

benthiavalicarb-isopropyl

ADDITIONAL INFORMATION ON ENDOCRINE PROPERTIES

**ASSESSMENT OF NEGLIGIBLE EXPOSURE
UNDER REALISTIC CONDITIONS OF USE**

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1 INTRODUCTION

Regulation (EU) No 844/2012 lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Regulation (EU) No 686/2012. Benthiavalicarb-isopropyl is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 13(3a) of Regulation (EU) No 844/2012, as amended by Regulation (EU) No 2018/1659 in view of the implementation of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) No 2018/605, the European Food Safety Authority (EFSA) was able to conclude that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 are met. The notifying company, K-I Chemical Europe SA/NV, has critically reviewed the detailed justifications provided in the letter received on 18 January 2019 and provides its comments on the assessment in Appendix A.

Notwithstanding the Applicant's disagreement on the outcome of the assessment that benthiavalicarb-isopropyl is considered to meet the criteria of an endocrine disruptor in humans, further information is submitted to demonstrate that benthiavalicarb-isopropyl can be used such that exposure of consumers, operators, workers, bystanders and residents is negligible under the authorised conditions of use (Appendix B) and that a derogation under Art. 4(7) of Reg. (EC) No 1107/2009 can be scientifically supported in conventional crop production (Appendix C).

In this document it is demonstrated that exposure of consumers, operators, workers, bystanders and residents to benthiavalicarb-isopropyl can be considered negligible under the authorised conditions of use in potatoes and onions, including garlic and shallots. The assessment took into account the Commission Notice regarding the *Assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use* (SANCO 2014-12096, May 2015) and was carried out in accordance with the *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products* (EFSA, 2015).

2 NEGLIGIBLE EXPOSURE TO HUMANS

2.1 Dietary exposure

Benthiavalicarb was included in Annex I of Directive 91/414/EEC on 1 August 2008. The EFSA issued on 22 August 2012 a Reasoned Opinion on the review of the existing MRLs for benthiavalicarb in compliance with Article 12(2) of Regulation (EC) No 396/2005. The EU MRLs for benthiavalicarb were published in Regulation (EU) No 398/2014 of 22 April 2014.

K-I Chemical Europe SA/NV proposes to allow the use of benthiavalicarb-isopropyl on potatoes and bulb vegetables. The formulations authorised for use on potatoes and onions include a wettable granule formulation containing 150 g/kg benthiavalicarb-isopropyl (Versilus®) and another wettable granule formulation containing 17.5 g/kg benthiavalicarb-isopropyl and 700 g/kg mancozeb (Valbon®). The use directions indicated that the maximum use rate is up to 8 foliar applications to potatoes during the main growth phase at 75 g as/ha per application, *i.e.* 600 g as/ha per season, with a minimum pre-harvest interval (PHI) of 3 days. For onions, the maximum use rate is for up to 6 foliar applications at 28 g as/ha per application, *i.e.* 168 g as/ha per season, from beginning of crop cover up to 4 weeks before harvest.

The toxicological database for benthiavalicarb-isopropyl is complete and adequate for risk assessment purposes. None of the observed effects were the results of a single exposure to benthiavalicarb-isopropyl. As a result an acute dietary exposure assessment is not needed. The selection of the Acceptable Daily Intake (ADI) for the chronic dietary risk assessment is based on liver effects seen in the chronic rat study. The NOAEL of 9.9 mg/kg/day is protective for the uterine tumours in female rats observed at a dose of 318 mg/kg/day. The standard uncertainty factor of 100 for inter- and intra-species variability is being used. Therefore, the ADI is 0.1 mg/kg/day.

For the purpose of the risk assessment the nature of the residue has been adequately described in the available metabolism studies in grapes, tomatoes and potatoes. In grapes and tomatoes the metabolism of benthiavalicarb-isopropyl was minimal with the parent substance being the only major residue in fruit and foliage (55 - 97% TRR). The parent substance was also the principle radioactive residue in potato foliage (88 - 90% TRR) but also other minor metabolites were identified. In potatoes, the metabolism of benthiavalicarb-isopropyl occurs primarily via direct hydroxylation of the phenyl ring or via defluorination and hydroxylation of the phenyl ring. Secondary metabolism occurs via conjugation of glucuronic acid with hydroxyl groups. Although two major metabolites (> 10% TRR) were observed in potato tubers, the absolute levels of these metabolites, which were suggested to be sugar conjugates, were ≤ 0.006 mg/kg. Chiral analysis of potato foliage also indicated that there was no isomeric conversion of the parent *R-L* isomer to the other possible stereoisomers. Based on the results the residue definition for both enforcement and risk assessment is the sum of the *R-L*, *S-L*, *R-D* and *S-D* isomers. The nature of the residue in livestock was not determined as it was not required because there is no significant livestock dietary intake associated with the authorised use in potatoes and onions.

The appropriateness of the multi-residue method DFG S19 for the determination of residues of benthiavalicarb-isopropyl and the *S-L* isomer was tested in orange, lettuce, potato and rape seeds. The samples are extracted with acetone and partitioned in ethyl acetate / cyclohexane and sodium chloride. Rape seed samples were mixed with acetone and acetonitrile with synthetic calcium silicate. The organic phase is cleaned by gel permeation chromatography (GPC) on Bio Beads S-X3 polystyrene gel. Residues of benthiavalicarb-isopropyl and its *S-L* isomer are analysed by HPLC with tandem mass spectrometric detection (MS/MS). The LOQ and LOD were 0.01 and 0.003 mg/kg, respectively, for each isomer in all crops. The method was adequately validated. Independent laboratory validations of the analytical enforcement method were conducted in rape seed oil, potato starch, orange fruit and lettuce leaves fortified at 0.01 and 0.10 mg/kg with both benthiavalicarb-isopropyl and the *S-L* isomer. Residue levels were determined by HPLC with tandem mass spectrometric detection operated in MRM mode (m/z 382 → m/z 180). Average recoveries were within the range of 70 to 110% and the RSD were ≤ 20%. The LOQ and LOD were 0.01 and 0.003 mg/kg, respectively, for both isomers.

Adequate storage stability data are available indicating that benthiavalicarb-isopropyl and its *S-L* isomer are stable under frozen conditions at temperatures $\leq -18^{\circ}\text{C}$ for at least 12 months in potatoes. These data support the maximum storage intervals (1 - 4 months) from the potato and onion field trials.

The available field trial data are adequate and are representative for the authorised use patterns in potatoes and onions. The number and geographic distribution of the field trials are adequate. For potatoes, a total of 8 field trials were conducted throughout Europe, in which potatoes were treated at the maximum authorised use rate and harvested at the minimum PHI of 3 days. Residue levels of benthiavalicarb-isopropyl in potato tubers were < 0.01 mg/kg; residues of the *S-L* isomer were not detectable. For onions, 4 trials were conducted at the maximum rate and harvested at the minimum PHI of 28 days. All field trials were performed throughout Northern Europe on field-grown onions. Residue levels of benthiavalicarb-isopropyl in onion bulbs were < 0.01 mg/kg; residues of the *S-L* isomer were not detectable. The individual field trial residue values used to set the maximum residue limits (MRLs) for potatoes and bulb vegetables are provided in Table 2.1-1.

Table 2.1-1 Summary of residue data from the crop field trials

commodity	formulation ⁽¹⁾	total rate (g as/ha) ⁽²⁾	PHI (days)	region	combined residue levels of benthiavalicarb-isopropyl (mg/kg)			
					individual results	STMR	HR	MRL
potatoes	Versilus®	591 - 606	3	North	$4 \times < 0.01$	< 0.01	< 0.01	0.02
		573 - 616	3	South	$4 \times < 0.01$	< 0.01	< 0.01	
onions	Valbon®	210 - 217	28	North	$4 \times < 0.01$	< 0.01	< 0.01	0.02
		no data	-	South	no data	-	-	

⁽¹⁾ Versilus® is a wettable granule (WG) containing 150 g/kg benthiavalicarb-isopropyl;

Valbon® is a wettable granule (WG) containing 17.5 g/kg benthiavalicarb-isopropyl + 700 g/kg mancozeb

⁽²⁾ The target rate for potatoes is 600 g as/ha per season; the total rate applied is 96 - 103% of the target rate.

The target rate for onions is 168 g as/ha per season; the total rate applied is 125 - 129% of the target rate.

A chronic dietary risk assessment is conducted using EFSA's Pesticide Residue Intake Model (PRIMO version 3.0) considering potatoes, garlic, onions and shallots. Chronic exposure is calculated using a worst-case approach where it is assumed that all crops under consideration have been treated and contain residues at the level of the default MRL of 0.02 mg/kg. On the basis of European regional diets, it is estimated that the TMDIs for all considered consumer groups are not more than 0.1% of the ADI (0.1 mg/kg/day) providing a 100,000-fold safety margin for consumers. The model output is provided in Annex 1 to this document and summarized in Table 2.1-2.

Table 2.1-2 Theoretical Maximum Daily Intake for different population groups via consumption of potatoes, onions, garlic and shallots using the MRL of 0.02 mg/kg

population group	exposure ($\mu\text{g/kg bw/day}$)	calculated exposure (% of the ADI)	commodity with the highest contribution
Portugal, general population	0.114	0.11%	potatoes
Finland, 3-year old child	0.102	0.10%	potatoes
Sweden, general population	0.093	0.09%	potatoes
Romania, general population	0.091	0.09%	potatoes
the Netherlands, toddler	0.089	0.09%	potatoes
GEMS/Food G08	0.089	0.09%	potatoes
Finland, 6 year old child	0.084	0.08%	potatoes
GEMS/Food G15	0.083	0.08%	potatoes
GEMS/Food G11	0.082	0.08%	potatoes
GEMS/Food G07	0.082	0.08%	potatoes
Poland, general population	0.075	0.08%	potatoes
United Kingdom, toddler	0.075	0.07%	potatoes
GEMS/Food G10	0.072	0.07%	potatoes
the Netherlands, child	0.072	0.07%	potatoes
United Kingdom, infant	0.069	0.07%	potatoes
Lithuania, adult	0.063	0.06%	potatoes
Germany, child	0.056	0.06%	potatoes
GEMS/Food G06	0.056	0.06%	potatoes
Denmark, child	0.054	0.05%	potatoes
the Netherlands, general population	0.053	0.05%	potatoes
Ireland, adult	0.051	0.05%	potatoes

2.2 Non-dietary exposure

Dietary exposure to benthiavalicarb-isopropyl residues is negligible following the authorised uses of benthiavalicarb-isopropyl in potatoes and onions (see point 2.1). As a result, only the authorised uses on potatoes and bulb vegetables are considered in the non-dietary exposure assessments.

Versilus® is a water-dispersable granule (WG) containing 150 g/kg of benthiavalicarb-isopropyl. The product is applied to field-grown potatoes using tractor-mounted boom sprayers fitted with hydraulic nozzles for up to maximum 8 foliar applications per season at a dose rate of 0.5 l/ha (0.075 kg as/ha) per application. Valbon® is a water dispersible granule (WG) containing 17.5 g/kg benthiavalicarb-isopropyl and 700 g/kg mancozeb. Valbon® is authorised for use in field-grown bulb vegetables, including onions, shallots and garlic. The product is applied by foliar spraying using tractor-mounted boom sprayers fitted with hydraulic nozzles for up to 6 applications per season at a maximum dose rate of 1.6 kg/ha (0.028 kg as/ha) per application. Table 2.2-1 provides an overview of the uses being assessed.

Table 2.2-1 Summary of uses of benthiavalicarb considered in the exposure assessments

use	crop	formulation	outdoor or indoor	max no. of applications (interval)	application rate (kg as/ha)	spray volume (L/ha)	minimum re-entry interval	application equipment
1	potato	Versilus®	open field	8 per season (5 days)	0.075	250 - 1000	24 hours	tractor-mounted boom sprayer, downward (LCTM)
2	onion	Valbon®	open field	6 per season (7 days)	0.028	200 - 400	24 hours	tractor-mounted boom sprayer, downward (LCTM)

The repeated non-dietary exposures are related to the AOEL to provide an estimate of the extent to which the acceptable long-term exposure level is accounted for. The AOEL for benthiavalicarb-isopropyl is 0.1 mg/kg/day based on a repeated-dose toxicity NOEL value of 10 mg/kg/day from a rat developmental toxicity study and a 100-fold safety factor. The AOEL selected for the risk assessment is based on hepatotoxic effects that are the main effects of concern and is protective to the different tumour types observed in the long-term carcinogenicity studies. Although none of the observed effects were the result of a single exposure to benthiavalicarb-isopropyl, an endpoint needed to be selected for the acute bystander exposure assessment. An AAOEL value of 6.7 mg/kg/day is being proposed based on a slight effect on motor activity seen in an acute neurotoxicity at the limit dose of 2000 mg/kg. The standard 100-fold uncertainty factor for inter- and intra-species variability was increased with an additional safety factor of 3 because of the slight neurotoxic effect observed at the limit dose.

2.2.1 Operator exposure

Non-dietary exposure assessments were carried out in accordance with EFSA's *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products* (EFSA, 2014). Operator exposure is estimated using the Agricultural Operator Exposure Model (AOEM).

For the purpose of the operator exposure assessment only the worst case scenario for the authorised use of Versilus® in potatoes has been addressed. The maximum application rate is 75 g as/ha. A work rate of 50 ha per day has been assumed. A dermal absorption value of 1.23% was used for the concentrated product formulation during mixing and loading and a value of 13.1% was used for the diluted product during spraying.

The actual calculations are presented in Table 2.2-2. It should be noted that the exposure estimates generated by the AOEM model are 75th percentile values. The calculations were made assuming operators weighing 60 kg, which is believed to be a worst case assumption.

Table 2.2-2 Estimation of operator exposure in relation to the AOEL

Product:	Versilus®	Formulation type:	wettable granule (WG)	
Active substance:	benthiavalicarb-isopropyl	Concentration:	150 g/kg	
Maximum rate:	0.075 kg/ha	Area treated per day:	50 ha	
Amount handled per day:	3.75 kg			
Exposure for:	tractor sprayer, low growing crop			
Exposure (µg/kg/day) during mixing and loading		without work wear and without gloves	with work wear but without gloves	with work wear and with gloves
	hands	0.743	0.743	0.008
	body	0.641	0.012	0.012
	head	0.005	0.005	0.005
	inhalation	0.922	0.922	0.922
	sum	2.312	1.683	0.948
Exposure (µg/kg/day) during application	hands	1.214	1.214	0.190
	body	0.679	0.019	0.019
	head	0.032	0.032	0.032
	inhalation	0.033	0.033	0.033
	total	1.959	1.299	0.274
Total systemic exposure (µg/kg/day)		4.271	2.982	1.222
Total systemic exposure (% of the AOEL)		4.271	2.982	1.222
Margin of safety		2342	3356	8197

Operator exposure to Versilus® during mixing, loading and spraying does not involve a significant risk. If work wear and gloves as recommended in normal agricultural practice are used, the exposure is further minimised and accounts for only 1.22% of the AOEL providing a large 8000-fold safety margin for operators.

2.2.2 Estimation of worker exposure

Worker exposure is assessed in accordance with EFSA's *Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products* (EFSA, 2014). A summary of the uses considered for the calculations is presented in Table 2.2-1. Worker exposure is assessed against the AOEL of 0.1 mg/kg/day. A worst-case dermal absorption rate of 13.1% for the diluted spray solution is used. Three scenarios have been assessed for worker re-entry into treated crops: (1) crop inspection in potatoes, (2) hand picking of bulb vegetables and (3) crop inspection in onions. Potential exposure during mechanical harvesting of potatoes and onions is assumed to be very low and is not further addressed.

Potatoes - Crop inspection

Most crop maintenance and harvesting activities include frequent contacts with the foliage of the crop. Therefore, dermal exposure is considered to be the most important exposure route during worker re-entry into treated crops. Worker exposure estimates for the inhalation route after outdoor applications are considered unnecessary for benthiavalicarb-isopropyl as it is of low volatility. The level of dermal exposure depends on the amount of residue on foliage, the intensity of contact with the foliage and the overall duration of contact. The potential dermal exposure (*PDE*) from contact with residues on foliage is estimated as the product of the dislodgeable foliar residue (*DFR*), the transfer coefficient (*TC*) and the task duration (*T*).

$$PDE \text{ (mg/day)} = DFR \text{ (}\mu\text{g/cm}^2\text{)} \times TC \text{ (cm}^2\text{/h)} \times T \text{ (hours/day)} \div 1000$$

In a dislodgeable foliar residue study carried out at one field site in Northern France, dislodgeable foliar residues (*DFR*) of benthiavalicarb-isopropyl were measured in a potato crop (Roussel, 2015). The plot was treated with Versilus® in accordance with the authorised use for up to 8 applications with a 5-days interval at the maximum use rate of 75 g as/ha during the period from end of flowering up to 4 weeks before harvest. A maximum *DFR* value of 0.155 µg/cm² benthiavalicarb-isopropyl was measured one day after the last application. Residue levels of the *S-L* isomer were very low. Residues of benthiavalicarb-isopropyl declined rapidly to a value of 0.002 µg/cm² at 29 days after the last application. Benthiavalicarb-isopropyl residues did not accumulate in between successive applications. The foliar half-life (*DT*₅₀) of benthiavalicarb-isopropyl on potato leaves is calculated

using the US-EPA Occupational Pesticide Re-entry Exposure Calculator based on 1st order kinetics (Table 2.2-3). DFR values from six sampling events during the period from 0 to 29 days after the 8th application were used in the calculation. The foliar DT_{50} is calculated to be 5.2 days. The calculated initial residue on potato leaves after the last application is $0.069 \mu\text{g}/\text{cm}^2$ and corresponds to a normalised DFR_0 of $0.92 \mu\text{g}/\text{cm}^2$ foliage per kg active substance applied per hectare.

Table 2.2-3 Calculation of DFR_0 and DT_{50} of benthiavalicarb-isopropyl on potato leaves after eight foliar applications (US-EPA Occupational Pesticide Re-entry Exposure Calculator; January 2017)

days after last application	average <i>DFR</i> (μg/cm ²)	ln <i>DFR</i>	modelled ln <i>DFR</i>	modelled <i>DFR</i>
0	0.1116	− 2.1928	− 2.6728	0.0691
1	0.1549	− 1.8650	− 2.8070	0.0604
3	0.0323	− 3.4327	− 3.0754	0.0462
8	0.0073	− 4.9199	− 3.7466	0.0236
14	0.0069	− 4.9762	− 4.5519	0.0105
29	0.0024	− 6.0323	− 6.5653	0.0014
Residue Dissipation				
decay constant, <i>k</i> (d ^{−1})	= − 0.134			
daily dissipation (%)	= 0.126			
<i>DT</i> ₅₀ (days)	= 5.164			
Initial Residue				
<i>DFR</i> ₀ (μg/cm ²)	= 0.069			
% of application rate	= 0.092			

The calculated initial DFR value of $0.069 \mu\text{g}/\text{cm}^2$ is more than $2 \times$ lower than the maximum residue of $0.155 \mu\text{g}/\text{cm}^2$ that was observed one day after the last application (Figure 2.2-1). This maximum observed DFR_0 corresponding to $2.06 \mu\text{g}\cdot\text{ha}\cdot\text{cm}^{-2}\cdot\text{kg}^{-1}$ is used in the risk assessments for worker re-entry into treated potato crops. Since this value represents the maximum residue observed after eight applications of benthiavalicarb-isopropyl, the number of applications was set to 1 in the calculator.

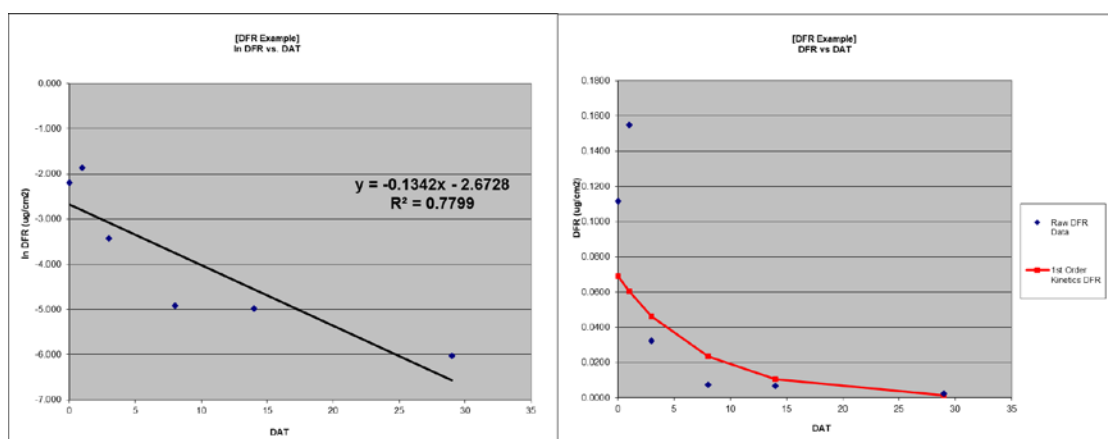


Figure 2.2-1 Decline of benthiavalicarb-isopropyl residues on potato leaves after eight applications of Versilus® (US-EPA Occupational Pesticide Re-entry Exposure Calculator; January 2017)

A default TC value of $12500 \text{ cm}^2/\text{h}$ was used in the calculation of the potential dermal exposure. Since it can however be assumed that agricultural workers will wear clothing that covers the arms, body and legs a TC value of $1400 \text{ cm}^2/\text{h}$ is used. It is believed that the lower figure represents a more realistic scenario for workers. A default exposure duration (T) of 2 hours is assumed. The calculations were made assuming workers weighing 60 kg. For the purpose of calculating the systemic exposure a dermal absorption value of 13.1% was used. Using these data the estimated worker exposure is $0.00095 \text{ mg}/\text{kg}/\text{day}$, which is equivalent to 0.94% of the AOEL. In the worst case where no work wear or gloves are worn, the estimated worker exposure is $0.00843 \text{ mg}/\text{kg}/\text{day}$, which is equivalent to 8.43% of the AOEL.

Bulb vegetables - Manual harvesting

To assess worker exposure in bulb vegetables two scenarios are selected, i.e. (1) 'bulb vegetables' representing manual harvesting and (2) 'root and tuber vegetables' representing crop inspection. The reason for the additional assessment is that like potatoes field onions are rather harvested mechanically than by hand picking.

In this assessment hand picking of bulb vegetables is nonetheless considered based on the scenario for 'bulb vegetables'. Due to the lack of specific residue data on onions, a default of DT_{50} of 30 days and a default DFR_0 of $3 \mu\text{g}/\text{cm}^2$ per kg active substance applied per hectare as recommended in the Guidance Document (EFSA, 2014) are used to assess worker exposure during hand picking of bulb vegetables. Since the assessment considers the exposure to dislodgeable foliar residues after a minimum waiting period of 28 days following 6 successive applications with a 7-day interval at a use rate of 0.028 kg as/ha, the dissipation of foliar residues over time is taken into account by applying a Multiple Application Factor (MAF) of 4.2 and a reduction of the foliar residue level by 48% resulting in a total single application rate of 0.061 kg as/ha. A standard TC value of $5800 \text{ cm}^2/\text{h}$ is used for the case where no work wear is worn and a TC value $2500 \text{ cm}^2/\text{h}$ is used for the more realistic case where workers are wearing clothing covering the arms, body and legs. The exposure duration for a typical working day is assumed to be 8 hours. For the calculation of the systemic exposure a default absorption value of 50% is used based on Valbon® being a solid formulation. The calculations show that when no work clothing is worn during hand picking of bulb vegetables, 70.7% of the AOEL is accounted for. The calculation assuming workers wearing work clothing shows that the systemic exposure accounts for 30.5% of the AOEL.

Onions - Crop inspection

In this assessment crop inspection is considered based on the scenario for 'root and tuber vegetables'. Due to the lack of specific residue data on onions, a default of DT_{50} of 30 days and a default DFR_0 of $3 \mu\text{g}/\text{cm}^2$ per kg active substance applied per hectare as recommended in the Guidance Document (EFSA, 2014) are used to assess worker exposure during crop inspection following 6 applications with a 7-day spray interval at a use rate of 0.028 kg as/ha. A standard TC value of $12500 \text{ cm}^2/\text{h}$ is used for the case where no work wear is worn and a TC value $1400 \text{ cm}^2/\text{h}$ is used for the more realistic case where workers are wearing clothing covering the arms, body and legs. The exposure duration is assumed to be 2 hours. For the calculation of the systemic exposure a default absorption value of 50% is used based on Valbon® being a solid formulation. The calculations show that when no work clothing is worn, 72.8% of the AOEL is accounted for. The calculation assuming workers wearing work clothing show that the systemic exposure accounts for 8.2% of the AOEL.

Conclusions

Exposure of agricultural workers to benthiavalicarb-isopropyl during crop maintenance or harvesting does not involve significant health risks. Where work wear is worn as used in normal agricultural practice the risks are further minimised. Safety margins (MoE) between the estimated exposure levels and the AOEL range from more than 330 up to 11000 (Table 2.2-4).

Table 2.2-4 Estimated worker exposure following application of benthiavalicarb-isopropyl to potatoes and bulb vegetables (onions)

crop - tasks	potential exposure	work wear - arms, body and legs covered (no gloves)	work wear - arms, body and legs covered (with gloves)
potato - crop inspection (re-entry interval = 24 hours)			
total systemic exposure (mg/kg /day)	0.00843	0.00094	-
percentage of the AOEL	8.43	0.94	-
Margin of Exposure (MoE)	1186	10588	-
bulb vegetables - hand-picking (re-entry interval = 28 days) (*)			
Total systemic exposure (mg/kg/day)	≤ 0.07074	≤ 0.03049	≤ 0.00707
Percentage of the AOEL	≤ 70.7	≤ 30.5	≤ 7.07
Margin of Exposure (MoE)	≥ 141.4	≥ 328.9	≥ 1414
onion - crop inspection (re-entry interval = 24 hours) (*)			
Total systemic exposure (mg/kg/day)	≤ 0.0728	≤ 0.00815	-
Percentage of the AOEL	≤ 72.8	≤ 8.15	-
Margin of Exposure (MoE)	≥ 137.4	≥ 1227	-

(*) 'worst-case' estimates based on the use of default dermal absorption value and default foliar residue data

2.2.3 Estimation of bystander exposure

For assessing the exposure of bystanders each of the following scenarios is considered: (1) exposure to spray drift at the time of application, (2) exposure from inhalation of the active substance volatilising from the plant surface after the application has been made and (3) exposure through contact with spray drift deposits. For the assessment of exposure through contact with contaminated plant surfaces following re-entry into the treated crop, reference is made to the estimation of resident exposure (see point 2.2.4). Assessments are provided for applications made to potatoes and onions using tractor-mounted boom sprayers.

Potatoes - Tractor-mounted boom sprayers

The estimation of bystander exposure to spray drift is based on data from the BREAM project. The 95th percentile values for potential dermal exposure of adult and child bystanders positioned 2 metres from the sprayer are 1.21 and 0.74 ml spray/person, respectively. Assuming protection from light clothing, the potential dermal exposure to spray drift is reduced by 18% for both adults and children. Assuming high breathing rates the values for inhalation exposure for adults and children are 0.00050 and 0.00112 ml spray/person, respectively. The calculations are made assuming a body weight of 60 kg for adults and a body weight of 10 kg for children. It is believed that the selected typical body weight for a 1- to 3-year old child represents a worst case scenario for child bystanders. The maximum application rate is 75 g as/ha. The spray volume ranges from 250 to 1000 litres per hectare with 250 litres being the worst case for bystander exposure as this gives the most concentrated spray solution (0.30 g as/L). A dermal absorption value of 13.1% is used. Using these data the estimated adult and child bystander exposures to spray drift are calculated to be 0.0007 and 0.0024 mg/kg/day, respectively. The highest of these values accounts for 0.04% of the AAOEL. The actual calculations are presented in Table 2.2-5.

Table 2.2-5 Systemic exposure of bystanders from spray drift at time of application to potatoes

parameters	children (10 kg)		adults (60 kg)	
	dermal	inhalation	dermal	inhalation
potential exposure (ml spray)	0.74	0.00112	1.21	0.00050
concentration in spray (mg as/mL)	0.30	0.30	0.30	0.30
adjustment for light clothing (%)	18	N/A	18	N/A
percentage absorption (%)	13.1	100	13.1	100
total systemic exposure (mg/day)	0.0242		0.0391	
total systemic exposure (mg/kg/day)	0.0024		0.0007	
total systemic exposure (% of the AAOEL)	0.04		0.01	

A value of $1 \mu\text{g}/\text{m}^3$ is used to predict exposure from vapour after spray application. For an adult weighing 60 kg and a 1- to 3-year old child weighing 10 kg, the breathing rates used in the calculations are 13.8 and $10.7 \text{ m}^3/\text{day}$, respectively. The potential exposures of adults and children to the pesticide vapour after application of the product would be 0.00023 and 0.00107 mg/kg/day. The highest exposure for children accounts for 0.02% of the AAOEL.

Spray drift may be deposited in gardens adjacent to the treated areas. Bystanders in such locations may become exposed through contact with such deposits. Such exposures are estimated using surface deposit data from the BREAM project and the approach used by the US EPA to estimate exposure from contact with treated lawns. Allowing a 2-m distance from the sprayer, the surface deposits are predicted to be equivalent to 8.5% of the total applied rate. The parameter values used to calculate children's hand-to-mouth and object-to-mouth exposures are presented in Annex 4. Total exposure for children is estimated as the sum of the dermal, hand-to-mouth and object-to-mouth exposure and is 0.0012 mg/kg/day accounting for 0.02% of the AAOEL. Total exposure of adults is 0.0004 mg/kg/day accounting for 0.01% of the AAOEL.

Onions - Tractor-mounted boom sprayers

The estimation of bystander exposure to spray drift is based on data from the BREAM project. The 95th percentile values for potential dermal exposure of adult and child bystanders positioned 2 metres from the sprayer are 1.21 and 0.74 ml spray/person, respectively. Assuming protection from light clothing, the potential dermal exposure to spray drift is reduced by 18% for both adults and children. Assuming high breathing rates the values for inhalation exposure for adults and children are 0.00050 and 0.00112 ml spray/person, respectively. The calculations are made assuming a body weight of 60 kg for adults and a body weight of 10 kg for children. It is believed that the selected typical body weight for a 1- to 3-year old child represents a worst case scenario for child bystanders. The maximum application rate is 28 g as/ha. The spray volume ranges from 200 to 400 litres per hectare with 200 litres being the worst case for bystander exposure as this gives the most concentrated spray solution (0.14 g as/L). In the absence of specific data, a default dermal absorption value of 50% was used based on Valbon[®] being a solid formulation. Using these data the estimated adult and child bystander exposures to spray drift are calculated to be 0.0012 and 0.0043 mg/kg/day, respectively. The highest of these value accounts for 0.06% of the AAOEL. The actual calculations are presented in Table 2.2-6.

Table 2.2-6 Systemic exposure of bystanders from spray drift at time of application to onions

parameters	children (10 kg)		adults (60 kg)	
	dermal	inhalation	dermal	inhalation
potential exposure (ml spray)	0.74	0.00112	1.21	0.00050
concentration in spray (mg as/mL)	0.14	0.14	0.14	0.14
adjustment for light clothing (%)	18	N/A	18	N/A
percentage absorption (%)	50	100	50	100
total systemic exposure (mg/day)		0.0426		0.0695
total systemic exposure (mg/kg/day)		0.0043		0.0012
total systemic exposure (% of the AAOEL)		0.06		0.02

A value of $1 \mu\text{g}/\text{m}^3$ is used to predict exposure from vapour after spray application. For an adult weighing 60 kg and a 1- to 3-year old child weighing 10 kg, the breathing rates used in the calculations are 13.8 and $10.7 \text{ m}^3/\text{day}$, respectively. The potential exposures of adults and children to the pesticide vapour after application of the product would be 0.00023 and 0.00107 mg/kg/day. The highest exposure for children accounts for 0.02% of the AAOEL.

Spray drift may be deposited in gardens adjacent to the treated areas. Bystanders in such locations may become exposed through contact with such deposits. Such exposures are estimated using surface deposit data from the BREAM project and the approach used by the US EPA to estimate exposure from contact with treated lawns. Allowing a 2-m distance from the sprayer, the surface deposits are predicted to be equivalent to 8.5% of the total amount applied. The parameters values used to calculate children's hand-to-mouth and object-to-mouth exposures are presented in Annex 4. Total exposure for children is estimated as the sum of the dermal, hand-to-mouth and object-to-mouth

exposure and amounts to 0.0028 mg/kg/day, which is 0.04% of the AAOEL. Total exposure of adults is 0.0012 mg/kg/day or 0.02% of the AAOEL.

Conclusions

Exposure of bystanders to vapours, spray drift and surface deposits is likely to be less than 0.1% of the AAOEL (Table 2.2-7). The conditions of usage of benthiavalicalarb-isopropyl as authorised pose no risk to possible bystanders.

Table 2.2-7 Estimated exposure of bystanders at a 2-m distance from the field boundary due to downward tractor-mounted boom spraying of potatoes and onions

Exposure pathways	potatoes		bulb vegetables (onions)	
	adult	child	adult	child
Bystander exposure to spray drift (95th percentile)				
Systemic exposure (mg/kg/day)	0.00065	0.00242	0.00116	0.00426
Percentage of the AAOEL	0.01%	0.04%	0.02%	0.06%
Margin of Exposure to LOAEL	3.1×10^6	826,000	1.7×10^6	469,000
Bystander exposure to vapour (95th percentile)				
Systemic exposure (mg/kg bw/day)	0.00023	0.00107	0.00023	0.00107
Percentage of the AAOEL	< 0.01%	0.02%	< 0.01%	0.02%
Margin of Exposure to LOAEL	8.7×10^6	1.9×10^6	8.7×10^6	1.9×10^6
Bystander exposure from surface deposits following spray drift (95th percentile)				
Systemic exposure via dermal route (mg/kg/day)	0.00041	0.00088	0.00119	0.00257
Systemic exposure via hand to mouth contact (mg/kg/day)	-	0.00025	-	0.00019
Systemic exposure via object to mouth contact (mg/kg/day)	-	0.00006	-	0.00004
Total systemic exposure (mg/kg/day)	0.00041	0.00120	0.00119	0.00282
Percentage of the AAOEL	0.01%	0.02%	0.02%	0.04%
Margin of Exposure to LOAEL	4.9×10^6	1.7×10^6	1.6×10^6	709,000

2.2.4 Estimation of resident exposure

For assessing the exposure of residents each of the following scenarios is considered: (1) exposure to spray drift at the time of application, (2) exposure from inhalation of the active substance volatilising from the plant surface after the application has been made, (3) exposure through contact with spray drift deposits and (4) exposure through contact with contaminated plant surfaces following re-entry into the treated crop. Assessments are provided for applications made to potatoes and onions using tractor-mounted boom sprayers.

Potatoes - Tractor-mounted boom sprayers

The estimation of resident exposure to spray drift is based on data from the BREAM project. The 75th percentile values for potential dermal exposure of adult and child residents at 2 metres from the field boundary are 0.47 and 0.33 ml spray/person, respectively. Assuming protection from light clothing, the potential dermal exposure to spray drift is reduced by 18% for both adults and children. Assuming average breathing rates the values for inhalation exposure for adults and children are 0.00010 and 0.00022 ml spray/person, respectively. The calculations are made assuming a body weight of 60 kg for adults and a body weight of 10 kg for children. It is believed that the selected typical body weight for a 1- to 3-year old child represents a worst case scenario for child residents. The maximum application rate is 75 g as/ha. The spray volume ranges from 250 to 1000 litres per hectare with 250 litres being the worst case for resident exposure as this gives the most concentrated spray solution (0.30 g as/L). A dermal absorption value of 13.1% is used. Using these data the estimated adult and child resident exposures to spray drift are calculated to be 0.0003 and 0.0011 mg/kg/day, respectively. The highest of these values accounts for 1.1% of the AOEL. The actual calculations are presented in Table 2.2-8.

Table 2.2-8 Systemic exposure of residents from spray drift at time of application to potatoes

parameters	children (10 kg)		adults (60 kg)	
	dermal	inhalation	dermal	inhalation
potential exposure (ml spray)	0.33	0.00022	0.47	0.00010
concentration in spray (mg as/mL)	0.30	0.30	0.30	0.30
adjustment for light clothing (%)	18	N/A	18	N/A
percentage absorption (%)	13.1	100	13.1	100
total systemic exposure (mg/day)	0.0106		0.0152	
total systemic exposure (mg/kg/day)	0.0011		0.0003	
total systemic exposure (% of the AOEL)	1.06		0.25	

A value of $1 \mu\text{g}/\text{m}^3$ is used to predict exposure from vapour after spray application. For an adult weighing 60 kg and a 1- to 3-year old child weighing 10 kg, the breathing rates used in the calculations are 13.8 and $10.7 \text{ m}^3/\text{day}$, respectively. The potential exposures of adults and children to the pesticide vapour after application of the product would be 0.00023 and $0.00107 \text{ mg}/\text{kg}/\text{day}$. The highest exposure for children accounts for 1.1% of the AOEL.

Spray drift may be deposited in gardens adjacent to the treated areas. Residents in such locations may become exposed through contact with such deposits. Such exposures are estimated using surface deposit data from the BREAM project and the approach used by the US EPA to estimate exposure from contact with treated lawns. At a distance of 2 m away from the field boundary, the surface deposits are predicted to be equivalent to 5.6% of the total amount applied. The parameter values used to calculate children's hand-to-mouth and object-to-mouth exposures are presented in Annex 5. Total exposure for children is estimated as the sum of the dermal, hand-to-mouth and object-to-mouth exposure and is $0.0004 \text{ mg}/\text{kg}/\text{day}$ accounting for 0.42% of the AOEL. Total exposure of adults is $0.0001 \text{ mg}/\text{kg}/\text{day}$ accounting for 0.14% of the AOEL.

For the dermal exposure from walking in a treated potato crop field, the initial dislodgeable foliar residue was re-calculated by dividing the observed *DFR* value of $0.155 \mu\text{g}/\text{cm}^2$ with the application rate of $0.075 \text{ kg as}/\text{ha}$ multiplied with a Multiple Application Factor (*MAF*). A *MAF* of 2.04 was calculated based on a foliar *DT*₅₀ of 5.2 days, 8 spray applications and a 5-days spray interval. Default *TC* values are used in the calculations and are $7500 \text{ cm}^2/\text{h}$ for adults and $2500 \text{ cm}^2/\text{h}$ for children. The exposure time is assumed to be 15 minutes. The calculated systemic exposures for children and adults are 0.0011 and $0.0006 \text{ mg}/\text{kg}/\text{day}$, respectively. The highest of these values accounts for 1.1% of the AOEL.

Total resident exposure is calculated as the sum of the exposures to spray drift, vapour, surface deposits and foliar residues. The actual calculation is presented in Annex 5. It is believed that the 75th percentile value represent an unrealistic worst-case estimate of the total exposure for residents. The calculation made is therefore based on average values. The estimated total exposures for child and adult residents account for 2.87 and 0.96% of the AOEL, respectively. Total exposure of residents to benthiavalicalarb-isopropyl does not involve a significant risk for the authorised use in potatoes.

Onions - Tractor-mounted boom sprayers

The estimation of resident exposure to spray drift is based on data from the BREAM project. The 75th percentile values for potential dermal exposure of adult and child residents at 2 metres from the field boundary are 0.47 and 0.33 ml spray/person, respectively. Assuming protection from light clothing, the potential dermal exposure to spray drift is reduced by 18% for both adults and children. Assuming high breathing rates the values for inhalation exposure for adults and children are 0.00010 and $0.00022 \text{ ml spray}/\text{person}$, respectively. The calculations are made assuming a body weight of 60 kg for adults and a body weight of 10 kg for children. It is believed that the selected typical body weight for a 1- to 3-year old child represents a worst case scenario for child bystanders. The maximum application rate is $28 \text{ g as}/\text{ha}$. The spray volume ranges from 200 to 400 litres per hectare with 200 litres being the worst case for bystander exposure as this gives the most concentrated spray solution ($0.14 \text{ g as}/\text{L}$). In the absence of specific data, a default dermal absorption value of 50% was used based on Valbon[®] being a solid formulation. Using these data the estimated adult and child resident

exposures to spray drift are calculated to be 0.0004 and 0.0019 mg/kg/day, respectively. The highest of these value accounts for 1.9% of the AOEL. The actual calculations are presented in Table 2.2-9.

Table 2.2-9 Systemic exposure of residents from spray drift at time of application to onions

parameters	children (10 kg)		adults (60 kg)	
	dermal	inhalation	dermal	inhalation
potential exposure (ml spray)	0.33	0.00022	0.47	0.00010
concentration in spray (mg as/mL)	0.14	0.14	0.14	0.14
adjustment for light clothing (%)	18	N/A	18	N/A
percentage absorption (%)	50	100	50	100
total systemic exposure (mg/day)	0.0188		0.0270	
total systemic exposure (mg/kg/day)	0.0019		0.0004	
total systemic exposure (% of the AOEL)	1.88		0.45	

A value of $1 \mu\text{g}/\text{m}^3$ is used to predict exposure from vapour after spray application. For an adult weighing 60 kg and a 1- to 3-year old child weighing 10 kg, the breathing rates used in the calculations are 13.8 and 10.7 m^3/day , respectively. The potential exposures of adults and children to the pesticide vapour after application of the product would be 0.00023 and 0.00107 mg/kg/day. The highest exposure for children accounts for 1.1% of the AOEL.

Spray drift may be deposited in gardens adjacent to the treated areas. Residents in such locations may become exposed through contact with such deposits. Such exposures are estimated using surface deposit data from the BREAM project and the approach used by the US EPA to estimate exposure from contact with treated lawns. At a distance of 2 m away from the field boundary, the surface deposits are predicted to be equivalent to 5.6% of the total amount applied. The parameters values used to calculate children's hand-to-mouth and object-to-mouth exposures are presented in Annex 5. Total exposure for children is estimated as the sum of the dermal, hand-to-mouth and object-to-mouth exposure and amounts to 0.0009 mg/kg/day, which is 0.94% of the AOEL. Total exposure of adults is 0.0004 mg/kg/day or 0.40% of the AOEL.

For the dermal exposure from walking in a treated onion crop field, the default values for initial dislodgeable residue and foliar half-life are used. The assessment is based on 6 foliar applications with a 7-day spray interval. Default TC values are used in the calculations and are $7500 \text{ cm}^2/\text{h}$ for adults and $2500 \text{ cm}^2/\text{h}$ for children. The exposure time is assumed to be 15 minutes. The calculated systemic exposures for children and adults are 0.0098 and 0.0055 mg/kg/day, respectively. The highest of these values accounts for 9.8% of the AOEL.

Total resident exposure is calculated as the sum of the exposures to spray drift, vapour, surface deposits and foliar residues. The actual calculation is presented in Annex 5. It is believed that the 75th percentile value represent an unrealistic worst-case estimate of the total exposure for residents. The calculation made is therefore based on average values. The estimated total exposures for child and adult residents account for not more than 10.6 and 5.09% of the AOEL, respectively. Total exposure of residents to benthiavalicarb-isopropyl does not involve a significant risk for the authorised use in onions.

Conclusions

Exposure of residents to spray drift, vapour, surface deposits and contact with treated foliage is likely to be less than 10% of the AOEL (Table 2.2-10). The conditions of the usage of benthiavalicarb-isopropyl as authorised pose no risk for residents.

Table 2.2-10 Estimated exposure of residents at a 2-m distance from the field boundary due to downward tractor-mounted boom spraying of potatoes and onions

Exposure pathway	potatoes		bulb vegetables (onions)	
	adult	child	adult	child
Spray drift (75th percentile)				
Systemic exposure (mg/kg/day)	0.00025	0.00106	0.00045	0.00188
Percentage of the AOEL	0.25%	1.06%	0.45%	1.88%
Margin of Exposure to NOAEL	39500	9430	22200	5319
Vapour (75th percentile)				
Systemic exposure (mg/kg/day)	0.00023	0.00107	0.00023	0.00107
Percentage of the AOEL	0.23%	1.07%	0.23%	1.07%
Margin of Exposure to NOAEL	43500	9350	43500	9350
Surface deposits (75th percentile)				
Systemic exposure via dermal route (mg/kg/day)	0.00014	0.00029	0.00040	0.00085
Systemic exposure via hand to mouth contact (mg/kg/day)	N/A	0.00008	N/A	0.00006
Systemic exposure via object to mouth contact (mg/kg/day)	N/A	0.00004	N/A	0.00003
Total systemic exposure (mg/kg/day)	0.00014	0.00042	0.00040	0.00094
Percentage of the AOEL	0.14%	0.42%	0.40%	0.94%
Margin of Exposure to NOAEL	73400	24100	25200	10600
Entry into treated crops (75th percentile)				
Systemic exposure (mg/kg bw/day)	0.000635	0.00114	0.00546	0.00983
Percentage of the AOEL	0.63%	1.14%	5.46%	9.83%
Margin of Exposure to NOAEL	15800	8760	1832	1018
All pathways (mean)				
Systemic exposure via spray drift (mg/kg/day)	0.00012	0.00059	0.00021	0.00104
Systemic exposure to vapour (mg/kg/day)	0.00023	0.00107	0.00023	0.00107
Systemic dermal exposure to surface deposit (mg/kg/day)	0.00010	0.00021	0.00029	0.00062
Systemic oral exposure via hand to mouth (mg/kg/day)	N/A	0.00006	N/A	0.00005
Systemic oral exposure via object to mouth (mg/kg/day)	N/A	0.00003	N/A	0.00002
Systemic exposure via entry into treated crops (mg/kg/day)	0.00051	0.00091	0.00435	0.00783
Systemic exposure for all pathways (mg/kg/day)	0.00096	0.00287	0.00509	0.01063
Percentage of the AOEL	0.96%	2.87%	5.09%	10.6%
Margin of Exposure to NOAEL	10500	3480	1970	941

3 NEGLIGIBLE EXPOSURE TO NON-TARGET ORGANISMS IN THE ENVIRONMENT

Negligible exposure to non-target organisms in the environment was not addressed. Benthiavalicalarb-isopropyl was not considered to have endocrine disrupting properties in accordance with the criteria under point 3.8.2 of Annex II of Regulation (EC) No 1107/2009.


4 OVERALL CONCLUSION

Regarding dietary exposure residues of benthiavalicarb-isopropyl in potato tubers and onion bulbs do not exceed the default MRL of 0.02 mg/kg under the authorised conditions of use. As for these uses negligible exposure to consumers can be assumed, the non-dietary exposure routes were assessed. For those crops for which MRL are set, a derogation on the basis of Article 4(7) of Regulation (EC) No 1107/2009 has been applied for (*cf.* Appendix C).

Following the assessment of the non-dietary exposure routes it can be concluded that there is negligible exposure and, where it is confirmed that benthiavalicarb-isopropyl satisfies the criteria for an endocrine disruptor in humans (*cf.* Appendix A) and presumed human carcinogen (Carc Cat 1B), the active substance can be approved as a Candidate for Substitution in accordance with Article 24 of Regulation (EC) No 1107/2009. Negligible exposure has been demonstrated for the use of benthiavalicarb-isopropyl on potatoes and onions by tractor-mounted boom spraying. Furthermore, no special restrictions were considered to demonstrate negligible exposure. The currently authorised products containing the active substance benthiavalicarb-isopropyl are solely intended for professional use.

Annex 1

Output of the PRIMo v.3.0 model for chronic consumer risk assessment

<div><div>European Food Safety Authority</div><div>EFSA PRIMo revision 3.0; 2017/12/11</div></div>		Input values		Supplementary results - chronic risk assessment		Details - chronic risk assessment		Supplementary results - chronic risk assessment											
				Details - acute risk assessment/children		Details - acute risk assessment/adults													
Comments:		Normal mode																	
Chronic risk assessment: JMPR methodology (IED/TMDI)																			
TMDI/NED/IED calculation (based on average food consumption)		Calculated exposure (% of ADI)		No of diets exceeding the ADI :		Commodity / group of commodities		2nd contributor to MS diet (in % of ADI)		Commodity / group of commodities		3rd contributor to MS diet (in % of ADI)		Commodity / group of commodities		Exposure resulting from MRLs set at commodities not under assessment (in % of ADI)			
0.1%		PT general		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		FI 3 yr		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		SE general		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		RO general		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		NL toddler		0.1%		Potatoes		0.0%		Onions		0.0%		Shallots		0.1%			
0.1%		GEMS/Food G08		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		FI 6 yr		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		GEMS/Food G15		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		GEMS/Food G11		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		GEMS/Food G07		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		PL general		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		UK toddler		0.1%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		GEMS/Food G10		0.1%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		NL child		0.1%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		UK infant		0.1%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		LT adult		0.1%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		DE child		0.1%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		GEMS/Food G06		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		DK child		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.1%			
0.1%		NL general		0.0%		Potatoes		0.0%		Onions		0.0%		Grapefruits		0.1%			
0.1%		IE adult		0.0%		Potatoes		0.0%		Onions		0.0%		Shallots		0.1%			
0.0%		FR toddler 2-3 yr		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		ES child		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		FR infant		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		FR child 3-15 yr		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		UK vegetarian		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		UK adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		DK adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		DE general		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		FI adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		DE women 14-50 yr		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		ES adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		IT toddler		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		FR adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		IT adult		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
0.0%		IE child		0.0%		Potatoes		0.0%		Onions		0.0%		Garlic		0.0%			
Conclusion:		The estimated long-term dietary intake (TMDI/NED/IED) was below the ADI.																	
		The long-term intake of residues of Benthiavalicarb-isopropyl is unlikely to present a public health concern.																	

Annex 2 Detailed calculations operator exposure**Annex 2.1 Potatoes - Tractor-mounted boom spraying****Annex 2.1.1 Potential Exposure and Work Wear only (no Gloves)**

Application rate of active substance		0.075 kg a.s./ha	<i>I_AppRate</i>
Assumed area treated		50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied		3.75 kg a.s./day	<i>I_AmountAS</i>
Dermal absorption of the product		1.23%	<i>I_AbsorpProduct</i>
Dermal absorption of in-use dilution		13.10%	<i>I_AbsorInuse</i>
Formulation type		Wettable granules, soluble granules	
Indoor or Outdoor application		Outdoor	
Application method		Downward spraying	
Application equipment		Vehicle-mounted	
Season		not relevant	

Mixing and loading	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
	Hands	3626	17498	AOEM	
	Body	3127	23594	AOEM	
	Head	24	336	AOEM	
	Protected hands (gloves)	39	118	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	60	233	AOEM	
	Protected head (hood and face shield)	0	19	AOEM	
	Inhalation	55	268	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	556	6034	AOEM	
	Body	311	1603	AOEM	
	Head	15	44	AOEM	
	Protected hands (gloves)	87	3888	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	9	21	AOEM	
	Inhalation	2	6	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0.2562492	0.1788963	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0042708	0.0029816	
% of RVNAS	4.27%	2.98%	
Acute			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.7898364	1.2952252	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0298306	0.0215871	
% of RVAAS	0.45%	0.32%	

Annex 2.1.2 Potential Exposure and Work Wear with Gloves

Application rate of active substance	0.075 kg a.s./ha	<i>i_AppRate</i>
Assumed area treated	50 ha/day	<i>d_AreaTreated</i>
Amount of active substance applied	3.75 kg a.s./day	<i>i_AmountAS</i>
Dermal absorption of the product	1.23%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	13.10%	<i>i_AbsorInuse</i>
Formulation type	Wettable granules, soluble granules	
Indoor or Outdoor application	Outdoor	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	
Outdoor/Wettable granules, soluble granules/Downward spraying/vehicle-mounted		

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	Hands	3626	17498	AOEM	
	Body	3127	23594	AOEM	
	Head	24	336	AOEM	
	Protected hands (gloves)	39	118	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	60	233	AOEM	
	Protected head (hood and face shield)	0	19	AOEM	
	Inhalation	55	268	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	Yes		Ind. in AOEM model	
Application	Clothing	Work wear - arms, body and legs covered		Ind. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	
	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Application	Hands	556	6034	AOEM	
	Body	311	1603	AOEM	
	Head	15	44	AOEM	
	Protected hands (gloves)	87	3888	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	9	21	AOEM	
	Inhalation	2	6	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
Gloves	Yes		Ind. in AOEM model		
Clothing	Work wear - arms, body and legs covered		Ind. in AOEM model		
Head and respiratory PPE	None		1	1	
Closed cab	No		vehicle mounted upward spraying only		

1. Total

	Without RPE/PPE	With RPE/PPE
Longer term		
Total systemic exposure from mixing, loading and application (mg a.s./day)	0.2562492	0.0732868
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0042708	0.0012214
% of RVNAS	4.27%	1.22%
Acute		
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.7898364	0.8004311
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0298306	0.0133405
% of RVAAS	0.45%	0.20%

Annex 3 Detailed calculations of worker exposure**Annex 3.1 Potatoes - Crop Inspection**

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	0.075 kg a.s./ha		<i>i_AppRate</i>
Number of applications	1		<i>i_AppNo</i>
Interval between multiple applications	365 days		<i>i_AppInt</i>
Half-life of active substance	5.2 days		<i>d_HalfLifeAS</i>
Multiple application factor	1.0		<i>d_MAF</i>
Dermal absorption of the product	1.23%		<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	13.10%		<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.1545 µg a.s./cm ²		<i>d_DFR</i>
Working hours	2 hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³		<i>d_InhalTcSort</i>
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0.5059875	0.0566706	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0084331	0.0009445	
% of RVNAS	8.43%	0.94%	
2. Details			
	Systemic exposure		Formula
	[mg a.s./day]	[mg a.s./kg bw/day]	
Dermal - Potential	0.5059875	0.0084331	$d_DermTcUCV * d_WorkHr * i_DFR * i_MAF / 1000 * i_Absorplnuse$
Dermal - Work wear - arms, body and legs covered	0.0566706	0.0009445	$d_DermTcCV1 * d_WorkHr * d_DFR * d_MAF / 1000 * i_Absorplnuse$
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTcCV2 * d_WorkHr * d_DFR * d_MAF / 1000 * i_Absorplnuse$
Inhalation			Na for outdoor activities

Annex 3.2 Bulb vegetables - Manual harvesting

Crop type	Bulb 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	0.060979314 kg a.s./ha		<i>i_AppRate</i>
Number of applications	1		<i>i_AppNo</i>
Interval between multiple applications	365 days		<i>i_AppInt</i>
Half-life of active substance	30 days		<i>d_HalfLifeAS</i>
Multiple application factor	1.0		<i>d_MAF</i>
Dermal absorption of the product	10.00%		<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%		<i>i_Absorplnuse</i>
Dislodgeable foliar residue ($i_AppRate \cdot i_DFR$)	0.182937941 µg a.s./cm ²		<i>d_DFR</i>
Working hours	8 hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr		<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³		<i>d_InhalTcSort</i>
1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	4.2441602	1.8293794	0.4244160
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0707360	0.0304897	0.0070736
% of RVNAS	70.74%	30.49%	7.07%
2. Details			
	Systemic exposure		Formula
	[mg a.s. /day]	[mg a.s./kg bw/day]	
Dermal - Potential	4.2441602	0.0707360	$d_DermTcUCV \cdot d_WorkHr \cdot i_DFR \cdot i_MAF / 1000 \cdot i_Absorplnuse$
Dermal - Work wear - arms, body and legs covered	1.8293794	0.0304897	$d_DermTcCV1 \cdot d_WorkHr \cdot d_DFR \cdot d_MAF / 1000 \cdot i_Absorplnuse$
Dermal - Working wear and gloves	0.4244160	0.0070736	$d_DermTcCV2 \cdot d_WorkHr \cdot d_DFR \cdot d_MAF / 1000 \cdot i_Absorplnuse$
Inhalation			Na for outdoor activities

application rate of active substance = $0.028 \text{ (kg/ha)} \times 4.2 \times (1 - 0.48) = 0.0601 \text{ kg as/ha}$

based on multiple application factor = 4.2

decline of foliar residue during 28 days = 48%

Annex 3.3 Onions - Crop inspection

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	0.028	kg a.s./ha		<i>i_AppRate</i>
Number of applications	6			<i>i_AppNo</i>
Interval between multiple applications	7	days		<i>i_AppInt</i>
Half-life of active substance	30	days		<i>d_HalfLifeAS</i>
Multiple application factor	4.2			<i>d_MAF</i>
Dermal absorption of the product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of the in-use dilution	50.00%			<i>i_Absorplnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.084	µg a.s./cm ²		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		<i>d_DermTcUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		<i>d_DermTcCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment			<i>d_DermTcCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcCut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 [^] (-3)		<i>d_InhalTcSort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	4.3669189	0.4890949	no TC available for this assessment	
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0727820	0.0081516		
% of RVNAS	72.78%	8.15%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s. /day]	[mg a.s./kg bw/day]		
Dermal - Potential	4.3669189	0.0727820	$d_DermTcUCV * d_WorkHr * i_DFR * i_MAF / 1000 * i_Absorplnuse$	
Dermal - Work wear - arms, body and legs covered	0.4890949	0.0081516	$d_DermTcCV1 * d_WorkHr * d_DFR * d_MAF / 1000 * i_Absorplnuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTcCV2 * d_WorkHr * d_DFR * d_MAF / 1000 * i_Absorplnuse$	
Inhalation				Na for outdoor activities

Annex 4 Detailed calculations of bystander exposure**Annex 4.1 Potatoes - Tractor-mounted boom spraying**

Croptype	Root and tuber vegetables	
Application method	Downward spraying	
Application equipment	Vehicle-mounted	<i>i_AppEquip</i>
Formulation type	Wettable granules, soluble granules	
Application rate of the product	0.075 kg a.s./ha	<i>i_AppRate</i>
Buffer strip	2-3 m	<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0.3 g a.s./l	<i>d_ConcAS</i>
Dermal absorption of product	1.23%	<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	13.10%	<i>i_AbsorpInuse</i>
Oral absorption	100.00%	<i>i_AbsorpOrallnuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.075980392 µg a.s./cm ²	<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa	<i>i_Volat</i>
Concentration in air	0.001 mg/m ³	<i>d_AirCon</i>
Bystander dermal spray drift exposure - adult	1.21 ml spray dilution/person	
Bystander dermal spray drift exposure - child	0.74 ml spray dilution/person	
Bystander inhal. spray drift exposure - adult	0.00050 ml spray dilution/person	
Bystander inhal. spray drift exposure - child	0.00112 ml spray dilution/person	
Exposure duration	2 hours	<i>d_ByExpDur</i>
Exposure duration entry into treated crops	0.25 hours	<i>d_ExpDurTreatCrap</i>
Light clothing adjustment factor	18.0%	<i>d_ClothAF</i>
Breathing rate adult	0.23 m ³ /kg bw/day	<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07 m ³ /kg bw/day	<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	8.50%	
Turf transferable residues percentage	5.00%	<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500 cm ² /hour	<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm ² /hour	<i>d_ByTCCh</i>
Saliva extraction percentage	50.00%	<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²	<i>d_AreaHM</i>
Frequency of hand to mouth activity	20 events/hour	<i>d_ByFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²	<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%	<i>d_DRP</i>
Transfer coefficient for entry into treated crops - a	7500 cm ² /h	<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - cl	2250 cm ² /h	<i>d_TcEntryCh</i>

1. Total				
1.1 1-3 year old child				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0241832	0.0107000	0.0120865	0.0113992
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0024183	0.0010700	0.0012087	0.0011399
% of RVAAS	0.04%	0.02%	0.02%	0.02%
1.2 Adult				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0391435	0.0138000	0.0246545	0.0379972
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0006524	0.0002300	0.0004109	0.0006333
% of RVAAS	0.01%	0.00%	0.01%	0.01%

* input for dislodgeable foliar residue = $DFR_0 \div (MAF \times AR) = 0.155 \text{ (}\mu\text{g.ha.cm}^{-2}.\text{kg}^{-1}\text{)} \div (2.04 \times 0.075) = 1.013 \text{ }\mu\text{g.ha.cm}^{-2}.\text{kg}^{-1}$

Annex 4.2 Onions - Tractor-mounted spraying

Croptype	Bulb vegetables			
Application method	Downward spraying			
Application equipment	Vehicle-mounted			<i>i_AppEquip</i>
Formulation type	Wettable granules, soluble granules			
Application rate of the product	0.028 kg a.s./ha			<i>i_AppRate</i>
Buffer strip	2-3 m			<i>i_Buffer</i>
Concentration of active substance (in-use dilution for liquid applications)	0.14 g a.s./l			<i>d_ConcAS</i>
Dermal absorption of product	10.00%			<i>i_AbsorpProduct</i>
Dermal absorption of in-use dilution	50.00%			<i>i_AbsorpInuse</i>
Oral absorption	100.00%			<i>i_AbsorpOrallInuse</i>
Dislodgeable foliar residue (<i>i_AppRate</i> * <i>i_DFR</i>)	0.084 µg a.s./cm ²			<i>d_DFR</i>
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa			<i>i_Volat</i>
Concentration in air	0.001 mg/m ³			<i>d_AirCon</i>
Bystander dermal spray drift exposure - adult	1.21 ml spray dilution/person			
Bystander dermal spray drift exposure - child	0.74 ml spray dilution/person			
Bystander inhal. spray drift exposure - adult	0.00050 ml spray dilution/person			
Bystander inhal. spray drift exposure - child	0.00112 ml spray dilution/person			
Exposure duration	2 hours			<i>d_ByExpDur</i>
Exposure duration entry into treated crops	0.25 hours			<i>d_ExpDurTreatCrop</i>
Light clothing adjustment factor	18.0%			<i>d_ClothAF</i>
Breathing rate adult	0.23 m ³ /kg bw/day			<i>d_BreathRAAd</i>
Breathing rate child (1-3 year old)	1.07 m ³ /kg bw/day			<i>d_BreathRCh</i>
Drift percentage on surface (90th percentile)	8.50%			
Turf transferable residues percentage	5.00%			<i>d_Turf</i>
Transfer coeff. of surface deposits-adult	14500 cm ² /hour			<i>d_ByTCAd</i>
Transfer coeff. of surface deposits-child (1-3 year old)	5200 cm ² /hour			<i>d_ByTCCh</i>
Saliva extraction percentage	50.00%			<i>d_SalExt</i>
Surface area of hands mouthed	20 cm ²			<i>d_AreaHM</i>
Frequency of hand to mouth activity	20 events/hour			<i>d_ByFreqHM</i>
Ingestion rate for mouthing of grass per day	25 cm ²			<i>d_MouthGrass</i>
Dislodgeable residues percentage transferability for object to mouth	20.00%			<i>d_DRP</i>
Transfer coefficient for entry into treated crops - a	7500 cm ² /h			<i>d_TcEntryAd</i>
Transfer coefficient for entry into treated crops - cl	2250 cm ² /h			<i>d_TcEntryCh</i>
1. Total				
1.1 1-3 year old child				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0426328	0.0107000	0.0282103	0.0982557
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0042633	0.0010700	0.0028210	0.0098256
% of RVAAS	0.06%	0.02%	0.04%	0.15%
1.2 Adult				
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Total systemic exposure (mg a.s./day)	0.0695240	0.0138000	0.0717630	0.3275189
Total systemic exposure per kg body weight (mg/kg bw/day)	0.0011587	0.0002300	0.0011961	0.0054586
% of RVAAS	0.02%	0.00%	0.02%	0.08%

Annex 5 Detailed calculations of resident exposure**Annex 5.1 Potatoes - Tractor-mounted spraying**

Croptype	Root and tuber 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	0.075 kg a.s./ha				
Concentration of active substance (in-use dilution for liquid applications)	0.3 g a.s./l				
Dermal absorption of product	1.23%				
Dermal absorption of in-use dilution	13.10%				
Oral absorption	100.00%				
Dislodgeable foliar residue (i_AppRate*_i_DFR)	0.075980392 µg a.s./cm²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa				
Concentration in air	0.001 mg/m³				
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 m³/day/kg				
Breathing rate child (1-3 year old)	1.07 m³/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 cm²/hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				
Saliva extraction percentage	50.00%				
Surface area of hands mouthed	20 cm²				
Frequency of hand to mouth activity	9.5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm²				
Dislodgeable residues percentage transferability for object to mouth	20.00%				
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				
1. Total					
1.1 1-3 year old child					
Spray drift (75th percentile)		Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0106039	0.0107000	0.0041525	0.0113992	0.0286808
Total systemic exposure per kg body weight	0.0010604	0.0010700	0.0004152	0.0011399	0.0028681
% of RVNAS	1.06%	1.07%	0.42%	1.14%	2.87%
1.2 Adult					
Spray drift		Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0151762	0.0138000	0.0081775	0.0379972	0.0573027
Total systemic exposure per kg body weight	0.0002529	0.0002300	0.0001363	0.0006333	0.0009550
% of RVNAS	0.25%	0.23%	0.14%	0.63%	0.96%

* input for dislodgeable foliar residue = $DFR_0 \div (MAF \times AR) = 0.155 (\mu\text{g} \cdot \text{ha} \cdot \text{cm}^{-2} \cdot \text{kg}^{-1}) \div (2.04 \times 0.075) = 1.013 \mu\text{g} \cdot \text{ha} \cdot \text{cm}^{-2} \cdot \text{kg}^{-1}$

Croptype	Bulb vegetables				
Application method	Downward spraying				
Application equipment	Vehicle-mounted				i_AppEquip
Formulation type	Wettable granules, soluble granules				i_FormVal
Buffer strip	2-3 m				i_Buffer
Application rate of the product	0.028 kg a.s./ha				i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0.14 g a.s./l				d_ConcAS
Dermal absorption of product	10.00%				i_AbsorpProduct
Dermal absorption of in-use dilution	50.00%				i_AbsorpInuse
Oral absorption	100.00%				i_AbsorpOrallnuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	0.084 µg a.s./cm²				d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa			i_Volat
Concentration in air	0.001 mg/m³				d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	0.47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0.327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0.00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0.00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0.22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0.18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0.00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0.00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ReExpDur
Exposure duration inhalation	24 hours				d_ReExpDurlnhal
Exposure duration entry into treated crops	0.25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%				d_ClothAF
Breathing rate adult	0.23 m³/day/kg				d_BreathRad
Breathing rate child (1-3 year old)	1.07 m³/day/kg				d_BreathRCh
Drift percentage on surface (75th percentile)	5.60%				
Drift percentage on surface (mean)	4.10%				
Turf transferable residues percentage	5.00%				d_Turf
Transfer coeff. of surface deposits-adult	7300 cm²/hour				d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour				d_ReTCCCh
Saliva extraction percentage	50.00%				d_SalExt
Surface area of hands mouthed	20 cm²				d_AreaaHM
Frequency of hand to mouth activity	9.5 events/hour				d_ReFreqHM
Ingestion rate for mouthing of grass per day	25 cm²				d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - chi	2250 cm²/h				d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h				d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h				d_TcEntryCh
1. Total					
1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0188006	0.0107000	0.0094232	0.0982557	0.1062975
Total systemic exposure per kg body weight	0.0018801	0.0010700	0.0009423	0.0098256	0.0106297
% of RVNAS	1.88%	1.07%	0.94%	9.83%	10.63%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.0269920	0.0138000	0.0238026	0.3275189	0.3051918
Total systemic exposure per kg body weight	0.0004499	0.0002300	0.0003967	0.0054586	0.0050865
% of RVNAS	0.45%	0.23%	0.40%	5.46%	5.09%