7: Exposure models for intended uses**

Critical uses	<p>Sugarbeet (max 2 x 1.5 L product/ha) Tomatoes (max. 3 x 1.5 L product/ha) Strawberry (max. 2 x 1.8 L product/ha) Ornamentals (max. 2 x <b>0.18</b> L product/ha) Cherry (max. 2 x 1.0 L product/ha)</p>
Model	<p>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</p>

**Table 6.6-8: Estimated resident exposure (longer term exposure)**

		Pyraclostrobin		Boscalid	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to vegetables use Buffer zone: 2-3 m Drift reduction technology: no DT <sub>50</sub> : 4.52 days for Pyraclostrobin and 7.67 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 8 days					
Number of applications and application rate		3 x 0.1 kg a.s./ha		3 x 0.4 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0020631	13.75	0.0082523	8.25
	Vapour (75 <sup>th</sup> perc.)	0.0010700	7.13	0.0010700	1.07
	Deposits (75 <sup>th</sup> perc.)	0.0005739	3.83	0.0025510	2.55
	Re-entry (75 <sup>th</sup> perc.)	0.0053531	35.69	0.0267159	26.72
	<b>Sum (mean)</b>	0.0068956	45.97	0.0287883	28.79
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0004930	3.29	0.0019720	1.97
	Vapour (75 <sup>th</sup> perc.)	0.0002300	1.53	0.0002300	0.23
	Deposits (75 <sup>th</sup> perc.)	0.0002161	1.44	0.0010787	1.08
	Re-entry (75 <sup>th</sup> perc.)	0.0029739	19.83	0.0148422	14.84
	<b>Sum (mean)</b>	0.0029938	19.96	0.0137913	13.79
Tractor mounted boom spray application outdoors to stawberry use Buffer zone: 2-3 m Drift reduction technology: no DT <sub>50</sub> : 3.51 days for Pyraclostrobin and 5.96 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.1206 kg a.s./ha		2 x 0.4806 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0014928	9.95	0.0059491	5.95
	Vapour (75 <sup>th</sup> perc.)	0.0010700	7.13	0.0010700	1.07
	Deposits (75 <sup>th</sup> perc.)	0.0006215	4.14	0.0027769	2.78
	Re-entry (75 <sup>th</sup> perc.)	0.0064246	42.83	0.0290816	29.08
	<b>Sum (mean)</b>	0.0074705	49.80	0.0295702	29.57
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0003567	2.38	0.0014216	1.42
	Vapour (75 <sup>th</sup> perc.)	0.0002300	1.53	0.0002300	0.23
	Deposits (75 <sup>th</sup> perc.)	0.0002594	1.73	0.0011742	1.17
	Re-entry (75 <sup>th</sup> perc.)	0.0035692	23.79	0.0161564	16.16
	<b>Sum (mean)</b>	0.0034353	22.90	0.0146475	14.65
Tractor mounted boom spray application outdoors to ornamentals use Buffer zone: 2-3 m Drift reduction technology: no DT <sub>50</sub> : 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha					



Interval between treatments: 7 days					
Number of applications and application rate		2 x 0.0121 kg a.s./ha		2 x 0.0481 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0007489	4.99	0.0029770	2.98
	Vapour (75 <sup>th</sup> perc.)	0.0010700	7.13	0.0010700	1.07
	Deposits (75 <sup>th</sup> perc.)	0.0000841	0.56	0.0003299	0.33
	Re-entry (75 <sup>th</sup> perc.)	0.0008691	5.79	0.0034550	3.45
	Sum (mean)	0.0022374	14.92	0.0057074	5.71
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.0001790	1.19	0.0007114	0.71
	Vapour (75 <sup>th</sup> perc.)	0.0002300	1.53	0.0002300	0.23
	Deposits (75 <sup>th</sup> perc.)	0.0000351	0.23	0.0001395	0.14
	Re-entry (75 <sup>th</sup> perc.)	0.0004829	3.22	0.0019194	1.92
	Sum (mean)	0.0007258	4.84	0.0022007	2.20
Tractor mounted boom spray application outdoors to cherry use Buffer zone: 5 m Drift reduction technology: no DT50: 8.61 days for Pyraclostrobin and 14.62 days for Boscalid DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha Interval between treatments: 5 days					
Number of applications and application rate		2 x 0.067 kg a.s./ha		2 x 0.267 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.0042905	28.60	0.0170981	17.10
	Vapour (75 <sup>th</sup> perc.)	0.0010700	7.13	0.0010700	1.07
	Deposits (75 <sup>th</sup> perc.)	0.00013116	8.74	0.0049913	4.99
	Re-entry (75 <sup>th</sup> perc.)	0.0043392	28.93	0.0185388	18.54
	Sum (mean)	0.0083239	55.49	0.0307970	30.80
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.00023761	15.84	0.0094689	9.47
	Vapour (75 <sup>th</sup> perc.)	0.0002300	1.53	0.0002300	0.23
	Deposits (75 <sup>th</sup> perc.)	0.0004940	3.29	0.00021105	2.11
	Re-entry (75 <sup>th</sup> perc.)	0.0024106	16.07	0.0102993	10.30
	Sum (mean)	0.0040716	27.14	0.0161967	16.20

#### 6.6.4.2 Measurement of resident and/or bystander exposure

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

## 6.6.5 Combined exposure

The product is a mixture of two active substances.

### 6.6.5.1 Exposure assessment of pyraclostrobin and boscalid in SHA 7273A / CASINO ROYALE

Comments of zRMS:	<p>Bearing in minds the comments of zRMS to operator, worker, bystander &amp; resident exposure calculations, the estimation of combined exposure to pyraclostrobin and boscalid contained in SHA 7273A / Casino Royale is accepted.</p> <p>The results of combined exposure assessment indicate that there is no unacceptable risk for operator, worker, bystander and resident health if all mitigation measures are implemented because the condition of Hazard Index &lt; 1 is met for all intended uses presented in the GAP Table.</p>
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Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. The Hazard Index (HI) is the sum of the individual HQs.

**Table 6.6-9: Risk assessment from combined exposure**

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
<b>Tomato and sugarbeet</b> Operators –Work wear (arms, body and legs covered) M/L	Pyraclostrobin	0.50
	Boscalid	0.24
	<b>Cumulative risk operators (HI)</b>	<b>0.74</b>
<b>Strawberry</b> Operators –Work wear (arms, body and legs covered) M/L	Pyraclostrobin	0.59
	Boscalid	0.28
	<b>Cumulative risk operators (HI)</b>	<b>0.87</b>
<b>Ornamentals</b> Operators –Work wear (arms, body and legs covered) M/L	Pyraclostrobin	0.64
	Boscalid	0.35
	<b>Cumulative risk operators (HI)</b>	<b>0.99</b>
<b>Cherry</b> Operators –Work wear (arms, body and legs covered) M/L +gloves M/L and A	Pyraclostrobin	0.32
	Boscalid	0.17
	<b>Cumulative risk operators (HI)</b>	<b>0.49</b>
<b>Tomato greenhouses</b> Operators –Work wear (arms, body and legs covered) ECPA model	Pyraclostrobin	0.29
	Boscalid	0.18
	<b>Cumulative risk operators (HI)</b>	<b>0.46</b>
<b>Ornamentals greenhouses</b> Operators –Work wear (arms, body	Pyraclostrobin	0.03
	Boscalid	0.02

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
and legs covered) ECPA model	Cumulative risk operators (HI)	0.05
Tomato greenhouses Operators – Work wear (arms, body and legs covered) M/L + gloves M/L and A+ powered full-face filtering devices with filtertype 2 Duch model	Pyraclostrobin	0.60
	Boscalid	0.36
	Cumulative risk operators (HI)	0.96
Ornamentals greenhouses Operators – Work wear (arms, body and legs covered) Duch model	Pyraclostrobin	0.54
	Boscalid	0.32
	Cumulative risk operators (HI)	0.86
Sugarbeet Workers – Work wear (arms, body and legs covered)	Pyraclostrobin	0.39
	Boscalid	0.24
	Cumulative risk operators (HI)	0.63
Tomato Workers – Work wear (arms, body and legs covered) and gloves	Pyraclostrobin	0.49
	Boscalid	0.37
	Cumulative risk operators (HI)	0.86
Strawberry Workers – Work wear (arms, body and legs covered) and gloves – Re-entry period of 2 days	Pyraclostrobin	0.50
	Boscalid	0.40
	Cumulative risk operators (HI)	0.90
Ornamentals Workers – Work wear (arms, body and legs covered)	Pyraclostrobin	0.20
	Boscalid	0.12
	Cumulative risk operators (HI)	0.32
Cherry Workers – Work wear (arms, body and legs covered) and gloves – Re-entry period of 15 days	Pyraclostrobin	0.46
	Boscalid	0.49
	Cumulative risk operators (HI)	0.95
Ornamentals Indoor Workers – Work wear (arms, body and legs covered)	Pyraclostrobin	0.20
	Boscalid	0.12
	Cumulative risk operators (HI)	0.32
Tomato Indoor Workers – Work wear (arms, body and legs covered) and gloves – Re-entry period of 2 days	Pyraclostrobin	0.50
	Boscalid	0.40
	Cumulative risk operators (HI)	0.90
Vegetables Resident – child – 2-3-m buffer zone	Pyraclostrobin	
	Drift	0.14
	Vapour	0.07
	Deposits	0.04
	Re-entry	0.36
	Sum of all pathways	0.46
	Boscalid	

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Drift	0.08
	Vapour	0.01
	Deposits	0.03
	Re-entry	0.27
	Sum of all pathways	0.29
	<b>Cumulative risk resident – child (HI)</b>	
	Drift	0.22
	Vapour	0.08
	Deposits	0.07
	Re-entry	0.63
	Sum of all pathways	<b>0.75</b>
Resident – adult	Pyraclostrobin	
	Drift	0.03
	Vapour	0.01
	Deposits	0.01
	Re-entry	0.20
	Sum of all pathways	0.20
	Boscalid	
	Drift	0.02
	Vapour	0.001
	Deposits	0.01
	Re-entry	0.15
	Sum of all pathways	0.14
	<b>Cumulative risk resident – adult (HI)</b>	
	Drift	0.05
	Vapour	0.05
	Deposits	0.02
	Re-entry	0.35
	Sum of all pathways	<b>0.34</b>
<b>Strawberry</b> Resident – child – 2-3-m buffer zone	Pyraclostrobin	
	Drift	<b>0.10</b>
	Vapour	0.07
	Deposits	0.04
	Re-entry	0.43
	Sum of all pathways	<b>0.50</b>
	Boscalid	
	Drift	<b>0.06</b>

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.01
	Deposits	0.03
	Re-entry	0.29
	Sum of all pathways	0.30
	<b>Cumulative risk resident – child (HI)</b>	
	Drift	0.16
	Vapour	0.08
	Deposits	0.06
	Re-entry	0.72
	Sum of all pathways	0.80
Resident – adult	Pyraclostrobin	
	Drift	0.02
	Vapour	0.02
	Deposits	0.02
	Re-entry	0.24
	Sum of all pathways	0.23
	Boscalid	
	Drift	0.01
	Vapour	0.01
	Deposits	0.01
	Re-entry	0.16
	Sum of all pathways	0.15
	<b>Cumulative risk resident – adult (HI)</b>	
	Drift	0.03
	Vapour	0.03
	Deposits	0.03
	Re-entry	0.40
	Sum of all pathways	0.38
<b>Ornammentals</b> Resident – child – 2-3-m buffer zone	Pyraclostrobin	
	Drift	0.05
	Vapour	0.07
	Deposits	0.02
	Re-entry	0.06
	Sum of all pathways	0.15
	Boscalid	
	Drift	0.03
	Vapour	0.01

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Deposits	0.01
	Re-entry	0.03
	Sum of all pathways	0.06
	<b>Cumulative risk resident – child (HI)</b>	
	Drift	0.08
	Vapour	0.08
	Deposits	0.03
	Re-entry	0.09
	Sum of all pathways	0.21
Resident – adult	Pyraclostrobin	
	Drift	0.01
	Vapour	0.02
	Deposits	0.01
	Re-entry	0.03
	Sum of all pathways	0.05
	Boscalid	
	Drift	0.02
	Vapour	0.02
	Deposits	0.01
	Re-entry	0.02
	Sum of all pathways	0.02
	<b>Cumulative risk resident – adult (HI)</b>	
	Drift	0.03
	Vapour	0.04
	Deposits	0.02
	Re-entry	0.27
	Sum of all pathways	0.07
<b>Cherry</b> Resident – child – 5-m buffer zone	Pyraclostrobin	
	Drift	0.29
	Vapour	0.07
	Deposits	0.09
	Re-entry	0.05
	Sum of all pathways	0.55
	Boscalid	
	Drift	0.17
	Vapour	0.01
	Deposits	0.05

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Re-entry	0.19
	Sum of all pathways	0.31
	<b>Cumulative risk resident – child (HI)</b>	
	Drift	0.46
	Vapour	0.08
	Deposits	0.14
	Re-entry	0.48
	<b>Sum of all pathways</b>	<b>0.86</b>
Resident – adult	Pyraclostrobin	
	Drift	0.16
	Vapour	0.02
	Deposits	0.03
	Re-entry	0.16
	Sum of all pathways	0.27
	Boscalid	
	Drift	0.10
	Vapour	0.002
	Deposits	0.02
	Re-entry	0.10
	Sum of all pathways	0.16
	<b>Cumulative risk resident – adult (HI)</b>	
	Drift	0.23
	Vapour	0.02
	Deposits	0.05
	Re-entry	0.16
	<b>Sum of all pathways</b>	<b>0.43</b>

## 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 7.6.2	Ashwinkumar V Meru	2020	In Vitro percutaneous dermal absorption study of Pyraclostrobin 6.7% + Boscalid 26.7% WG, through human skin, G18514_DER-ABS GLP, Unpublished	N	Owner

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

No additional study submitted.

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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
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	The classification of the formulation SHA 7273 A / Casino Royale is based on toxicological data of individual ingredients of the mixture (additivity formula).
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### A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273 A / Casino Royale <b>does not require classification with regard to oral acute toxicity.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Pyraclostrobin 6.7% + Boscalid 26.7% WG recipe classified as acute oral toxicity.

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273 A / Casino Royale <b>does not require classification with regard to dermal acute toxicity.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Pyraclostrobin 6.7% + Boscalid 26.7% WG recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273 A / Casino Royale <b>does not require classification with regard to inhalation acute toxicity.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute inhalation toxicity of Pyraclostrobin 6.7% + Boscalid 26.7% WG was calculated as follow:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{6.8\%}{0.69}} = 69.013 \frac{mg}{l}$$

The acute inhalation toxicity of Pyraclostrobin 6.7% + Boscalid 26.7% WG was estimated to be > 5 mg/l.

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273 A / Casino Royale <b>does not require classification with regard to skin irritation.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273A / Casino Royale <b>requires classification with regard to eye irritation as Eye Irrit. 2, H319.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The product contains < 10% of formulants considered as eye damage (classified as: Eye Dam. 2; H319: Causes serious eye irritation). Under the GHS classification system the severe irritant component is at the value of < 10% for formulants/co-formulants for the H319: Causes serious eye irritation. Therefore Pyraclostrobin 6.7% + Boscalid 26.7% WG will be considered as an eye irritant according to Regulation (EC)

no. 1272/2008.

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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	Taking into account the composition of the product and the provisions of Regulation EC No. 1272/2008, the formulation SHA 7273A / Casino Royale <b>does not require classification with regard to skin sensitization.</b> (for details check dRR part C)
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Acute toxicity studies for Pyraclostrobin 6.7% + Boscalid 26.7% WG were not evaluated as part of the EU review of Pyraclostrobin + Boscalid . 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 Pyraclostrobin 6.7% + Boscalid 26.7% WG can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

There is no co-formulant in the Pyraclostrobin 6.7% + Boscalid 26.7% WG recipe classified as skin sensitizer.

According to the Regulation EC No. 1272/2008, Pyraclostrobin 6.7% + Boscalid 26.7% WG 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)**

No data available.

#### **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)**

##### **A 2.10.1 Study 1 – Pyraclostrobin + Boscalid in Pyraclostrobin 6.7% + Boscalid 26.7% WG**

##### **Comparative dermal absorption, in vitro using rat and human skin**

Comments of zRMS:	The study presented by the applicant (Ashwinkumar V Meru, 2020) is acceptable. The use of joint measurement result for Pyraclostrobin and Boscalid is assumed to represent
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	the worst case scenario. Consequently, the ZRMS agrees to use the values of 4.6 and 23 % for concentrate and in-use dilution, respectively, for pyraclostrobin. These values have been used for operator, worker, bystander & resident exposure assessments.
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Reference	KCP 7.6.2
Report	In Vitro percutaneous dermal absorption study of Pyraclostrobin 6.7% + Boscalid 26.7% WG, through human skin, 2020, G18514_DER-ABS
Guideline(s)	OECD Guideline 428 “Skin Absorption: in vitro Method” April 2004
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

### Materials and methods

<b>Test material</b>	Name (Lot/Batch No.)	Pyraclostrobin 6.7% + Boscalid 26.7% WG (S020-446)
	Test preparation	radioformulation
	Specific activity	58.1 mCi/mmol (Pyraclostrobin), 81.0 mCi/mmol (Boscalid)
	Radiochemical purity	99.9%
Product	Name (Lot/Batch No.)	Pyraclostrobin 6.7% + Boscalid 26.7% WG (S020-446)
	Company code	SHA 7273 A
	Concentration a.s.	68.391 + 267.853 [g/kg]
	Formulation type	WG
Blank product	Name (Lot/Batch No.)	Pyraclostrobin 6.7% + Boscalid 26.7% WG Blank Formulation (SCL-22987)
	Concentration a.s.	0 [g/L or g/kg]

<b>Test system</b>		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 ml/h
	Exposed skin area	0.64 cm <sup>2</sup>
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2-0.4 µm
	Skin donors age	20, 53, 39, 32
	Skin donors sex	m+f
	Location	abdomen
	Integrity test	yes
Receptor	Receptor medium	Ultima Gold scintillation liquid
	Solubility in receptor medium	n
Sample Time	Exposure time	8 h
	Observation time	16 h
Sampling	Sample intervals	24 h
Washing		At 8 h using water and a mild soap solution (3% Dove)
Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n
Remarks:		

Tested doses	Concentrate	Spray dilution 1
Target concentration [g/kg, g/L]	Pyraclostrobin: 67 Boscalid: 267	Pyraclostrobin: 0.1 Boscalid: 0.4
Tested concentration [g.kg <sup>-1</sup> g/L]	Pyraclostrobin: 68.91 Boscalid: 267.853	Pyraclostrobin: 0.1 Boscalid: 0.4

Area dose [ $\mu\text{g}/\text{cm}^2$ ]	289 + 1130	Pyraclostrobin: 1 Boscalid: 4
Specific activity [ $\text{MBq}\cdot\text{mg}^{-1}$ , $\text{MBq}/\text{ml}^{-1}$ ]	0.014	3.14
No. of donors	4	4
No of cells used/valid cells*	8/8	8/8

\* Justification for excluded cells, if applicable

## Results and discussions

**Table A 1: In-vitro dermal penetration of Pyraclostrobin + Boscalid formulated as Pyraclostrobin 6.7% + Boscalid 26.7% WG through human skin - Recovery data**

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution)	
Target concentration [g/kg, g/L]	Pyraclostrobin: 67 Boscalid: 267		Pyraclostrobin: 0.1 Boscalid: 0.4	
Target dose [g.kg <sup>-1</sup> g/L]	Pyraclostrobin: 68.91 Boscalid: 267.853		Pyraclostrobin: 0.1 Boscalid: 0.4	
Mean actual applied dose [ $\mu\text{g}/\text{cm}^2$ ]	289 + 1130		Pyraclostrobin: 1 Boscalid: 4	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
<b>Dislodgeable dose</b>				
Skin washing	91.220	3.708	65.451	8.754
Donor chamber wash	0.234	0.304	4.079	8.068
<b>Dose associated to skin</b>				
Tape strips: 1 <sup>st</sup> sample, strips 1 + 2	1.708	1.131	8.550	1.180
Tape strips: 2 <sup>nd</sup> sample; strips 3 - n	1.581	1.146	14.296	2.779
Skin stripped	1.046	0.376	4.020	1.130
<b>Absorbed dose</b>	1.742	0.417	6.632	0.999
Receptor fluid	0.650	0.174	2.031	0.216
Receptor chamber wash	0.045	0.021	0.559	0.673
<b>Total recovery<sup>1</sup></b>	96.485	3.885	99.007	5.126
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t <sub>0.5</sub> ]	No (35%)		No (38%)	
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	N/A	N/A	N/A	N/A
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) <sup>2</sup>	3.323	1.174	20.928	2.982
Absorption estimate normalised <sup>3</sup>	3.323 $\pm$ 0.84 x 1.174		20.928 $\pm$ 0.84 x 2.982	
Relevant absorption estimate	3.323 $\pm$ 0.99		20.928 $\pm$ 2.5	
<b>Total absorption<sup>4</sup></b>	<b>4.3%</b>		<b>23%</b>	

- <sup>1</sup> Values may not calculate exactly due to rounding of figures
- <sup>2</sup> In accordance with the EFSA Guidance on Dermal Absorption ([EFSA Journal 2017;15\(6\):4873](#)) the radioactivity in the second tape-strip pool (3<sup>rd</sup> to n<sup>th</sup> tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study (see Table 7.6.2-1) Finally, the skin preparation is also considered potentially absorbable.
- <sup>3</sup> According to the EFSA Guidance on Dermal Absorption, cells with insufficient recovery (< 95%) can be corrected by normalisation of absorption estimate to 100% recovery; explanation should be included.
- <sup>4</sup> In accordance with the EFSA Guidance on Dermal Absorption, one standard deviation was added to the mean% dermal penetration in cases where the standard deviation was  $\geq 25\%$  of the mean value.
- <sup>5</sup> Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

#### **Conclusion/endpoint:**

**Conclusion/endpoint:** 4.3 % of dose for undiluted Pyraclostrobin 6.7% + Boscalid 26.7% WG (concentrate)  
23 % of dose for actual spray strength used in the field dilution

#### **A 2.11 Other/Special Studies**

No data submitted.

## Appendix 3 Exposure calculations

### A 3.1 Operator exposure calculations (KCP 7.2.1.1)

#### A 3.1.1 Calculations for Pyraclostrobin

**Table A 2: Input parameters considered for the estimation of operator exposure (tomato use)**

Substance	pyraclostrobin	Formulation = Wettable granules, soluble granules	Application rate-0,1 kg a.s. /ha	Spray dilution = 0,333333333333333 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Fruiting vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 8 days
Percentage Absorption	Dermal for product = 4,52	Dermal for in use dilution = 23	Oral = 100	Inhalation = 100	
RVNAS	0,015 mg/kg bw/day		RVAAS	0,015 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	4,52 days	
Operator Model					
		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0119	% of RVNAS	79,12%
	Acute systemic exposure mg/kg bw/day		0,0777	% of RVAAS	518,29%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 3: Estimation of longer term operator exposure towards Pyraclostrobin according to EFSA guidance (tomato use)**

	Without RPE/PPE	With RPE/PPE	
<b>Longer term</b>			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,7121201	0,4498204	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0118687	0,0074970	
% of RVNAS	79,12%	49,98%	

**Table A 4: Input parameters considered for the estimation of operator exposure (strawberry use)**

Substance	pyraclostrobin	Formulation = Wettable granules, soluble granules	Application rate-0,1206 kg a.s. /ha	Spray dilution = 0,402 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Low berries and other small fruits / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 5 days
Percentage Absorption	Dermal for product = 4,52	Dermal for in use dilution = 23	Oral = 100	Inhalation = 100	
RVNAS	0,015 mg/kg bw/day		RVAAS	0,015 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	3,51 days	
<b>Operator Model</b> Mixing, loading and application AOEM					
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0138	% of RVNAS	91,99%
	Acute systemic exposure mg/kg bw/day		0,0875	% of RVAAS	583,00%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No



**Table A 5: Estimation of longer term operator exposure towards Pyraclostrobin according to EFSA guidance (strawberry use)**

	Without RPE/PPE	With RPE/PPE	
<b>Longer term</b>			
Total systemic exposure from mixing, loading and application (mg a.s./day)	<b>0,8278997</b>	<b>0,5227726</b>	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	<b>0,0137983</b>	<b>0,0087129</b>	
% of RVNAS	<b>91,99%</b>	<b>58,09%</b>	

**Table A 6: Input parameters considered for the estimation of operator exposure (ornamentals use)**

Substance	pyraclostrobin	Formulation = Wettable granules, soluble granules	Application rate=0,1201 kg a.s. /ha	Spray dilution = 1,201 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Ornamentals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 7 days
Percentage Absorption	Dermal for product = 4,52	Dermal for in use dilution = 23	Oral = 100	Inhalation = 100	
RVNAS	0,015 mg/kg bw/day		RVAAS	0,015 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	3,95 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0207	% of RVNAS	138,08%
	Acute systemic exposure mg/kg bw/day		0,0535	% of RVAAS	356,62%
Mixing and Loading		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = No	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 7: Estimation of longer term operator exposure towards Pyraclostrobin according to EFSA guidance ((ornamentals use)**

	Without RPE/PPE	With RPE/PPE	
<b>Longer term</b>			
Total systemic exposure from mixing, loading and application (mg a.s./day)	<b>1,2426916</b>	<b>0,5737669</b>	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	<b>0,0207115</b>	<b>0,0095628</b>	
% of RVNAS	<b>138,08%</b>	<b>63,75%</b>	

**Table A 8: Input parameters considered for the estimation of operator exposure (cherry use)**

Substance	pyraclostrobin	Formulation = Wetttable granules, soluble granules	Application rate=0,067 kg a.s. /ha	Spray dilution = 0,134 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 5 days
Percentage Absoprtion	Dermal for product = 4,52	Dermal for in use diluation = 23	Oral = 100	Inhalation = 100	
RVNAS	0,015 mg/kg bw/day		RVAAS	0,015 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	8,61 days	
Operator Model		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0352	% of RVNAS	234,79%
	Acute systemic exposure mg/kg bw/day		0,1858	% of RVAAS	1238,69%
Mixing and Loading		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application		Gloves = Yes	Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 9: Estimation of longer term operator exposure towards Pyraclostrobin according to EFSA guidance ((cherry use)**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,1131080	0,2869767	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0352185	0,0047829	
% of RVNAS	234,79%	31,89%	

**Table A 10: ECPA greenhouses (tomato use)**

Data entry screen & summary calculation sheet				GREENHOUSE MODEL v_2.1	
Product:		75th percentile			
Formulation:	WG				
Body weight [kg]:	60				
Active substance(s):	Pyraclostrobin	Substance 2	Substance 3	Substance 4	Add substance
Concentration [g/l or kg]:	67	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					Remove substance
Concentrate:	4,6	0,0	0,0	0,0	
Dilution:	23,0	0,0	0,0	0,0	
AOEL [mg/kg bw/day]	0,015	0,0	0,0	0,0	
<b>Scenario 1:</b>	Low crop, standard				
Application rate [l or kg product/ha]:	2,0				
Dose [kg a.s./ha]:	0,134	0,0	0,0	0,0	Add application scenario
Work rate [ha/day]:	1,00				
PPE during mix/loading:		PPE during application:			
Respiration:	None	Respiration:	None		
Hands:	None	Hands:	None		
	None	Head:	None		
		Body:	Coverall	Remove application scenario	

### Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model

75th percentile

Active substance	Protection	Systemic exposure [mg/kg bw/day]	AOEL [mg/kg bw/day]	% of AOEL
<b>Low crop, standard</b>				
Pyraclostrobin	None	0,00439	0,015	29,2
	With			

**Table A 11:** ECPA greenhouses (ornamentals use)

### Data entry screen & summary calculation sheet

**GREENHOUSE MODEL v\_2.1**

Product:		75th percentile			
Formulation:	WG				
Body weight [kg]:	60				
Active substance(s):	Pyraclostrobin	Substance 2	Substance 3	Substance 4	Add substance
Concentration [g/l or kg]:	67	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					Remove substance
Concentrate:	4,6	0,0	0,0	0,0	
Dilution:	23,0	0,0	0,0	0,0	
AOEL [mg/kg bw/day]	0,015	0,0	0,0	0,0	

  

<b>Scenario 1:</b>	Low crop, standard				
Application rate [l or kg product/ha]:	0,18				
Dose [kg a.s./ha]:	0,0121	0,0	0,0	0,0	Add application scenario
Work rate [ha/day]:	1,00				
PPE during mix/loading:	PPE during application:				
Respiration:	None				
Hands:	None				
Head:	None				
Body:	Coverall				
		Remove application scenario			

### Summary

### Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model

75th percentile

Active substance	Protection	Systemic exposure [mg/kg bw/day]	AOEL [mg/kg bw/day]	% of AOEL
<b>Low crop, standard</b>				
Pyraclostrobin	None	0,00039	0,015	2,6
	With			

**Table A 12: Dutch greenhouses (ornamentals use)**

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form			Application including mixing and loading	
a.s.	Pyraclostrobin			
Parameter		Value	Unit	References, comments
<b>MANUAL SPRAYING in greenhouses</b>				
AR	Application rate	0,0121	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
<b>Inhalation Exposure</b>				without PPE
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	0,0121	mg a.s./ day	IE = SV x AR x A
<b>Inhalation Exposure (with PPE)</b>				with PPE
	PPE-factor	1		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	0,0121	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
<b>Dermal Exposure</b>				without PPE
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
	Dermal Exposure	2,42	mg a.s./ day	DE = SV x AR x A
<b>Dermal Exposure (with PPE)</b>				with PPE
	PPE-factor	1		Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	2,42	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
<b>Internal exposure</b>				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	23	%	
	AOEL	1,05	mg a.s./ day	based on 70 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
<b>Internal exposure</b>		[mg a.s. / day ]	[mg a.s. / day]	
	Inhalation	0,0121	0,0121	IE(int) = IE x (IA/100)
	Dermal	0,5566	0,5566	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>0,5687</b>	<b>0,5687</b>	<b>sum</b>
<b>% AOEL</b>				
	Inhalation	1	1	%AOEL = 100 x IE(int) / AOEL
	Dermal	53	53	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>54</b>	<b>54</b>	<b>sum</b>

**Table A 13: Dutch greenhouses (tomato use)**

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form			Application including mixing and loading	
a.s.	Pyraclostrobin			
Parameter		Value	Unit	References, comments
<b>MANUAL SPRAYING in greenhouses</b>				
AR	Application rate	0,134	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
<b>Inhalation Exposure</b>				
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	0,134	mg a.s./ day	IE = SV x AR x A
<b>Inhalation Exposure (with PPE)</b>				
	PPE-factor	10		with PPE Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	0,0134	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
<b>Dermal Exposure</b>				
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Dermal Exposure	26,8	mg a.s./ day	DE = SV x AR x A
<b>Dermal Exposure (with PPE)</b>				
	PPE-factor	10		with PPE Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	2,68	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
<b>Internal exposure</b>				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	23	%	
	AOEL	1,05	mg a.s./ day	based on 70 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
<b>Internal exposure</b>		[mg a.s. / day ]	[mg a.s. / day]	
	Inhalation	0,1340	0,0134	IE(int) = IE x (IA/100)
	Dermal	6,1640	0,6164	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>6,2980</b>	<b>0,6298</b>	<b>sum</b>
<b>% AOEL</b>				
	Inhalation	13	1	%AOEL = 100 x IE(int) / AOEL
	Dermal	587	59	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>600</b>	<b>60</b>	<b>sum</b>

### A 3.1.2 Calculations for Boscalid

**Table A 14:** Input parameters considered for the estimation of operator exposure (tomato use)

Substance	boscalid	Formulation = Wetttable granules, soluble granules	Application rate-0,4 kg a.s. /ha	Spray dilution = 1,3333333333333333 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Fruiting vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 8 days
Percentage Absorption	Dermal for product = 4,6	Dermal for in use dilution = 23	Oral = 44	Inhalation = 100	
RVNAS	0,1 mg/kg bw/day		RVAAS	0,1 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	7,67 days	
Operator Model					
		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0376	% of RVNAS	37,59%
	Acute systemic exposure mg/kg bw/day		0,1976	% of RVAAS	197,60%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 15:** Estimation of longer term operator exposure towards Boscalid according to EFSA guidance (tomato use)

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,2553517	1,4298595	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0375892	0,0238310	
% of RVNAS	37,59%	23,83%	

**Table A 16:** Input parameters considered for the estimation of operator exposure (strawberry use)

Substance	boscalid	Formulation = Wettable granules, soluble granules	Application rate-0,4806 kg a.s. /ha	Spray dilution = 1,602 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Low berries and other small fruits / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 2, Application interval = 5 days
Percentage Absorption	Dermal for product = 4,6	Dermal for in use dilution = 23	Oral = 44	Inhalation = 100	
RVNAS	0,1 mg/kg bw/day		RVAAS	0,1 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	5,96 days	
Operator Model					
		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0439	% of RVNAS	43,94%
	Acute systemic exposure mg/kg bw/day		0,2253	% of RVAAS	225,26%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 17:** Estimation of longer term operator exposure towards Boscalid according to EFSA guidance (strawberry use)

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	2,6362386	1,6738642	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0439373	0,0278977	
% of RVNAS	43,94%	27,90%	

**Table A 18: Input parameters considered for the estimation of operator exposure (ornamentals use)**

Substance	boscalid	Formulation = Wetttable granules, soluble granules	Application rate=0,4801 kg a.s. /ha	Spray dilution = 4,801 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa Number applications = 2, Application interval = 7 days
Scenario	Ornamentals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	
Percentage Absorption	Dermal for product = 4,6	Dermal for in use dilution = 23	Oral = 44	Inhalation = 100	
RVNAS	0,1 mg/kg bw/day		RVAAS	0,1 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	6,71 days	
Operator Model					
		Mixing, loading and application AOEM			
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0784	% of RVNAS	78,41%
	Acute systemic exposure mg/kg bw/day		0,1422	% of RVAAS	142,23%
Mixing and Loading	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 19: Estimation of longer term operator exposure towards Boscalid according to EFSA guidance (ornamentals use)**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	4,7043438	2,1124728	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0784057	0,0352079	
% of RVNAS	78,41%	35,21%	

**Table A 20: Input parameters considered for the estimation of operator exposure (cherry use)**

Substance	boscalid	Formulation = Wetttable granules, soluble granules	Application rate-0,267 kg a.s. /ha	Spray dilution = 0,534 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Scenario	Pome fruit / Outdoor / Upward spraying / Vehicle-mounted			Buffer = 5	Number applications = 2, Application interval = 5 days
Percentage Absorption	Dermal for product = 4,6	Dermal for in use dilution = 23	Oral = 44	Inhalation = 100	
RVNAS	0,1 mg/kg bw/day		RVAAS	0,1 mg/kg bw/day	
DFR	3 µg a.s./cm2 per kg a.s./ha		DT50	14,62 days	
Operator Model					
Mixing, loading and application AOEM					
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,1319	% of RVNAS	131,88%
	Acute systemic exposure mg/kg bw/day		0,6978	% of RVAAS	697,80%
Mixing and Loading	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

**Table A 21: Estimation of longer term operator exposure towards Boscalid according to EFSA guidance (cherry use)**

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	7,9126193	0,9687852	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1318770	0,0161464	
% of RVNAS	131,88%	16,15%	

**Table A 22: ECPA greenhouses (tomato use)**

**Data entry screen & summary calculation sheet**

**GREENHOUSE MODEL v\_2.1**

Product:		<b>75th percentile</b>			
Formulation:	WG				
Body weight [kg]:	60				
Active substance(s):	Boscalid	Substance 2	Substance 3	Substance 4	Add substance
Concentration [g/l or kg]:	267	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					Remove substance
Concentrate:	4,6	0,0	0,0	0,0	
Dilution:	23,0	0,0	0,0	0,0	
AOEL [mg/kg bw/day]	0,1	0,0	0,0	0,0	

  

<b>Scenario 1:</b>	Low crop, standard				
Application rate	0,18				
[l or kg product/ha]:					
Dose [kg a.s./ha]:	0,0481	0,0	0,0	0,0	Add application scenario
Work rate [ha/day]:	1,00				
PPE during application:					
PPE during mix/loading:	Respiration:	None			
Respiration:	None	Hands:	None		
Hands:	None	Head:	None		
Remove application scenario					
Body:		Coverall			

**Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model**

**75th percentile**

Active substance	Protection	Systemic exposure [mg/kg bw/day]	AOEL [mg/kg bw/day]	% of AOEL
<b>Low crop, standard</b>				
Boscalid	None	0,01748	0,1	17,5
	With			



**Table A 23: ECPA greenhouses (ornamentals use)**

**Data entry screen & summary calculation sheet**

**GREENHOUSE MODEL v\_2.1**

Product:		<b>75th percentile</b>			
Formulation:	WG				
Body weight [kg]:	60				
Active substance(s):	Boscalid	Substance 2	Substance 3	Substance 4	Add substance
Concentration [g/l or kg]:	267	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					Remove substance
Concentrate:	4,6	0,0	0,0	0,0	
Dilution:	23,0	0,0	0,0	0,0	
AOEL [mg/kg bw/day]	0,1	0,0	0,0	0,0	

  

<b>Scenario 1:</b>	Low crop, standard				
Application rate	0,18				
[l or kg product/ha]:					
Dose [kg a.s./ha]:	0,0481	0,0	0,0	0,0	Add application scenario
Work rate [ha/day]:	1,00				
PPE during application:					
PPE during mix/loading:	Respiration:	None			
Respiration:	Hands:	None			
Hands:	Head:	None			
	Body:	Coverall			
		Remove application scenario			

**Summary**

**Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model**

**75th percentile**

Active substance	Protection	Systemic exposure [mg/kg bw/day]	AOEL [mg/kg bw/day]	% of AOEL
<b>Low crop, standard</b>				
Boscalid	None	0,00157	0,1	1,6
	With			

**Table A 24: Dutch greenhouses (ornamentals use)**

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form			Application including mixing and loading	
a.s.	Boscalid			
Parameter		Value	Unit	References, comments
<b>MANUAL SPRAYING in greenhouses</b>				
AR	Application rate	0,0481	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
<b>Inhalation Exposure</b>				
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	0,0481	mg a.s./ day	IE = SV x AR x A
<b>Inhalation Exposure (with PPE)</b>				
	PPE-factor	1		with PPE Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	0,0481	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
<b>Dermal Exposure</b>				
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Dermal Exposure	9,62	mg a.s./ day	DE = SV x AR x A
<b>Dermal Exposure (with PPE)</b>				
	PPE-factor	1		with PPE Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	9,62	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
<b>Internal exposure</b>				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	23	%	
	AOEL	7	mg a.s./ day	based on 70 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
<b>Internal exposure</b>		[mg a.s. / day ]	[mg a.s. / day]	
	Inhalation	0,0481	0,0481	IE(int) = IE x (IA/100)
	Dermal	2,2126	2,2126	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>2,2607</b>	<b>2,2607</b>	<b>sum</b>
		<b>% AOEL</b>		
	Inhalation	1	1	%AOEL = 100 x IE(int) / AOEL
	Dermal	32	32	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>32</b>	<b>32</b>	<b>sum</b>

**Table A 25: Dutch greenhouses (tomato use)**

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form			Application including mixing and loading	
a.s.	Boscalid			
Parameter		Value	Unit	References, comments
<b>MANUAL SPRAYING in greenhouses</b>				
AR	Application rate	0,534	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
<b>Inhalation Exposure</b>				
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Inhalation Exposure (without PPE)	0,534	mg a.s./ day	IE = SV x AR x A
<b>Inhalation Exposure (with PPE)</b>				
	PPE-factor	10		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
	Inhalation Exposure (with PPE)	0,0534	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
<b>Dermal Exposure</b>				
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
	Dermal Exposure	106,8	mg a.s./ day	DE = SV x AR x A
<b>Dermal Exposure (with PPE)</b>				
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
	Dermal Exposure (with PPE)	10,68	mg a.s./ day	DE(PPE) = (1/PPE-factor) x DE
<b>Internal exposure</b>				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	23	%	
	AOEL	7	mg a.s./ day	based on 70 kg bw
		<b>Without PPE</b>	<b>With PPE</b>	
<b>Internal exposure</b>		[mg a.s. / day ]	[mg a.s. / day]	
	Inhalation	0,5340	0,0534	IE(int) = IE x (IA/100)
	Dermal	24,5640	2,4564	DE(int) = DE x (DA/100)
	<b>Total</b>	<b>25,0980</b>	<b>2,5098</b>	<b>sum</b>
		<b>% AOEL</b>		
	Inhalation	8	1	%AOEL = 100 x IE(int) / AOEL
	Dermal	351	35	%AOEL = 100 x DE(int) / AOEL
	<b>Total</b>	<b>359</b>	<b>36</b>	<b>sum</b>

## A 3.2 Worker exposure calculations (KCP 7.2.3.1)

### A 3.2.1 Calculations for Pyraclostrobin

**Table A 26: Input parameters considered for the estimation of worker exposure (sugarbeet use)**

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	0,1 kg a.s./ha
Number of applications	2
Interval between multiple applications	8 days
Half-life of active substance	30 days
Multiple application factor	1,8
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3 µg a.s./cm <sup>2</sup>
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 27: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (sugarbeet use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	<b>3,1588854</b>	<b>0,3537952</b>	<b>no TC available for this assessment</b>
Total systemic exposure per kg body weight (mg/kg bw/day)	<b>0,0526481</b>	<b>0,0058966</b>	
% of RVNAS	<b>350,99%</b>	<b>39,31%</b>	

**Table A 28: Input parameters considered for the estimation of worker exposure (tomato)**

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	0,1 kg a.s./ha
Number of applications	3
Interval between multiple applications	8 days
Half-life of active substance	4,52 days
Multiple application factor	1,4
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 29: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (sugarbeet use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	<b>4,4156744</b>	<b>1,9033079</b>	<b>0,4415674</b>
Total systemic exposure per kg body weight (mg/kg bw/day)	<b>0,0735946</b>	<b>0,0317218</b>	<b>0,0073595</b>
% of RVNAS	<b>490,63%</b>	<b>211,48%</b>	<b>49,06%</b>

**Table A 30: Input parameters considered for the estimation of worker exposure (strawberry use)**

Crop type	Low berries and other small fruits
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 forearm
Application rate of active substance	0,1206 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	3,51 days
Multiple application factor	1,4
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,3618 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	3000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	750 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 31: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (strawberry use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	5,2995861	2,7411652	0,6852913
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0883264	0,0456861	0,0114215
% of RVNAS	588,84%	304,57%	76,14%

**Table A 32: Input parameters considered for the estimation of worker exposure (strawberry use) re-entry period of 2 days**

Crop type	Low berries and other small fruits
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 forearm
Application rate of active substance	0,1206 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	3,51 days
Multiple application factor	1,4
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,238788 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	3000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	750 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 33: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (strawberry use) re-entry period of 2 days**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	3,4977268	1,8091690	0,4522923
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0582954	0,0301528	0,0075382
% of RVNAS	388,64%	201,02%	50,25%

**Table A 34: Input parameters considered for the estimation of worker exposure (ornamentals use)**

Worker exposure from residues on foliage for	
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	0,0121 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	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0363 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	14000 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	5000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	1400 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 35: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (ornamentals use)**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	1,7305367	0,6180488	0,1730537	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0288423	0,0103008	0,0028842	
% of RVNAS	192,28%	68,67%	19,23%	

**Table A 36: Input parameters considered for the estimation of worker exposure cherry use)**

Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,067 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	8,61 days
Multiple application factor	1,7
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,201 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 37: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (cherry use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	13,8853374	2,7770675	1,3885337
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2314223	0,0462845	0,0231422
% of RVNAS	1542,82%	308,56%	154,28%

**Table A 38: Input parameters considered for the estimation of worker exposure cherry use) re-entry period of 15 days**

Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,067 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	8,61 days
Multiple application factor	1,7
Dermal absorption of the product	4,52%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0603 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 39: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (cherry use) re-entry period of 15 days**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	<b>4,1656012</b>	<b>0,8331202</b>	<b>0,4165601</b>
Total systemic exposure per kg body weight (mg/kg bw/day)	<b>0,0694267</b>	<b>0,0138853</b>	<b>0,0069427</b>
% of RVNAS	<b>462,84%</b>	<b>92,57%</b>	<b>46,28%</b>

**Table A 40: Input parameters considered for the estimation of worker exposure (ornamentals indoor use)**

Worker exposure from residues on foliage for		
Crop type	Ornamentals	
Indoor or outdoor	Indoor	
Application method	Spray application	
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	0,0121 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	4,60%	
Dermal absorption of the in-use dilution	23,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0363 µg a.s./cm <sup>2</sup>	
Working hours	8 hr	
Dermal transfer coefficient - Total potential exposure	14000 cm <sup>2</sup> /hr	
Dermal transfer coefficient - arms, body and legs covered	5000 cm <sup>2</sup> /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	1400 cm <sup>2</sup> /hr	
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>	
Inhalation transfer coefficient for cutting ornamentals	0,1 ha/hr*10 <sup>^(-3)</sup>	
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01 ha/hr*10 <sup>^(-3)</sup>	

**Table A 41: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (ornamentals indoor use)**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	<b>1,7402167</b>	<b>0,6277288</b>	<b>0,1827337</b>	Calculation is based on inhalation exposure of task with the higher value
Total systemic exposure per kg body weight (mg/kg bw/day)	<b>0,0290036</b>	<b>0,0104621</b>	<b>0,0030456</b>	
% of RVNAS	<b>193,36%</b>	<b>69,75%</b>	<b>20,30%</b>	

**Table A 42: Input parameters considered for the estimation of worker exposure (tomato indoor use)**

Worker exposure from residues on foliage for	
Crop type	Fruiting vegetables
Indoor or outdoor	Indoor
Application method	Spray application
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,134 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	4,52 days
Multiple application factor	1,5
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,2881 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^</sup> (-3)
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^</sup> (-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^</sup> (-3)

**Table A 43: Estimation of longer term worker exposure towards Pyraclostrobin according to EFSA guidance (tomato indoor use)**

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4,5028106	1,9408667	0,4502811	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0750468	0,0323478	0,0075047	
% of RVNAS	500,31%	215,65%	50,03%	

### A 3.2.2 Calculations for Boscalid

**Table A 44: Input parameters considered for the estimation of worker exposure (sugarbeet use)**

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	0,4 kg a.s./ha
Number of applications	2
Interval between multiple applications	8 days
Half-life of active substance	30 days
Multiple application factor	1,8
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,2 µg a.s./cm <sup>2</sup>
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^</sup> (-3)
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^</sup> (-3)
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^</sup> (-3)



**Table A 45: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (sugarbeet use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	12,6355415	1,4151806	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,2105924	0,0235863	
% of RVNAS	210,59%	23,59%	

**Table A 46: Input parameters considered for the estimation of worker exposure (tomato use)**

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	0,4 kg a.s./ha
Number of applications	3
Interval between multiple applications	8 days
Half-life of active substance	7,67 days
Multiple application factor	1,7
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,2 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 47: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (tomato use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	22,0376838	9,4990016	2,2037684
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3672947	0,1583167	0,0367295
% of RVNAS	367,29%	158,32%	36,73%

**Table A 48: Input parameters considered for the estimation of worker exposure (strawberry use)**

Crop type	Low berries and other small fruits
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 forearm
Application rate of active substance	0,4806 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	5,96 days
Multiple application factor	1,6
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,4418 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	3000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	750 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 49: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (strawberry use)**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	23,9890769	12,4081432	3,1020358
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3998179	0,2068024	0,0517006
% of RVNAS	399,82%	206,80%	51,70%

**Table A 50: Input parameters considered for the estimation of worker exposure (strawberry use) re-entry period of 2 days**

Crop type	Low berries and other small fruits
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 forearm
Application rate of active substance	0,4806 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	5,96 days
Multiple application factor	1,6
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,114992 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	3000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	750 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>-3</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>-3</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>-3</sup>

**Table A 51: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (strawberry use) re-entry period of 2 days**

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	18,5515528	9,5956308	2,3989077
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3091925	0,1599272	0,0399818
% of RVNAS	309,19%	159,93%	39,98%

**Table A 52: Input parameters considered for the estimation of worker exposure (ornamentals use)**

Worker exposure from residues on foliage for		
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	0,0481 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	4,60%	
Dermal absorption of the in-use dilution	23,00%	
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,1443 µg a.s./cm <sup>2</sup>	
Working hours	8 hr	
Dermal transfer coefficient - Total potential exposure	14000 cm <sup>2</sup> /hr	
Dermal transfer coefficient - arms, body and legs covered	5000 cm <sup>2</sup> /hr	
Dermal transfer coefficient - hands, arms, body and legs covered	1400 cm <sup>2</sup> /hr	
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>-3</sup>	
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>-3</sup>	
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>-3</sup>	

**Table A 53: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (ornamentals use)**

1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	6,8792407	2,4568717	0,6879241	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1146540	0,0409479	0,0114654	
% of RVNAS	114,65%	40,95%	11,47%	

**Table A 54:** Input parameters considered for the estimation of worker exposure (cherry use)

Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,267 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	14,62 days
Multiple application factor	1,8
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,801 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 55:** Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (cherry use)

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	59,3240314	11,8648063	5,9324031
Total systemic exposure per kg body weight (mg/kg bw/day)	0,9887339	0,1977468	0,0988734
% of RVNAS	988,73%	197,75%	98,87%

**Table A 56:** Input parameters considered for the estimation of worker exposure (cherry use) re-entry period of 15 days

Crop type	Pome fruit
Indoor or outdoor	Outdoor
Application method	Upward spraying
Application equipment	Vehicle-mounted
Worker's task	Searching, reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,267 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	14,62 days
Multiple application factor	1,8
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,39249 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	22500 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	4500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	2250 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 57:** Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (cherry use) re-entry period of 15 days

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	29,0687754	5,8137551	2,9068775
Total systemic exposure per kg body weight (mg/kg bw/day)	0,4844796	0,0968959	0,0484480
% of RVNAS	484,48%	96,90%	48,45%

**Table A 58: Input parameters considered for the estimation of worker exposure (ornamentals indoor use)**

Worker exposure from residues on foliage for	
Crop type	Ornamentals
Indoor or outdoor	Indoor
Application method	Spray application
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	0,0481 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	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,1443 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	14000 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	5000 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	1400 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	0,1 ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	0,01 ha/hr*10 <sup>^(-3)</sup>

**Table A 59: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (ornamentals indoor use)**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	6,9177207	2,4953517	0,7264041	Calculation is based on inhalation exposure of task with the higher value
Total systemic exposure per kg body weight (mg/kg bw/day)	0,1152953	0,0415892	0,0121067	
% of RVNAS	115,30%	41,59%	12,11%	

**Table A 60: Input parameters considered for the estimation of worker exposure (tomato indoor use)**

Worker exposure from residues on foliage for	
Crop type	Fruiting vegetables
Indoor or outdoor	Indoor
Application method	Spray application
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,534 kg a.s./ha
Number of applications	2
Interval between multiple applications	5 days
Half-life of active substance	7,67 days
Multiple application factor	1,6
Dermal absorption of the product	4,60%
Dermal absorption of the in-use dilution	23,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	1,36704 µg a.s./cm <sup>2</sup>
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm <sup>2</sup> /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm <sup>2</sup> /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm <sup>2</sup> /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 <sup>^(-3)</sup>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 <sup>^(-3)</sup>

**Table A 61: Estimation of longer term worker exposure towards Boscalid according to EFSA guidance (tomato indoor use)**

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	23,8741907	10,2905995	2,3874191	
Total systemic exposure per kg body weight (mg/kg bw/day)	0,3979032	0,1715100	0,0397903	
% of RVNAS	397,90%	171,51%	39,79%	

### A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

#### A 3.3.1 Calculations for Pyraclostrobin

**Table A 62:** Input parameters considered for the estimation of longer term resident exposure (vegetables use)

Croptype	Fruiting vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,1 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,333333333 g a.s./l
Dermal absorption of product	4,52%
Dermal absorption of in-use dilution	23,00%
Oral absorption	100,00%
Dislodgeable foliar residue (L_AppRate*I_DFR)	0,3 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa Pa
Concentration in air	0,001 mg/m <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 63:** Estimation of longer term resident exposure towards Pyraclostrobin according to EFSA guidance (vegetables use)

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)	0,0206307	0,0107000	0,0057386	0,0535305	0,0689558
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0020631	0,0010700	0,0005739	0,0053531	0,0068956
% of RVNAS	13,75%	7,13%	3,83%	35,69%	45,97%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0295807	0,0138000	0,0129679	0,1784351	0,1796272
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0004930	0,0002300	0,0002161	0,0029739	0,0029938
% of RVNAS	3,29%	1,53%	1,44%	19,83%	19,96%

**Table A 64:** Input parameters considered for the estimation of longer term resident exposure (strawberry use)

Resident exposure for	
Croptype	Low berries and other small fruits
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,1206 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,2412 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	50,00%
Dislodgeable foliar residue (L_AppRate*_L_DFR)	0,3618 µg a.s./cm <sup>2</sup>
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 <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 65:** Estimation of longer term resident exposure towards Pyraclostrobin according to EFSA guidance (strawberry use)

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)	0,0149284	0,0107000	0,0062153	0,0642461	0,0747053
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0014928	0,0010700	0,0006215	0,0064246	0,0074705
% of RVNAS	9,95%	7,13%	4,14%	42,83%	49,80%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0214046	0,0138000	0,0155637	0,2141535	0,2061209
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0003567	0,0002300	0,0002594	0,0035692	0,0034353
% of RVNAS	2,38%	1,53%	1,73%	23,79%	22,90%

**Table A 66: Input parameters considered for the estimation of longer term resident exposure (ornamentals use)**

Resident exposure for	
Croptype	Ornamentals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,0121 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,121 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	50,00%
Dislodgeable foliar residue (L_AppRate*_L_DFR)	0,0363 µg a.s./cm <sup>2</sup>
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 <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 67: Estimation of longer term resident exposure towards Pyraclostrobin according to EFSA guidance (ornamentals use)**

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)	0,0074890	0,0107000	0,0008408	0,0086913	0,0223737
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0007489	0,0010700	0,0000841	0,0008691	0,0022374
% of RVNAS	4,99%	7,13%	0,56%	5,79%	14,92%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0107378	0,0138000	0,0021055	0,0289710	0,0435451
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0001790	0,0002300	0,0000351	0,0004829	0,0007258
% of RVNAS	1,19%	1,53%	0,23%	3,22%	4,84%

**Table A 68: Input parameters considered for the estimation of longer term resident exposure (cherry use)**

Croptype	Pome fruit
Application method	Upward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	5 m
Application rate of the product	0,067 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,134 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	100,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,201 µg a.s./cm <sup>2</sup>
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 <sup>3</sup>
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133 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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg
Drift percentage on surface (75th percentile)	15,79%
Drift percentage on surface (mean)	11,69%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 69: Estimation of longer term resident exposure towards Pyraclostrobin according to EFSA guidance (cherry use)**

<b>1.1 1-3 year old child</b>					
	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)	0,0429053	0,0107000	0,0131161	0,0433917	0,0832387
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0042905	0,0010700	0,0013116	0,0043392	0,0083239
% of RVNAS	28,60%	7,13%	8,74%	28,93%	55,49%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1425650	0,0138000	0,0296393	0,1446389	0,2442989
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0023761	0,0002300	0,0004940	0,0024106	0,0040716
% of RVNAS	15,84%	1,53%	3,29%	16,07%	27,14%



### A 3.3.2 Calculations for Boscalid

**Table A 70:** Input parameters considered for the estimation of longer term resident exposure (vegetables use)

Croptype	Fruiting vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,4 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	1,333333333 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	44,00%
Dislodgeable foliar residue (L_AppRate*i_DFR)	1,2 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa
Concentration in air	0,001 mg/m <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 71:** Estimation of longer term resident exposure towards Boscalid according to EFSA guidance (vegetables use)

<b>1.1 1-3 year old child</b>					
	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)	0,0825229	0,0107000	0,0255102	0,2671594	0,2878829
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0082523	0,0010700	0,0025510	0,0267159	0,0287883
% of RVNAS	8,25%	1,07%	2,55%	26,72%	28,79%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,1183227	0,0138000	0,0647199	0,8905314	0,8274769
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0019720	0,0002300	0,0010787	0,0148422	0,0137913
% of RVNAS	1,97%	0,23%	1,08%	14,84%	13,79%

**Table A 72: Input parameters considered for the estimation of longer term resident exposure (strawberry use)**

Resident exposure for	
Croptype	Low berries and other small fruits
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,4806 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,9612 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	44,00%
Dislodgeable foliar residue (L_AppRate*_I_DFR)	1,4418 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa Pa
Concentration in air	0,001 mg/m <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 73: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance (strawberry use)**

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)	0,0594908	0,0107000	0,0277691	0,2908159	0,2957023
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0059491	0,0010700	0,0027769	0,0290816	0,0295702
% of RVNAS	5,95%	1,07%	2,78%	29,08%	29,57%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0852988	0,0138000	0,0704507	0,9693862	0,8788490
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0014216	0,0002300	0,0011742	0,0161564	0,0146475
% of RVNAS	1,42%	0,23%	1,17%	16,16%	14,65%

**Table A 74: Input parameters considered for the estimation of longer term resident exposure (ornamentals use)**

Resident exposure for	
Croptype	Ornamentals
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	2-3 m
Application rate of the product	0,0481 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,481 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	44,00%
Dislodgeable foliar residue (L_AppRate*_L_DFR)	0,1443 µg a.s./cm <sup>2</sup>
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 <sup>3</sup>
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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /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 <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 75: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance (ornamentals use)**

<b>1.1 1-3 year old child</b>					
	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)	0,0297701	0,0107000	0,0032990	0,0345498	0,0570738
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0029770	0,0010700	0,0003299	0,0034550	0,0057074
% of RVNAS	2,98%	1,07%	0,33%	3,45%	5,71%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0426849	0,0138000	0,0083697	0,1151659	0,1320428
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0007114	0,0002300	0,0001395	0,0019194	0,0022007
% of RVNAS	0,71%	0,23%	0,14%	1,92%	2,20%

**Table A 76: Input parameters considered for the estimation of longer term resident exposure (cherry use)**

Croptype	Pome fruit
Application method	Upward spraying
Application equipment	Vehicle-mounted
Formulation type	Wettable granules, soluble granules
Buffer strip	5 m
Application rate of the product	0,267 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,534 g a.s./l
Dermal absorption of product	4,60%
Dermal absorption of in-use dilution	23,00%
Oral absorption	44,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,801 µg a.s./cm <sup>2</sup>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa Pa
Concentration in air	0,001 mg/m <sup>3</sup>
Resident dermal spray drift exposure 75th percentile - adult	5,63 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	1,689 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00210 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00164 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	3,68 ml spray dilution/person
Resident dermal spray drift exposure mean - child	1,11 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00170 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00133 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 <sup>3</sup> /day/kg
Breathing rate child (1-3 year old)	1,07 m <sup>3</sup> /day/kg
Drift percentage on surface (75th percentile)	15,79%
Drift percentage on surface (mean)	11,69%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm <sup>2</sup> /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm <sup>2</sup> /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm <sup>2</sup>
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm <sup>2</sup>
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm <sup>2</sup> /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm <sup>2</sup> /h

**Table A 77: Estimation of longer term resident exposure towards Boscalid according to EFSA guidance (cherry use)**

<b>1.1 1-3 year old child</b>					
	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)	0,1709809	0,0107000	0,0499135	0,1853876	0,3079700
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0170981	0,0010700	0,0049913	0,0185388	0,0307970
% of RVNAS	17,10%	1,07%	4,99%	18,54%	30,80%
<b>1.2 Adult</b>					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,5681322	0,0138000	0,1266315	0,6179587	0,9717991
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0094689	0,0002300	0,0021105	0,0102993	0,0161967
% of RVNAS	9,47%	0,23%	2,11%	10,30%	16,20%

## 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.