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NON-DIETARY RISK ASSESSMENT FOR THE SUPPORTED USES OF THE PRODUCTS:

Bumper 250 EC/Principle 250 EC/Propin 250 EC

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Executive summary

A risk assessment has been conducted in accordance with the newly updated EFSA (2022) guidance[1] on the assessment of exposure of operators, workers, residents, and bystanders to plant protection products.

The EFSA (2022) guidance document is designed to assist risk assessors when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). To support users in performing the assessment of exposure and risk, an online calculator (reflecting the guidance content) was also developed. The underlying principles of the guidance document and the related exposure calculator are the transparency of data, the traceability of information and the reproducibility of the outcomes. In establishing the guidance document and calculator, the EFSA working group considered only databases of raw data or peer-reviewed publications that could be accessed (if requested) by third parties in accordance with the Aarhus Convention[2]. The EFSA guidance is based on a comprehensive, peer reviewed dataset and is continually reviewed and amended as and when new data become available.

Considering the above, the EFSA web calculator has been selected as the most appropriate model to assess non-dietary exposure to propiconazole resulting from the application of the product Bumper 250 EC / Principle 250 EC / Propin 250 EC using vehicle mounted and/or handheld spraying equipment.

The EFSA web calculator is publicly available and accessible at: https://r4eu.efsa.europa.eu/

Exposure to propiconazole resulting from the aerial application of the product to field crops has been estimated using a combination of data taken from the EFSA model (mixing and loading activities) and the US EPA Occupational Pesticide Handler Exposure Surrogate Reference Table[3] (application by fixed wing aircraft). The EFSA mixing and loading data for large-scale equipment are considered the most representative dataset for mix/load activities that would occur prior to aerial application. The US EPA exposure values for fixed wing aerial applications are derived from the Agricultural Handler Exposure Task Force (AHETF). For other areas of the risk assessment (residents/bystander exposure) the risk assessment relies upon US EPA Pesticide Handler Exposure Database (PHED) data for 'flaggers' (ground-based individuals marking target crops during aerial spraying activities).

The data used in the calculations is openly available and is detailed in the Exposure Surrogate Reference Table for Pesticide Risk Assessment (US EPA) with further details of the exposure calculations are provided in the appendix. As the US AHETF model data only provides a mean statistical output, it is only possible to assess longer term exposure with this model.

The assessment confirms an acceptable risk assessment can be achieved for the products Bumper 250 EC/Principle 250 EC/Propin 250 EC for the proposed uses on orchard and field crops. A summary of the risk assessment for operators, workers, residents and bystanders is presented in the tables below.

[1] EFSA (2022) Guidance on the assessment of exposure of operators, workers, residents, and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032
[2] UN (1998) Convention on access to information, public participation in decision making and access to justice in environmental matters.
[3] US EPA (2021) Occupation Pesticide Handler Unit Exposure Surrogate Reference Table (May 2021)

Wheat, barley

	Result	PPE **/ Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted and aerial equipment: Gloves during mixing/loading Hand-held equipment: None*
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Pecan nuts

	Result	PPE **/ Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted equipment: Gloves during mixing/loading and application Hand-held equipment: Gloves and face shield during mixing/loading and gloves and rainsuit during application
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Mango

	Result	PPE** / Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted spray equipment: Gloves during mixing/loading and application Hand-held equipment: Gloves and face shield during mixing/loading and gloves and rainsuit during application
Workers	Acceptable	None*
Residents	Acceptable	None
Bystanders	Acceptable	None

None* means no PPE required but standard workwear (arms, body and legs covered)

Apricot, Cherry, Peach, Plum

	Result	PPE** / Risk mitigation measures
Operators	Acceptable	**Results of risk assessment:** Vehicle mounted spray equipment: Gloves during mixing/loading and application Hand-held equipment: Gloves and face shield during

	Result	PPE** / Risk mitigation measures
		mixing/loading and gloves and rainsuit during application.
Workers	Acceptable	No re-entry restrictions when Gloves are worn when handling treated crops
Residents	Acceptable	None
Bystanders	Acceptable	None

For workers, standard workwear (arms, body and legs covered) and additional PPE required, in this instance, gloves.

** PPE = Personal Protective Equipment

Potential precautionary measures based on classification and labelling:

The products Bumper 250 EC / Principle 250 EC / Propin 250 EC contain 250 g/L of the active substance propiconazole which is classified as a skin sensitizer (Category 1) [4].

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[5] and Regulation (EC) No 1272/2008 stipulates that in the absence of product specific data, mixtures containing substances (or mixtures of substances) are considered as sensitizing, if at least one of the ingredients is present at or above the appropriate generic cut-off value/concentration limits detailed in Table 3.4.5 of the GHS (2023) guidance document. The GHS generic concentration limit is 1% for substances (or mixtures of substances) classified as category 1 skin sensitizers. Therefore, where product specific data is not available, the concentrated products may be classified as potential skin sensitizers (Category 1).

The maximum proposed in-use spray dilutions of the products contain propiconazole (0.5%) below the 1% generic concentration limit for skin sensitization classification.

Thus, the spray solutions of the plant protection products in the evaluation are not considered as sensitizers for residents and bystanders or workers as they are only exposed to the diluted sprays.

If the product is warranted a skin sensitization classification (Category 1) then protective gloves, protective clothing and eye protection/face protection should be worn by the operator for mixing and loading.

It is noted that all users of pesticides should in any case comply with "SANS 10206 :2020. Ed 3". The handling, storage and disposal of pesticides" and that the above-mentioned PPEs for sensitizer for mixing and loading activities are strongly recommended in all cases when handling pesticides to provide additional protection against spills and splashes.

[4] ECHA (2016) Committee for Risk Assessment Annex 1 – Background document to the Opinion proposing harmonized classification and labelling at EU level of propiconazole (ISO): CAS Number: 60207-90-1. CLH-O-0000001412-86-139/F.

[5] United Nations (2023) Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Tenth revised edition.

Non-dietary risk assessment

Non-dietary risk assessments have been undertaken for the product considering the endpoints listed below in Table 1 and the product uses detailed in Table 2 (proposed GAP).

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

Product code and name	Bumper 250 EC/Principle 250 EC/Propin 250 EC
Formulation type	Emulsifiable concentrate (EC)
Category	Fungicide
Active substance (incl. content)	Propiconazole 250 g/L
AOEL systemic	0.1 mg/kg bw/d
AAOEL systemic	0.3 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	EFSA (2017)[6] default dermal absorption values for an EC formulation: Concentrate: 25% Dilution: 70%

Table 2: Identified GAP for the product Bumper 250 EC/Principle 250 EC/Propin 250 EC

Use No.	**Crop and/or situation**	**F, Fn, Fpn G, Gn, Gpn or I**	**Application**				**Application rate**			**PHI** (days)
			Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	
1	Pecan nuts	F	Foliar Spray (ground application)	1st application BBCH 15 2nd application 10 days after T1 3rd application 21 days after T2	3	10-21 days	a) 0.5-1.0 b) 1.5-3.0	a) 125-250 b) 375-750	1000 - 2000	90
2	Mango	F	Foliar Spray (ground application)	BBCH 65-70	2	10-14 days	a) 0.3 b) 0.6	a) 75 b) 150	1500	120
3	Apricot, Cherry, Peach, Plum	F	Foliar Spray (ground application)	BBCH 55-69	3	7 days	a) 0.4 b) 1.2	a) 100 b) 300	2000	10/14
4	Cherry, Peach	F	Foliar Spray (ground application)	BBCH 10-39, 60, 65, 69 and 91-97	3	14 days	a) 0.6 b) 1.8	a) 150 b) 450	3000	10/14

[6] EFSA (2017) Guidance on dermal absorption: EFSA Journal 2017;15(6):4873, 60 pp.

Use No.	Crop and/or situation	F, Fn, Fpn G, Gn, Gpn or I	Application				Application rate			PHI (days)
			Method/Kind	Timing/Growth stage of crop & season	Max. number per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	
5	Wheat	F	Foliar Spray (ground & aerial application)	BBCH 29-59	2 per crop	10 days	0.6	a) 150 b) 300	300 (aerial application: 30 L/ha water volume)	40
6	Barley	F	Foliar Spray (ground & aerial application)	BBCH 25-59	2 per crop	10 days	0.5	a) 125 b) 250	300 (aerial application: 30 L/ha water volume)	40

The worst case for the operator is given for the highest application rate (maximum individual dose) for each proposed application method.

- The outdoor application to pecan nuts is presented as the worst case for upward, vehicle mounted and manual handheld spray applications to high crops.
- The outdoor application to wheat is presented as the worst case for downward, vehicle mounted applications to low crops.
- The outdoor application to wheat is presented as the worst case for aerial spray applications to low crops.

The following worker exposure scenarios have been presented:

- Re-entry activities (searching/reaching/picking and inspection/irrigation tasks) in pecan nuts.
- Re-entry activities (searching/reaching/picking and inspection/irrigation tasks) in mango crops.
- Re-entry activities (maintenance/thinning, searching/reaching/picking and inspection/irrigation tasks) in cherry and peach crops. This assessment covers the proposed application to apricot and plum (Use 3).
- Re-entry activities (inspection/irrigation tasks) in wheat crops. Wheat crops represents the maximum application rate for cereal applications.

For further details regarding the selected re-entry activity tasks that have been assessed for each crop type, please refer to the worker exposure section below.

The worst case for bystanders and residents is given by the highest application rate and multiple applications to high crops; therefore, application to pecan nuts is presented as the worst case for outdoor ground spray applications. An assessment has also been undertaken considering bystander/resident exposure resulting from the aerial application of the product to wheat crops (highest aerial application rate).

Detailed exposure estimates/model outputs are provided separately in the downloaded report generated by the EFSA OPEX Web calculator. A table cross-referencing the summary results

present below and the uses/model outputs detailed in the EFSA generated report is contained in Appendix 1. An input parameter zip file that may be uploaded to the online web calculator to replicate the modelling undertaken is also provided (EFSA model may be accessed at: https://r4eu.efsa.europa.eu/app/ope).

Operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance during application of the product is presented in Table 3. The outcome of the estimation is presented in Tables 4, 5, 6 & 7. Detailed calculations are referenced in Appendix 1.

As there is no harmonised approach for estimating levels of exposure for operators applying plant protection products with aircraft, levels of exposure have been predicted using a combination of data taken from the EFSA AOEM model (mixing and loading) and the US EPA Occupational Pesticide Handler Exposure Surrogate Reference Table (application by fixed wing aircraft). As the US AHETF data set only provides mean exposure statistical values, it is only possible to assess longer term exposure with this model.

Table 3: Exposure models for intended uses

Critical uses:	Pecan nuts: 1L product/ha equivalent to 0.25 kg/ha propiconazole *Normal spacing* Vehicle mounted (upward) spray application outdoors Manual hand held (upward) spray application outdoors Manual knapsack (upward) spray application outdoors *Dense spacing* Manual hand held (upward) spray application outdoors Manual knapsack (upward) spray application outdoors
	Wheat: 0.6L product/ha equivalent to 0.15 kg/ha propiconazole Vehicle mounted (downward) spray application outdoors.
Model:	EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 Web calculator version: v 1.0.2
Critical uses:	Wheat: 0.6L product/ha equivalent to 0.15 kg/ha propiconazole Aerial spray application outdoors (fixed wing)
Model:	Mixing/loading: EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 Aerial application (fixed wing) US Environmental Protection Agency Office of Pesticide Programs. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table. May 2021. Exposure Surrogate Reference Table for Pesticide Risk Assessment | US EPA

Table 4: Estimated operator exposure (short-term or 'sub-chronic' exposure)

Model data	Level of PPE	Propiconazole	
		Total absorbed dose (mg/kg/day)	% of systemic AOEL
Vehicle mounted (downward) spray application outdoors to low crops			
Application rate and crop		0.15 kg a.s./ha (wheat)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L* and A**	0.1	139
	Work wear (arms, body and legs covered) and gloves M/L. Workwear (only) A	0.02	17
Vehicle mounted (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.2	167
	Work wear (arms, body and legs covered) and gloves M/L and A	0.04	41.2
Manual hand held (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.08	80.9
Manual knapsack (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.06	63.6
Manual hand held (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.6	616
	Work wear (arms, body and legs covered), gloves and respirator (FP2/P2) M/L and A	0.5	533
Manual knapsack (upward) spray application outdoors to high crops. Dense cultivation			

Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.6	642
	Work wear (arms, body and legs covered), gloves and respirator (FP2/P2) M/L and A	0.5	533
Aerial (fixed wing) application to cereal crops			
Application rate and crop		0.15 kg a.s./ha (wheat)	
Mixing/loading (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered)	0.1	126
	Work wear (arms, body and legs covered) and gloves	0.004	3.5
Spray application (US AHETF; mean) Body weight: 60 kg	Work wear (closed cockpit)	0.0008	0.81
Total Mixing and loading + aerial application	Work wear (arms, body and legs covered) and gloves M/L. Work wear A	0.004	4.3

*M/L: Mixing and loading
**A: Application

Table 5: Estimated operator exposure (acute exposure)

Model data	**Level of PPE**	**Propiconazole**	
		Total absorbed dose (mg/kg/day)	**% of systemic AAOEL**
Vehicle mounted (downward) spray application outdoors to low crops			
Application rate and crop		0.15 kg a.s./ha (wheat)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.6	203
	Work wear (arms, body and legs covered) and gloves M/L. Workwear (only) A	0.2	51
Vehicle mounted (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.6	210

	Work wear (arms, body and legs covered) and gloves M/L and A	0.3	86.4
Manual handheld (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.3	85.6
Manual knapsack (upward) spray application outdoors to high crops. Normal cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.2	57.3
Manual handheld (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	2.3	782
	Work wear (arms, body and legs covered), gloves and respirator (FP2/P2) M/L and A	2.2	732
Manual knapsack (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	2.4	803
	Work wear (arms, body and legs covered), gloves and respirator (FP2/P2) M/L and A	2.2	731

Except for the outdoor, manual applications to high (late season) crops (pecan nuts), levels of exposure to propiconazole in operators are predicted to be within the AOEL/AAOEL for all proposed application methods and crops when appropriate PPE (described above) are worn when handling the concentrate and when applying the spray solution. Aerial application is expected to result in lower operator exposure than tractor mounted application to high crops and this has been demonstrated by the modelling results detailed above.

For field/outdoor manual application to high crops, the EFSA model relies on different exposure data to model the operator exposure scenarios at early and late stage for orchards. For the early season scenario, exposure estimations are calculated with the 2021 outdoor EFSA Agricultural Operator Exposure Model (AOEM) based on no foliage for both manual handheld and knapsack applications.

For the late season scenario, the dense foliage data that underpins the outdoor high-crop hand-held (HCHH) exposure calculation using the outdoor EFSA model is not deemed suitable for predicting the operator exposure following manual application of the product to pecan nuts (critical GAP covering all proposed orchard uses) for the following reasons:

- The exposure modelling is based upon a small dataset and cannot be utilised as surrogate data, extrapolated to all use scenarios. As described by BfR in the joint development of a new AOEM, the dense foliage scenario available for orchards in the outdoor EFSA model (2021) is based on two studies only: HCHH 2 and HCHH 3; and only one active substance no longer approved for use in Europe. In brief, carbaryl was applied on dense citrus at a high rate of 6.7 to 16.1 kg a.s./ha and 5.3 to 19.2 kg a.s./ha in the respective studies.

- The maximum application rate of propiconazole to pecan nuts is 0.250 kg a.s./ha. The use rate is **21 times** lower than the minimum applied from EFSA AOEM HCHH dense foliage study data (5.3 kg/ha compared with 0.250 kg/ha). Therefore, due to the small set of studies conducted at such high rates, the outdoor EFSA AOEM cannot reliably interpolate exposure predictions for the correct (lower) application rates. As such, using an arbitrarily high surrogate exposure from the outdoor EFSA AOEM calculation leads to unrealistic exposure estimations.

In view of the lack of robustness of the EFSA model for outdoors application to dense orchard crops, the new 2021 EFSA Greenhouse Agricultural Operator Exposure Model (AOEM) has been used to demonstrate an alternative and more representative calculation of operator exposure to propiconazole following the manual application of the product on dense foliage.

The EFSA Greenhouse AOEM is based on a modern database of exposure studies with a more diverse range of studies that better reflects a predictive, generic exposure model. Whilst these data were generated from applications made to indoor crops, it is expected that levels of exposure would be similar for field applications as comparable equipment and sprayer technique is used. The scenario for high crop, intensive contact with a treated crop is deemed suitable to represent the handheld application on a dense orchard (pecan nuts) as a spray is targeted upwards to vertical crops where high dermal contact is anticipated and therefore, a similar level of contact is expected during the application.

In addition, this model mitigates exposure by utilising more protective PPE which are more appropriate for intensive contact with the crop, i.e., use of impervious clothing and gloves for mixing/ loading and application, for which exposure data is not available for the dense foliage scenario in the outdoor EFSA AOEM. The revised assessment is detailed below in Tables 6 and 7.

Table 6: Estimated operator exposure (short-term or 'sub-chronic' exposure) – Application to outdoor dense crops (pecan nuts) – Tier 2

Model data	Level of PPE	Propiconazole	
		Total absorbed dose (mg/kg/day)	% of systemic AOEL
Manual handheld (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (Greenhouse AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	2.1	2135
	Work wear (arms, body and legs covered), gloves and faceshield M/L. Rain suit and gloves A.	0.02	22.2
Manual knapsack (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (Greenhouse AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	2.2	2161
	Work wear (arms, body and legs covered), gloves and faceshield M/L. Rain suit and gloves A.	0.02	22.7

Table 7: Estimated operator exposure (acute exposure) – Application to outdoor dense crops (pecan nuts) – Tier 2

Model data	Level of PPE	Propiconazole	
		Total absorbed dose (mg/kg/day)	% of systemic AAOEL
Manual handheld (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	
Spray application (Greenhouse AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	4.5	1489
	Work wear (arms, body and legs covered), gloves and faceshield M/L. Rain suit and gloves A.	0.1	34.6
Manual knapsack (upward) spray application outdoors to high crops. Dense cultivation			
Application rate and crop		0.25 kg a.s./ha (pecan nuts)	

Spray application (Greenhouse AOEM; 95th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	4.5	1509
	Work wear (arms, body and legs covered), gloves and faceshield M/L. Rain suit and gloves A.	0.1	34.1

The exposure assessment for use on pecan nuts confirms an acceptable risk assessment is achieved for late season (dense canopy) applications where a rainsuit and gloves is worn for the spray application task in addition to gloves and face shield during mixing/loading tasks. The practicalities of using this type of PPE garment (rainsuit) mean that spray operators would perform these spray tasks early in the morning when ambient temperatures will be cooler. This pattern of behavior is no different to spray applications made to greenhouse crops where high temperatures during the warmer months of the year also dictates when spray applications can be made.

Worker exposure

Table 8 shows the exposure model used for the estimation of worker exposure after entry into a previously treated area or handling a crop treated with propiconazole according to the critical uses. For the worker risk assessment, it is assumed that the individual re-enters the treated crop immediately after the final product application has dried.

In addition to estimating worker exposure estimates, the EFSA Web calculator also derives a 'safe re-entry' interval (days) for each assessed task. The 'safe re-entry interval' is defined as the specific time point post application, after which the estimated worker exposure level would fall below the AOEL for the considered re-entry task/PPE combination. Where, the estimated level of worker exposure exceeds the AOEL, the required 'safe re-entry interval' has been presented in the following results tables. This re-entry interval may then be compared to the relevant PHI to determine if the proposed use is acceptable. For the sake of clarity, each assessed crop type has been presented separately, in turn below. Detailed calculations/model outputs are referenced in Appendix 1.

An acute AOEL has been set for propiconazole, however there is no guidance available on acute exposure assessment for the worker. Consequently, no acute risk assessment has been provided for this active substance.

Table 8: Exposure models for intended uses

Critical uses	Pecan nuts (3 x 1 L product/ha equivalent to 3 x 0.25 kg/ha propiconazole)
	Mango (2 x 0.3 L product/ha equivalent to 2 x 0.075 kg/ha propiconazole)
	Cherry, Peach (3 x 0.6 L product/ha equivalent to 3 x 0.15 kg/ha propiconazole)
	Wheat (2 x 0.6 L product/ha equivalent to 2 x 0.15 kg/ha propiconazole)
Model	EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 Web calculator version: v 1.0.2

Critical use: Pecan nuts (3 x 1 L product/ha equivalent to 3 x 0.25 kg/ha propiconazole)

The following assessment has considered an individual performing either searching/reaching/picking or inspection/irrigation tasks in treated pecan crops. It is noted that pecan nuts are typically mechanically harvested using tractor mounted equipment that shakes the trees and collects the fallen nuts. The following manual hand-harvesting assessment (searching/reaching/picking) is provided for information purposes only. Maintenance/thinning tasks (pruning) are conducted over the winter months prior to the application of the product; exposure to treated foliage would not occur during such maintenance activities.

Table 9: Estimated worker exposure: Pecan nuts.

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Safe re-entry interval (days) required
Number of applications and application rate:		3 x 0.25 kg a.s./ha		
Task: Searching, reaching, picking (outdoors) Work rate: 8 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 10 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	2.1	2118	133
	Work wear (arms, body and legs covered) TC: 3500 cm^2/person/h	0.6	593	78
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm^2/person/h	0.2	212	33
Number of applications and application rate:		3 x 0.25 kg a.s./ha		
Task: Inspection, irrigation Work rate: 2 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 10 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	0.5	529	73
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.06	59.3	0

Conclusion: Pecan nuts

Levels of exposure to propiconazole are predicted to be within the AOEL when workwear (long sleeved) is worn during inspection/irrigation activities. A safe re-entry interval of 33 days is required before an individual could harvest pecan nuts whilst wearing workwear (long sleeved) and gloves. A re-entry interval of 78 days is required when only workwear (long sleeved) is worn. These re-entry intervals are shorter than the PHI of 90 days; exposure to propiconazole resulting from hand harvesting activities will be within acceptable levels where the PHI of 90 days is followed. NB: Pecan nuts are typically mechanically harvested using tractor mounted equipment; hand harvesting activities are not envisaged.

Critical use: Mango (2 x 0.3 L product/ha equivalent to 2 x 0.075 kg/ha propiconazole)

The following assessment has considered an individual performing either searching/reaching/picking or inspection/irrigation tasks in mango crops. Maintenance/thinning tasks (pruning) are conducted over the winter months prior to the application of the product; exposure to treated foliage would not occur during such maintenance activities.

Table 10: Estimated worker exposure: Mango

Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Safe re-entry interval (days) required**
Number of applications and application rate:		2 x 0.075 kg a.s./ha		
Task: Searching, reaching, picking (outdoors) Work rate: 8 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 10 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	0.5	470	67
	Work wear (arms, body and legs covered) TC: 3500 cm^2/person/h	0.1	132	12
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm^2/person/h	0.05	47	0
Number of applications and application rate:		2 x 0.075 kg a.s./ha		
Task: Inspection, irrigation Work rate: 2 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 10 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	0.1	117	7
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.01	13.2	0

Conclusion: Mango

Levels of exposure to propiconazole are predicted to be within the AOEL when workwear (long sleeved) is worn during inspection/irrigation activities.

A safe re-entry interval of 12 days is required before an individual could harvest mangos whilst wearing workwear (long sleeved) only. No re-entry interval is required for harvesting activities when workwear (long sleeved) and gloves are worn. The required re-entry interval of 12 days is shorter than the PHI of 120 days; exposure to propiconazole resulting from hand harvesting activities will be within acceptable levels for an individual wearing workwear (only) when the PHI of 120 days is followed.

Critical use: Cherry, Peach (3 x 0.6 L product/ha equivalent to 3 x 0.15 kg/ha propiconazole)

The following assessment has considered an individual performing either maintenance/thinning (pruning), searching/reaching/picking or inspection/irrigation tasks in stone fruit crops. Maintenance/thinning tasks (pruning) are predominately conducted over the winter months prior to the application of the product. However, a very light summer pruning of early shoots (referred to as 'topping') may occur following early season (blossom) applications. Therefore, the following maintenance/thinning evaluation considers an individual re-entering the treated crop following an initial (single) application of the product.

Table 11: Estimated worker exposure: Cherry, Peach

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Safe re-entry interval (days) required
Number of applications and application rate:		1 x 0.15 kg a.s./ha		
Task: Maintenance/thinning (outdoors) Work rate: 8 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: n/a days Dermal absorption: 70%	Total potential exposure TC: 22500 cm^2/person/h	0.9	945	98
	Work wear (arms, body and legs covered) TC: 4500 cm^2/person/h	0.2	189	28
	Work wear (arms, body and legs covered) and gloves TC: 2250 cm^2/person/h	0.09	94.5	0
Number of applications and application rate:		3 x 0.15 kg a.s./ha		
Task: Searching, reaching, picking (outdoors) Work rate: 8 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 14 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	1.2	1181	107
	Work wear (arms, body and legs covered) TC: 3500 cm^2/person/h	0.3	331	52
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm^2/person/h	0.1	118	8
Number of applications and application rate:		3 x 0.15 kg a.s./ha		
Task: Inspection, irrigation Work rate: 2 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 14 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	0.3	295	47
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.03	33.1	0

Conclusion: Cherry, Peach

Levels of exposure to propiconazole are predicted to be within the AOEL when workwear (long sleeved) is worn during inspection/irrigation activities. Exposure to propiconzole is also within acceptable levels when workwear (long sleeved) and gloves are worn during maintenance/thinning activities. A safe re-entry interval of 8 days is required before an individual could harvest stone fruit whilst wearing workwear (long sleeved) and gloves. The required re-entry interval of 8 days is shorter than the PHI of 10 days. Exposure to propiconazole resulting from hand harvesting activities will be within acceptable levels for an individual wearing workwear and gloves when the PHI of 10 days is followed.

Critical use: Wheat (2 x 0.6 L product/ha equivalent to 2 x 0.15 kg/ha propiconazole)

The following assessment has considered an individual performing inspection/irrigation tasks in wheat crops.

Table 12: Estimated worker exposure: Wheat

Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**	**Safe re-entry interval (days) required**
Number of applications and application rate:		2 x 0.15 kg a.s./ha		
Task: Inspection, irrigation Work rate: 2 hours/day Body weight: 60 kg DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application interval: 10 days Dermal absorption: 70%	Total potential exposure TC: 12500 cm^2/person/h	0.2	235	37
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.03	26.3	0

Conclusion: Wheat

Levels of exposure to propiconazole in workers are predicted to be within the AOEL when workwear (long sleeved) is worn during crop re-entry activities.

Resident / Bystander exposure

A summary of the exposure models used for estimation of resident and bystander exposure to the active substance according to the critical use is presented in Table 13. The outcome of the estimations are presented in Tables 14, 15 and 16. Detailed calculations are referenced in Appendix 1.

Exposure to bystanders resulting from the aerial application of the product to cereal crops has been assessed using data from the US Pesticide Handler Exposure Database (PHED). The PHED contains exposure values for people on the ground who may be involved in marking

out the treatment area and are present during spraying (called 'flaggers'). Exposure to bystanders has been evaluated using the PHED 'Flagger scenario' model. This is considered a conservative evaluation approach as bystanders are likely to be exposed for shorter periods of time than 'flaggers'. Resident exposure to aerial applications is not foreseen; aerial applications are not undertaken near residential dwellings.

Table 13: Exposure models for intended uses

Critical uses	Pecan nuts (3 x 1 L product/ha equivalent to 3 x 0.25 kg/ha propiconazole) Minimum water volume: 1000 L/ha Vehicle mounted upward spray application
Model	EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032 Web calculator version: v 1.0.2
Critical uses	Wheat: (2 x 0.6L product/ha equivalent to 2 x 0.15 kg/ha propiconazole) Minimum water volume: 30 L/ha Aerial spray application outdoors (fixed wing)
Model	Aerial application (flagger dataset)* US Environmental Protection Agency Office of Pesticide Programs. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table. May 2021. Exposure Surrogate Reference Table for Pesticide Risk Assessment | US EPA

* Inhalation exposure has been assessed using the 'worst case' 'best fit' exposure value detailed in previous iterations of the US EPA Exposure Surrogate Reference Table (2018 version)

Table 14: Estimated resident exposure (EFSA guidance): ground application

Model data		**Propiconazole**	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
Vehicle mounted upward spray application outdoors (early season) Buffer: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Dermal absorption: 70%			
Application rate:		3 x 0.25 kg a.s./ha (pecan nuts)	
Vapour pressure		5.6 x 10^{-5} Pa at 25°C	
Resident (child) Body weight: 10 kg	Drift (75th perc.)	0.02	24.3
	Vapour (75th perc.)	0.0008	0.8
	Deposits (75th perc.)	0.02	18.8
	Re-entry (75th perc.)	0.07	71.5
	All pathways (mean)	0.09	87.6
Resident (adult) Body weight:60 kg	Drift (75th perc.)	0.01	13.5
	Vapour (75th perc.)	0.0003	0.3
	Deposits (75th perc.)	0.008	8.1
	Re-entry (75th perc.)	0.04	39.7

	All pathways (mean)	0.05	46.8

Table 15: Estimated bystander exposure (EFSA guidance): ground application

Model data		**Propiconazole**	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AAOEL**
Vehicle mounted upward spray application outdoors (early season) Buffer: 5 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Dermal absorption: 70%			
Application rate:		3 x 0.25 kg a.s./ha (pecan nuts)	
Vapour pressure		5.6 x 10^{-5} Pa at 25°C	
Resident (child) Body weight: 10 kg	Drift (95th perc.)	0.06	18.5
	Vapour (95th perc.)	0.0008	0.3
	Deposits (95th perc.)	0.05	15.6
	Re-entry (95th perc.)	0.07	23.8
Resident (adult) Body weight:60 kg	Drift (95th perc.)	0.03	10.3
	Vapour (95th perc.)	0.0003	0.09
	Deposits (95th perc.)	0.02	6.8
	Re-entry (95th perc.)	0.04	13.2

Table 16: Estimated bystander exposure (US PHED guidance): aerial application

Model data		**Propiconazole**	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AAOEL**
Aerial application (fixed wing) to cereal crops Dermal absorption: 70%			
Application rate:		2 x 0.15 kg a.s./ha (wheat)	
Vapour pressure		5.6 x 10^{-5} Pa at 25°C	
Bystander (child) Body weight: 10 kg	Flagger (best fit) (adult calculation adjusted for bodyweight)	0.0044	1.5

Bystander (adult) Body weight:60 kg	Flagger (best fit)	0.0267	8.9

Conclusions: Resident/Bystander exposure

The predicted levels of exposure to propiconazole in residents and/or bystanders are predicted to be within the AOEL value.

Human Health Risk Assessment Conclusion

The above exposure estimates confirm an acceptable risk assessment can be achieved for the product Bumper 250 EC / Principle 250 EC / Propin 250 EC for the proposed uses on orchard and cereal crops.

Operator exposure

Levels of exposure to propiconazole in operators are predicted to be within the AOEL when the following PPE is worn:

Pecan nuts, Mango, Apricot, Cherry, Peach & Plum

Normal crop spacing (ground application)

- Vehicle mounted (upward) spray application outdoors: M/L = Gloves. A= Gloves
- Manual handheld (upward) spray application outdoors: M/L = None. A= None
- Manual knapsack (upward) spray application outdoors: M/L = None. A= None

Dense crop spacing (ground application)

- Manual handheld (upward) spray application outdoors: M/L = Gloves and faceshield. A = Rainsuit and gloves
- Manual knapsack (upward) spray application outdoors: M/L = Gloves and faceshield. A = Rainsuit and gloves

Wheat & barley

Aerial application

- Fixed wing aerial application: M/L = Gloves. A = None

Ground application

- Vehicle mounted (downward) spray application outdoors: M/L = Gloves. A = None

Worker exposure

Levels of exposure to propiconazole in workers are predicted to be within the AOEL when the following PPE is worn during crop re-entry activities:

- Pecan nuts: None (workwear only)
- Mango: None (workwear only)
- Wheat / cereal crops: None (workwear only)
- Cherry, peach, apricot, plum: Gloves and workwear.

It should be noted that in the absence of actual studies with the products to derive a dermal absorption value and conduct more realistic risk assessments, the latter relied upon default values that are in essence extremely conservative. Despite this conservative approach, the risk assessments demonstrate that no health hazard to humans are expected when the products are used according to the recommendations.

The fact that Propiconazole is classified as skin sensitiser Cat 1 has no impact on residents and bystanders or workers as these would only be exposed to diluted sprays. The highest content of propiconazole in the diluted sprays is 0.5% which is below the 1% generic concentration limit for skin sensitization classification.

If the product before dilution is warranted a skin sensitization classification (Category 1) protective gloves, protective clothing and eye protection/face protection should be worn by the operator for mixing and loading.

It is noted that all users of pesticides should in any case comply with “SANS 10206 :2020. Ed 3”. The handling, storage and disposal of pesticides” and that the above-mentioned PPEs for sensitizer for mixing and loading activities are strongly recommended in all cases when handling pesticides to provide additional protection against spills and splashes.

Appendix 1

List of EFSA modelling reports submitted by the applicant and relied on.

EFSA calculator is available at:
https://r4eu.efsa.europa.eu

Each user must create an account and can then use the calculator. At the "Data Entry "page of the OPEX model the user can upload a previously saved zip file containing already entered data.

The zip files created in support of the propiconazole assessments are therefore accessible simply by dropping the provides zip files in the model. They are all listed in the tables below and provided to the Registrar.

Exposure table reference	Risk assessment	Use number (as listed in attached generated EFSA results report)	EFSA Web Calculator input parameter file & generated results report
Table 4 & Table 5: Estimated operator exposure: short-term/sub-chronic & acute	Operator exposure to propiconazole resulting from the application of the product to wheat using vehicle mounted downward spray equipment, outdoors. Application rate: 0.6 L product/ha Water volume: 300 L/ha	Use 5: Field Crops	 250 EC_20240614_11h53
Table 4 & Table 5: Estimated operator exposure: short-term/sub-chronic & acute	Operator exposure to propiconazole resulting from the application of the product to pine nuts using vehicle mounted and manual handheld upward spray equipment, outdoors (normal & dense cultivation). Application rate: 1 L product/ha Water volume: 1000-2000 L/ha	Use 1: Orchards	 250 EC_20240705.docx
Table 6 & Table 7: Estimated operator exposure: short-term/sub-chronic & acute – Tier 2	Operator exposure to propiconazole resulting from the application of the product to pine nuts using manual hand held upward spray equipment, outdoors (dense cultivation). Refined using AOEM glasshouse model. Application rate: 1 L product/ha Water volume: 1000-2000 L/ha	Use 1: Orchards	 250 EC_20240708_14h57  250 EC_20240708 (1).docx

Table 9: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to pecan nuts using vehicle mounted (upward) spray equipment. Task: Searching, reaching, picking DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 3 x 0.25 kg a.s./ha Interval: 10 days	Use 1: Orchards	 250 EC_20240703_14h27  250 EC_20240712.docx
Table 10: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to mango using vehicle mounted (upward) spray equipment. Task: Searching, reaching, picking DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 2 x 0.075 kg a.s./ha Interval: 10 days	Use 2: Orchards	
Table 11: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to cherry & peach using vehicle mounted (upward) spray equipment. Task: Searching, reaching, picking DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 3 x 0.15 kg a.s./ha Interval: 14 days	Use 4: Orchards	
Table 9: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to pecan nuts using vehicle mounted (upward) spray equipment. Task: Inspection, irrigation DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 3 x 0.25 kg a.s./ha Interval: 10 days	Use 1: Orchards	 250 EC_20240703_13h43  250 EC_20240712 (1).docx
Table 10: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to mango using vehicle mounted (upward) spray equipment. Task: Inspection, irrigation DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 2 x 0.075 kg a.s./ha	Use 2: Orchards	

	Interval: 10 days		
Table 11: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to cherry & peach using vehicle mounted (upward) spray equipment. Task: Inspection, irrigation DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 3 x 0.15 kg a.s./ha Interval: 14 days	Use 4: Orchards	
Table 12: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to wheat using vehicle mounted (downward) spray equipment. Task: Inspection, irrigation DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 2 x 0.15 kg a.s./ha Interval: 10 days	Use 5: Field crops	
Table 11: Estimated worker exposure	Worker re-entry exposure to propiconazole resulting from the application of the product to cherry & peach using vehicle mounted (upward) spray equipment. Task: Maintenance/thinning DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Application: 1 x 0.15 kg a.s./ha	Use 4: Orchards	250 EC_20240703_13h03 250 EC_20240712 (2).docx
Table 14 & Table 15 Estimated resident / bystander exposure	Resident / bystander exposure to propiconazole resulting from the application of the product to pine nuts using vehicle mounted, upward spray equipment outdoors. DRT: None Buffer zone: 5 m Application: 3 x 0.25 kg a.s./ha	Use 1: Orchards	250 EC_20240614_11h53 250 EC_20240705.docx

Aerial Application: Mixing/loading phase (EFSA Model outputs): Wheat 0.6 L product/ha equivalent to 0.15 kg/ha propiconazole. Input Parameters

Application Scenarios						
Product name	Clear all application data	umper 250 EC/Principle 250 EC/Propin				
Formulation type		Soluble concentrates, emulsifiable concentrate, etc.				
Crop type		**Activity**				
Field crops		Inspection, irrigation				
Scenario						
Indoor or Outdoor application		Outdoor				
Max. application rate of the product [L or kg/ha]		0.6	L/ha			
Minimum volume water for application (liquids)		30	L/ha			
Maximum volume water for application (liquids)		30	L/ha			
Application method		Downward spraying				
Application equipment		Vehicle-mounted		Drift reduction	0%	
Buffer strip		2-3	m			
Max. number of applications		3				
Interval between multiple applications		10	days			
Season (upward spraying orchards only)		not relevant				
Active substance properties						
Active substance name	Clear all A.S. data	**Propiconazole**				
Concentration of active substance [g a.s./L or kg]		250				g a.s./L
Minimum in-use-concentration of active substance		5.000	0.00	0.00	0.00	g a.s./L
Maximum in-use-concentration of active substance		5.00	0.00	0.00	0.00	g a.s./L
Maximum application rate of active substance		0.15	0.00	0.00	0.00	kg a.s./ha
Acceptable Operator Exposure Level (AOEL)		0.100				mg/kg bw/day
Acute Acceptable Operator Exposure Level (AAOEL)		0.30				mg/kg bw/day
Foliar DT50		30	30	30	30	days
Initial Dislodgeable Foliar Residue		3	3	3	3	µg/cm² of foliage/kg a.s. applied/ha
Dermal absorption of product		25.00%				
Dermal absorption of in-use dilution		0.00%				
Oral absorption of active substance		100.00%	100.00%	100.00%	100.00%	
Inhalation absorption of active substance		100.00%	100.00%	100.00%	100.00%	
Vapour pressure of active substance						Pa
Molecular weight of active substance						g/mol

Aerial Application: Mixing/loading phase (EFSA Model outputs): Wheat 0.6 L product/ha equivalent to 0.15 kg/ha propiconazole. Mix/Load exposure estimate - workwear only

Operator exposure for Bumper 250 EC/Principle 250 EC/Propin spray applications

	Propiconazole		
Application rate of active substance	0.15	kg a.s./ha	*i_AppRateAS*
Amount of active substance applied	7.5	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable conc		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Assumed area treated	50	ha/day	*d_AreaTreated*
Season	not relevant		

Reset to default PPE

		Propiconazole		
Mixing and loading	**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	**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**
	Cabin	Not relevant	**Vehicle-mounted upward spraying**	

1. Total	Propiconazole		Combined	
	Without RPE/PPE	**With RPE/PPE**	**Without RPE/PPE**	**With RPE/PPE**
Short-term				
Total systemic exposure from ML and application (mg a.s./day)	**11.5**	**7.55**		
Total systemic dose from ML and application per kg body weight (mg/kg bw/day)	**0.192**	**0.126**	**Hazard index**	
% of AOEL	**192%**	**126%**	**N/A**	**N/A**

Aerial Application: Mixing/loading phase (EFSA Model outputs): Wheat 0.6 L product/ha equivalent to 0.15 kg/ha propiconazole. Mix/Load exposure estimate - workwear and gloves

Operator exposure for Bumper 250 EC/Principle 250 EC/Propin spray applications

	Propiconazole		
Application rate of active substance	0.15	kg a.s./ha	*i_AppRateAS*
Amount of active substance applied	7.5	kg a.s./day	*i_AmountAS*
Dermal absorption of the product	25.00%		*i_AbsorpProduct*
Dermal absorption of in-use dilution	0.00%		*i_AbsorInuse*
Formulation type	Soluble concentrates, emulsifiable conc		
Indoor or Outdoor application	Outdoor		
Application method	Downward spraying		
Application equipment	Vehicle-mounted		
Assumed area treated	50	ha/day	*d_AreaTreated*
Season	not relevant		

Reset to default PPE

		Propiconazole		
Mixing and loading	**Protective Equipment**	Select for inclusion	Penetration factor	Inhalation Protection factor
	Gloves	Yes	**Incl. in AOEM model**	
	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	**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**
	Cabin	Not relevant	**Vehicle-mounted upward spraying**	

1. Total	Propiconazole		Combined	
	Without RPE/PPE	**With RPE/PPE**	**Without RPE/PPE**	**With RPE/PPE**
Short-term				
Total systemic exposure from ML and application (mg a.s./day)	**11.5**	**0.210**		
Total systemic dose from ML and application per kg body weight (mg/kg bw/day)	**0.192**	**0.00350**	**Hazard index**	
% of AOEL	**192%**	**3.50%**	**N/A**	**N/A**

Aerial Application: Application phase (US EPA Model): Wheat 0.6 L product/ha equivalent to 0.15 kg/ha propiconazole. No PPE (Closed cockpit)

US AHETF – Applicator, Aerial, Fixed-wing aircraft, Liquids				
Exposure route	Protection	Statistic	Unit exposure (µg/US lb a.s.)	Unit exposure (µg/kg a.s.)
Dermal	Single layer of clothing, no gloves	Best fit	2.08	4.59
Inhalation	No RPE	Best fit	0.0049	0.011

No PPE	AHETF unit exposure mg/person/day									
Application	AHETF unit exposure		Max. label rate		Area treated/day		Dermal absorption			
	(mg/kg a.s./ha)		(Kg/ha)		(ha)		(%)			
Dermal	4.59×10^{-3}	×	0.15	×	100	×	70%	=	0.048148	mg/person/day
Inhalation	1.08×10^{-5}	×	0.15	×	100	×	100%	=	0.000162	mg/person/day
							Total		0.048311	mg/person/day
							Total		0.00081	mg/kg bw/day

Estimation of operator exposure towards propiconazole - EFSA Guidance + US AHETF aerial application model – longer term exposure

No PPE

Mixing/loading (EFSA Guidance model)	0.126 mg a.s./kg bw/day
Application (US EPA AHETF)	0.00081 mg a.s./kg bw/day
Total	**0.127 mg a.s./kg bw/day (127% AOEL)**

Gloves (mix/load) PPE

Mixing/loading (EFSA Guidance model)	0.0035 mg a.s./kg bw/day
Application (US EPA AHETF)	0.00081 mg a.s./kg bw/day
Total	**0.0043 mg a.s./kg bw/day (4.3% AOEL)**

Estimation of longer-term resident exposure towards propiconazole according to US PHED EPA unit exposures

Exposure Scenario		Exposure Route	Personal Protective Equipment (PPE) Level	Data Source	Statistic	Total exposure (µg/lb ai handled)	Unit Exposure (µg/kg ai handled)
Flagger	Liquids	Dermal	Single layer, no gloves	PHED	« Best fit »	11	24.251
		Inhalation	No respirator	PHED	« Best fit »	0.35	0.772

Dermal exposure = total dermal exposure × application rate × dermal absorption

= 0.024251 mg/kg a.s. handled × 15 kg a.s. handled/ day × 70 %

= 0.255 mg / person / day

Inhalation exposure = total dermal exposure × application rate × inhalation absorption

= 0.000772 mg /kg a.s. handled × 15 kg a.s. handled / day × 100%

= 0.0116 mg /person / day

Adult (60kg) bodyweight

Total exposure = (DE + IE) / body weight

= (0.255 + 0.0116) / 60kg

= 0.0044 mg / kg bw / day (1.5% of the AAOEL)

Child (10kg) bodyweight

Total exposure = (DE + IE) / body weight

= (0.255 + 0.0116) / 10kg

= 0.0267 mg / kg bw / day (8.9% of the AAOEL)