



Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **assimilated Regulation No 1107/2009**
as it applies in Great Britain

**Aqueous extract from the germinated seeds
of sweet Lupinus albus**

Volume 3 – B.6 (PPP) PROBLAD **PLUS**

**Toxicology, Metabolism Data & Assessment of
Risks for Humans**

Great Britain

February 2025

Version History

| When | What |
|----------------------|--|
| June 2024 | Initial DAR |
| February 2025 | Updates made after ECP |
| February 2025 | Updates made after additional information submitted post ECP |
| | Updates made after public consultation |
| | Updates made after additional information submitted post public consultation |
| | [Updates made after any additional steps not covered by the above] |

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B.6. Toxicology and metabolism data and assessment of risks for humans

The active substance ‘aqueous extract from the germinated seeds of sweet *Lupinus albus*’ and the representative plant protection product ‘PROBLAD PLUS’ are identical in composition. Therefore, all acute toxicity information has been summarised in Volume 3 CA B6.

There may be references to PROBLAD PLUS within the DAR, however the applicant has confirmed that the tradename for the product will be PROBLAD in GB.

B.6.1. Acute toxicity of plant protection product

The acute toxicity, skin and eye irritation and skin sensitisation of the ‘aqueous extract from the germinated seeds of sweet *Lupinus albus*’ (identified as ‘PROBLAD PLUS’ on all study reports) was investigated in accordance with GLP and OECD compliant guideline studies, supplemented with published information where deemed appropriate.

B.6.1.1. Oral

Please see Volume 3 CA B6.2.1

B.6.1.2. Dermal

Please see Volume 3 CA B6.2.2

B.6.1.3. Inhalation

Please see Volume 3 CA B6.2.3

B.6.1.4. Skin irritation

Please see Volume 3 CA B6.2.4

B.6.1.5. Eye irritation

Please see Volume 3 CA B6.2.5

B.6.1.6. Skin sensitisation

Please see Volume 3 CA B6.2.6

B.6.1.7. Supplementary studies on the plant protection product

No data are supplied and none are considered necessary.

B.6.1.8. Supplementary studies for combinations of plant protection products

No data are supplied and none are considered necessary.

B.6.1.9. Summary of acute toxicity studies

These data confirm that PROBLAD PLUS is of extremely low oral, dermal and inhalation toxicity and is not a dermal or eye irritant, nor is it a skin sensitiser and does not require classification under the GB assimilated CLP Regulation.

B.6.2. Dermal absorption

The formulated product is identical to the active substance, 'aqueous extract from the germinated seeds of sweet *Lupinus albus*', and it is a plant extract. In general, such botanical active substances are complex mixtures comprising of numerous components and is regarded as a UVCB substance (Substance of Unknown or Variable composition, Complex reaction product or Biological material). Within the formulated product, the lead component has been identified as 'Banda de *Lupinus albus* doce', known as BLAD.

BLAD is a naturally occurring seed storage protein in germinated sweet lupines and is soluble in the formulated product. It is a 210 kDa glyco-oligomer which is mainly composed of a 20 kDa polypeptide (also termed BLAD), alongside several other polypeptides. The 210 kDa polypeptide is comprised of 173 amino acid residues and is a stable intermediate of the catabolism of β -conglutin, or characterised as a fragment of the amino acid sequence of β -conglutin, therefore, there is no specific molecular or structural formula.

Due to the UVCB nature and known composition of the formulated product, no experimental data have been provided to address this endpoint. Instead, the Applicant has presented a position paper in which the relatively poor dermal absorption of large proteins such as BLAD, and other macromolecules, in comparison to agrochemicals and pharmaceutical chemicals is discussed.

| | |
|---|--|
| Reference: | 5.2.6 |
| Report Title: | Expert opinion on the dermal penetration of BLAD |
| Author(s) & Year: | A. Gledhill (2019) |
| Document No, Authority registration No | Report No. 0387776-Tox3 |
| Substance assessed: | BLAD |
| Method of analysis: | N/A |
| Guideline(s): | N/A |
| Deviations: | N/A |
| GLP or GEP: | N/A |
| Acceptability: | Yes |

| | |
|---------------------------|--|
| Study relied upon: | Yes; data protection does not apply to expert opinions |
|---------------------------|--|

The Applicant has provided the following statement:

“It is difficult to provide definitive evidence for the lack of dermal absorption of proteins such as BLAD since the accepted scientific view on the skin barrier indicates dermal absorption studies on large protein molecules are pointless. However, by reference to proteins of pharmaceutical interest, it can be demonstrated that polypeptides such as insulin are not absorbable by the dermal route without significant measures to disrupt or bypass the stratum corneum. Insulin is a ca. 6 kDa polypeptide consisting of 51 amino acid residues, so is a smaller molecule than BLAD and is thus considered to provide a worse case assessment with respect to dermal absorption. Therefore, by analogy with a polypeptide such as insulin, it is reasonable to conclude that under normal use conditions BLAD will not reach the epidermis or dermis layers within the skin.”

HSE Conclusion

It is known that significant chemical or physical interventions are needed in order to ensure the dermal penetration of insulin e.g. electric, sonic, encapsulation and microneedle methods. Therefore, it is unlikely that relevant components of the active substance will penetrate the human dermis or epidermis. This leads to the conclusion that the dermal penetration of ‘aqueous extract from the germinated seeds of sweet *Lupinus albus*’ is unlikely to be significant, and a default value of 2510% (EFSA 2017) is acceptable for both the concentrate and in-use dilutions of the formulated product (water-based formulation) PROBLAD (1255 g/L – 2.51 g/L).

B.6.3. Available toxicological data relating to co-formulants

Acceptable SDS have been submitted for all of the co-formulants listed in Volume 4 C.1.3.4. Any co-formulants classified under the GB CLP Regulation for acute toxicity, skin and eye irritation and skin sensitisation have been adequately characterised by the experimental data summarised in Volume 3 CA B6.2.

No co-formulants pose any other hazards to human health.

OVERALL TOXICOLOGICAL CLASSIFICATION OF THE REPRESENTATIVE PRODUCT

‘PROBLAD’ IN ACCORDANCE WITH ASSIMILATED REGULATION No 1272/2008

No classification is required for Human Health Toxicology (Table 6.3-1).

Table 6.3-1: Summary of acute toxicity of ‘aqueous extract from the germinated seeds of sweet *Lupinus albus*’

| Guideline, reference | Species | Result | Classification |
|----------------------------------|----------------|-------------------------------------|-----------------------|
| Acute Oral toxicity | | | |
| OECD 425 [REDACTED] (2012a) | Rat | LD ₅₀ > 5000 mg/kg bw | None |
| Acute Dermal toxicity | | | |
| OECD 402 [REDACTED] (2012b) | Rat | LD ₅₀ > 2000 mg/kg bw | None |
| Acute Inhalation toxicity | | | |

| Guideline, reference | Species | Result | Classification |
|--------------------------------|------------|---|----------------|
| OECD 403 [REDACTED] (2012c) | Rat | LC ₅₀ 4h > 5.34 mg/L nose-only | None |
| Skin Irritation | | | |
| OECD 404 [REDACTED] (2012d) | Rabbit | Mild signs of initial irritation which were reversible | None |
| Eye Irritation | | | |
| OECD 405 [REDACTED] (2012e) | Rabbit | Mild signs of initial irritation which were reversible | None |
| Skin Sensitisation | | | |
| OECD 406 [REDACTED] (2012f) | Guinea Pig | Not sensitising (Buehler) | None |

B.6.4. Exposure data

The initial exposure assessment considered a dermal absorption value of 25% as proposed by the applicant. Subsequently it was noted that the 2017 guidance (EFSA Journal 2017; 15(6):4873) could apply. As a result the dermal absorption value was amended to 10% (in line with the 2017 guidance) and the exposure assessment was revised entirely.

'PROBLAD-PLUS' is the representative formulation for the approval of the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*. A summary of the application parameters pertinent to the operator, bystander, resident and worker exposure assessment for 'PROBLAD-PLUS' are presented below.

Table B.6.4-1: Summary of 'PROBLAD-PLUS' application parameters pertinent to the operator, bystander, resident and worker exposure assessment.

| 'PROBLAD-PLUS' (GWN-10320) | |
|---|--|
| Formulation type | Soluble concentrate (SL) |
| Use | For use as a professional fungicide on outdoor and protected tomatoes and strawberries. |
| Classification | From Section B.6.3: Not classified with respect to human health |
| Packaging | From DAR 16, Volume 3CP, Section B.4.4: HDPE: 4 L container |
| Active substance concentration | 100% w/w (1000 g/kg, equivalent to 1255 g/L aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>) |
| Systemic AOEL | Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>: 5 mg/kg bw/day |
| Systemic AAOEL | Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>: Not necessary |
| Dermal absorption | From Section B.6.2: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>: <ul style="list-style-type: none"> Concentrate: 10% Dilution: 10% |

| | |
|--|---|
| Vapour pressure | <p>From DAR 04, Volume 3CA, Section B.2.2:</p> <p>Aqueous extract from the germinated seeds of sweet Lupinus albus: Not applicable*</p> <p>*‘PROBLAD-PLUS’ is a protein based aqueous solution. Therefore, it is not technically feasible to determine vapour pressure on this substance. Theoretically it is possible to determine the vapour pressure of purified BLAD, but it is a large molecule (> 200 kDa), thus the vapour pressure is expected to be very low.</p> |
| Application Scenarios | |
| Maximum individual dose | <p>Outdoor:</p> <p>Strawberry: 3.2 L product/ha, equivalent to 4.016 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Tomatoes: 3.2 L product/ha, equivalent to 4.016 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Protected:</p> <p>Strawberry: 3.2 L product/ha, equivalent to 4.016 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Tomatoes: 3.2 L product/ha, equivalent to 4.016 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> |
| Maximum number of applications per year | 6 per year |
| Interval between applications | 8 days |
| Application volume | <p>Strawberries:</p> <p>450 – 1000 L/ha</p> <p>Tomatoes:</p> <p>200 – 1000 L/ha</p> |

| | |
|-----------------------------------|---|
| Spray concentration range | <p>Strawberries:</p> <p>Aqueous extract from the germinated seeds of sweet Lupinus albus: 2.51 – 8.92 g a.s./L*</p> <p>Tomatoes:</p> <p>Aqueous extract from the germinated seeds of sweet Lupinus albus: 2.51 – 20.08 g a.s./L*</p> <p>*Spray concentration range covers minimum and maximum proposed application rate in GAP.</p> |
| Maximum total dose | <p>Outdoor:</p> <p>Strawberry: 19.2 L product/ha, equivalent to 24.1 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Tomatoes: 19.2 L product/ha, equivalent to 24.1 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Protected:</p> <p>Strawberry: 19.2 L product/ha, equivalent to 24.1 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> <p>Tomatoes: 19.2 L product/ha, equivalent to 24.1 kg aqueous extract from the germinated seeds of sweet Lupinus albus/ha</p> |
| Application method | <p>Vehicle mounted boom sprayer</p> <p>Broadcast air-assisted sprayer</p> <p>Handheld manual (tank and lance) sprayer</p> <p>Handheld knapsack sprayer</p> <p>Trolley sprayer</p> |
| Latest time of application | BBCH 89 |

Estimates of operator, worker, bystander and resident exposure have been conducted in line with the 2014 EFSA exposure guidance¹ and the respective calculator (hereafter referred to as EFSA Calculator). In addition, at the time of this active substance evaluation, the 2022

¹ European Food Safety Authority (2014). Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, EFSA Journal 2014;12(10):3874.

EFSA exposure guidance² and the respective online model (hereafter referred to as online EFSA OPEX Model) has been implemented in GB. Therefore, in order to ensure consistent authorisations for future products, estimates of operator, worker, bystander and resident exposure have also been conducted in line with the 2022 EFSA guidance.

The two versions of the EFSA Exposure Guidance have different terminology for the non-dietary exposure assessment. Both versions of the guidance require an acute exposure assessment for substances that have the potential to induce an adverse health effect after a single exposure event (on one day). Acute exposure estimates are then compared to the acute acceptable operator exposure level (AAOEL). However, as aqueous extract from the germinated seeds of sweet *Lupinus albus* has not been assigned an AAOEL value, this assessment is not required. An assessment of exposure is also required where adverse effects may be caused by longer periods of contact ranging from weeks to months. The 2014 EFSA Exposure Guidance refers to this as longer term exposure, whilst the 2022 EFSA Guidance refers to this as short term exposure. These exposure estimates are compared to the acceptable operator exposure level (AOEL). For consistency, the 2022 EFSA Guidance Terminology of short term exposure has been used for the exposure assessment of Aqueous extract from the germinated seeds of sweet *Lupinus albus*.

B.6.4.1 Operator exposure

Considering the proposed uses of the representative product, the maximum application rate of 3.2 L product/ha intended for outdoor and protected tomatoes is the critical GAP for operator exposure. This use is considered for the non-dietary exposure assessment and covers use on outdoor and protected strawberries at an application rate of 3.2 L product/ha. HSE considers that outdoor tomatoes and strawberries are categorised as low crops, whilst protected tomatoes and strawberries are categorised as high crops, with strawberries commonly grown on tables/racking. This has been reflected in the assessment below.

Operator Exposure – Outdoor Environments

A Tier 1 estimate of operator exposure is presented based on the highest application rate and the highest dermal absorption values (worst-case scenario). A summary of the estimated short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for the proposed uses of 'PROBLAD-PLUS' is provided in the following tables. Outputs of the EFSA Calculator (Version: 30th March 2015, EFSA 2014 Guidance) and online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance) are presented in Appendix 1 (Estimates 1 - 6).

² European Food Safety Authority (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.

Table B.6.4.1-1: EFSA Calculator estimate of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* during the application of 'PROBLAD-PLUS' to outdoor tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet Lupinus albus | | | | |
|---|-------------------|-------------------|------------------------------------|-------------------------------------|
| Model data | Level of PPE | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| | Mix/Load | Application | | |
| Scenario: Vehicle mounted boom spray application (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 50 ha Season: Not relevant | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.5536 | 11 |
| Scenario: Handheld manual (tank and lance) sprayer (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 4 ha Season: Not relevant | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.2619 | 5 |
| Scenario: Handheld knapsack sprayer (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.0914 | 2 |

Table B.6.4.1-2: Online EFSA OPEX model estimate of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* during the application of 'PROBLAD-PLUS' to outdoor tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet Lupinus albus | | | | |
|---|----------------------|----------------------|------------------------------------|-------------------------------------|
| Model data | Level of PPE | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| | Mix/Load | Application | | |
| Scenario: Vehicle mounted boom spray application (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 50 ha Season: Not relevant | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.5 | 9.6 |
| Scenario: Handheld manual (tank and lance) sprayer (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 4 ha Season: Not relevant Crop Culture: 'Normal' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.3 | 5.5 |
| Scenario: Handheld knapsack sprayer (downwards) to low vegetables (tomatoes) Environment: Outdoors Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Normal' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application AOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.1 | 1.8 |

Based on the EFSA Calculator (EFSA 2014 Guidance), the predicted short term systemic operator exposure for the proposed use of 'PROBLAD-PLUS' on low vegetables (tomatoes) grown outdoors is predicted to be equivalent to:

- 11% of the AOEL of aqueous extract from the germinated seeds of sweet Lupinus albus for an operator mixing/loading and applying via vehicle mounted boom sprayer without PPE.

- 5% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld manual (tank and lance) without PPE.
- 2% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld knapsack sprayer without PPE.

The predicted operator exposure is within acceptable levels.

Based on the online EFSA OPEX Model (EFSA 2022 Guidance), the predicted short term systemic operator exposure for the proposed use of 'PROBLAD PLUS' on low vegetables (tomatoes) grown outdoors is predicted to be equivalent to:

- 9.6% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via vehicle mounted boom sprayer without PPE.
- 5.5% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld manual (tank and lance) sprayer without PPE.
- 1.8% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld knapsack sprayer without PPE.

The predicted operator exposure is within acceptable levels.

Operator Exposure – Protected Environments

The 2014 EFSA Exposure Guidance does not consider operator exposure in protected environments. The GB approach for assessing operator exposure during spray application via handheld equipment indoors (prior to the 2022 EFSA Guidance) is based on the results of a single study (Study 32) from the European Predictive Operator Exposure Model (EUROPOEM) database³. This study measured operator exposure during application of a plant protection product to ornamental plants via a tank spray gun. The 75th percentile exposure values from EUROPOEM Study 32 are used to estimate exposure to operators during application via manual handheld equipment (tank and lance). As the EUROPOEM data are based on a single study, the exposure estimates do not differentiate between upwards or downwards spraying or crop culture ('normal' or 'dense').

The EUROPOEM study data may under-estimate exposure during mixing/loading of knapsacks, as it is considered that more mix/load operations will be required and the tank

³ FAIR3 CT96-1406, 2002. The development, maintenance and dissemination of generic European databases and predictive exposure models to plant protection products. A Europeom Operator Exposure Database.

aperture is smaller than for a tank and lance set up. Therefore, to estimate exposure for application via knapsack sprayer, estimates of exposure during mixing/loading (sum value of hands, head, body and inhalation) of knapsack sprayers from the EFSA Calculator (2015) are added to the estimate of exposure during mixing/loading and application from the EUROPOEM Study 32 data. At the first tier, the operator exposure assessment for application via knapsack sprayer is based on a work rate of 1 ha/day.

The 2022 EFSA Exposure Guidance includes an assessment of short term operator exposure during handheld manual (tank and lance), handheld knapsack and manual trolley sprayer application in protected environments based on the Greenhouse Agricultural Operator Exposure Model (GAOEM). This model contains data from multiple studies for application to low and high crops in 'normal' and 'dense' crop culture. Dense crop culture is considered when operators are unable to avoid contact with the treated crop.

Application via handheld sprayers

A Tier 1 estimate of operator exposure is presented based on the highest application rate and the highest dermal absorption values (worst-case scenario). A summary of the estimated short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for the proposed uses of 'PROBLAD-PLUS' on high vegetables (tomatoes) grown in protected environments is provided in the following tables. Outputs from EUROPOEM and the EFSA Calculator (Version: 30th March 2015, EFSA 2014 Guidance), and the online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance), are presented in Appendix 1 (Estimates 7 - 13).

Table B.6.4.1-3: EFSA Calculator estimate of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* during the application of 'PROBLAD-PLUS' to protected tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | | |
|--|-------------------|-------------------|------------------------------------|-------------------------------------|
| Model data | Level of PPE | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| | Mix/Load | Application | | |
| Scenario: Handheld manual (tank and lance) sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: N/A | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| EUROPOEM Model 75 th Perc. Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.5848 | 12 |
| Scenario: Handheld knapsack sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) | | | | |

| | | | | |
|---|----------------------|----------------------|------------------|----|
| Work rate: 1 ha Season: Not relevant Crop Culture: N/A | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| EFSA 2014 AOEM 75 th Perc. [redacted] Body weight: 60 kg | Workwear (No PPE) | - | 0.0436 | - |
| EUROPOEM Model 75 th Perc. [redacted] Body weight: 60 kg | - | Workwear (No PPE) | 0.5848 | - |
| Total (M/L and App) EUROPOEM + AOEM Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.6284 | 13 |

Based on EUROPOEM and the EFSA Calculator (EFSA 2014 Guidance), the predicted short term systemic operator exposure for the proposed use of 'PROBLAD-PLUS' on high vegetables (tomatoes) grown in protected environments is predicted to be equivalent to:

- 12% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld manual (tank and lance) sprayer without PPE.
- 13% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld knapsack sprayer without PPE.

The predicted operator exposure is within acceptable levels.

Table B.6.4.1-4: Online EFSA OPEX model estimate of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* during the application of 'PROBLAD-PLUS' to protected tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | | |
|---|--------------|-------------|------------------------------------|-------------------------------------|
| Model data | Level of PPE | | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| | Mix/Load | Application | | |
| Scenario: Handheld manual (tank and lance) sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Normal' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |

| | | | | |
|--|----------------------|----------------------|------------------|-------------|
| Spray application GAOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.3 | 6.1 |
| Scenario: Handheld knapsack sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Normal' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application GAOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.3 | 6.3 |
| Scenario: Manual trolley sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Normal' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application GAOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 0.1 | 2.4 |
| Scenario: Handheld manual (tank and lance) sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Dense' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application GAOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 4.8 | 95.9 |
| Scenario: Handheld knapsack sprayer (upwards) to high vegetables (tomatoes) Environment: Protected Environment Formulation type: Soluble concentrate (SL) Work rate: 1 ha Season: Not relevant Crop Culture: 'Dense' | | | | |
| Application rate: | | | 4.016 kg a.s./ha | |
| Spray application GAOEM; 75 th percentile Body weight: 60 kg | Workwear (No PPE) | Workwear (No PPE) | 4.8 | 96.1 |

Based on the online EFSA OPEX Model (EFSA 2022 Guidance), the predicted short term systemic operator exposure for the proposed use of 'PROBLAD-PLUS' on high vegetables (tomatoes) grown in protected environments is predicted to be equivalent to:

- 6.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld manual (tank and lance) sprayer in a 'normal' crop scenario without PPE.
- 6.3% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld knapsack sprayer in a 'normal' crop scenario without PPE.
- 2.4% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via manual trolley sprayer in a 'normal' crop scenario without PPE.
- 95.9% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld manual (tank and lance) sprayer in a 'dense' crop scenario without PPE.
- 96.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an operator mixing/loading and applying via handheld knapsack sprayer in a 'dense' crop scenario without PPE.

The predicted operator exposure is within acceptable levels.

HSE notes that the online EFSA OPEX Model provides estimates of operator exposure for application via pedestrian trolley sprayers to high crops with a normal crop culture. The exposure estimates are based on a study where the trolley sprayers were pulled during spraying, leaving a spray cloud behind the trolley and thus avoiding contact of the operator with treated foliage. As the operators pulled the trolley equipment backwards through the crop, exposure is likely to be lower than where an operator pulls equipment through the crop rather than pushes equipment through the crop, where they could come into contact with treated foliage.

Therefore, to address these concerns, the following Other Specific Restriction (OSR) is required:

- When applying with a pedestrian controlled trolley sprayer, only apply by pulling equipment backwards and not pushing equipment forwards through the crop.

The operator exposure estimates for application via manual trolley sprayer in the online EFSA OPEX Model are only for application to high crops with a normal crop culture using a vertical boom. It is considered that this would also cover exposure for application to low crops via a trolley sprayer with a horizontal boom where there is no contact with treated crops i.e. where the equipment is pulled backwards.

Vehicle mounted broadcast air-assisted sprayers and variable geometry/vertical boom sprayers

It is understood that a range of horizontal or variable geometry boom spraying equipment and broadcast air-assisted sprayers with multiple nozzles are used in polytunnels and greenhouses, reflecting the need in commercial operations to achieve higher work rates than would be the case with hand held application with a single nozzle. This equipment can range from pedestrian controlled trolley sprayers, robotic sprayers, vehicle mounted/trailed boom sprayers and vehicle mounted/trailed broadcast air-assisted sprayers.

There are currently no exposure models that estimate exposure via vehicle mounted broadcast air-assisted sprayers or variable geometry/vertical boom sprayers in protected environments. Therefore, HSE has undertaken an ad-hoc approach for considering operator exposure based on underlying data in the online EFSA OPEX Model and a study undertaken by the European Crop Protection Association. A detailed consideration of operator exposure from the use of this equipment is provided in Appendix 2.

As the online EFSA OPEX Model only considers exposure for application via handheld equipment and trolley sprayers, there is uncertainty regarding operator exposure for application via other types of vehicle-mounted equipment with multiple nozzles in enclosed spaces. It is considered that a greater work rate can be achieved with application via vehicle mounted/trailed boom spraying equipment or broadcast assisted sprayers indoors than the default 1 ha/day work rate for handheld/trolley sprayer application. The default work rate of 4 ha/day for outdoor handheld manual (tank and lance) application is considered a more realistic reflection of the likely area that would be treated daily by vehicle mounted/trailed horizontal and variable geometry boom sprayers and broadcast air-assisted sprayers in a commercial polytunnel or greenhouse operation in the UK.

A comparison of the relative dermal exposure during application with single nozzle manual handheld equipment and vertical boom equipment with multiple nozzles is presented in Appendix 2. Based on this comparison, it is considered that the online EFSA OPEX Model's dermal exposure estimates for application via handheld manual (tank and lance) equipment are likely to be protective for dermal exposure during application via vehicle mounted/trailed boom sprayer or broadcast air-assisted sprayer, even when accounting for the assumption of a 4 ha/day work rate in comparison to the default work rate of 1 ha/day for handheld equipment.

However, HSE notes that for certain application scenarios, the difference in relative dermal exposure to manual application techniques is still unknown. There is uncertainty regarding the relative inhalation exposure during application via vehicle mounted/trailed equipment with multiple nozzles in comparison to single nozzle handheld equipment. Therefore, to address these concerns, additional operator protection phases are required to mitigate dermal and inhalation exposure to operators during indoor application via vertical boom sprayers and broadcast air-assisted sprayers:

- Broadcast air-assisted sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* during application in protected situations.

*Closed cabin meeting at least EN 15695 category 3.

- Vehicle-mounted or trailed horizontal or vertical boom sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* or suitable respiratory protective equipment** must be worn during application in protected situations.

*Closed cabin meeting at least EN 15695 category 3

**Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

Classification of 'PROBLAD-PLUS'

The product 'PROBLAD-PLUS' is not classified for human health effects. Thus, there are no additional PPE requirements.

B.6.4.2 Bystander and resident exposure

Considering the proposed uses of the representative product, the maximum application rate of 3.2 L product/ha in a minimum water volume of 200 L/ha intended for use on outdoor and protected tomatoes is the critical GAP for bystander/resident exposure. This use is considered for the non-dietary exposure assessment and covers use on strawberries at an application rate of 3.2 L product/ha in a minimum water volume of 450 L/ha.

Resident Exposure

For exposure of residents and bystanders to vapour, the EFSA Guidance specifies default values for the average concentration of active substance in the air 24 hours after application of the product. These values are based on the volatility of the active substance (preferably at 25°C):

- Substances with low volatility having a vapour pressure of $<5 \times 10^{-3}$ Pa (the default average concentration in air in the 24 hours after application is $1 \mu\text{g}/\text{m}^3$).
- Moderately volatile substances with a vapour pressure between 5×10^{-3} Pa and 10^{-2} Pa (the default average concentration in air in the 24 hours after application is $15 \mu\text{g}/\text{m}^3$).

The vapour pressure of aqueous extract from the germinated seeds of sweet *Lupinus albus* has not been assigned. According to DAR 04, Volume 3CA, Section B.2.2 "PROBLAD PLUS" is a protein based aqueous solution. Therefore, it is not technically feasible to determine vapour pressure on this substance. Theoretically, it is possible to determine the vapour pressure of purified BLAD, but it is a large molecule (> 200 kDa). Thus, the vapour

pressure is expected to be very low.”. Therefore, for the purposes of the resident and bystander exposure assessment, the active substance is considered to have low volatility. When modelling resident and bystander exposure with the EFSA Calculator (Version: 30th March 2015), the low volatility option for vapour pressure has been selected. A vapour pressure of 0.001 Pa (default value for low volatility) has been used in the online EFSA OPEX Model (Version 1.0.2) for consideration of resident and bystander exposure.

Resident (Short Term) Exposure

A Tier 1 estimate of resident exposure is presented based on the highest application rate, the minimum proposed water volume and the highest dermal absorption values (worst-case scenario). A summary of the estimated short term exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for the proposed uses of ‘PROBLAD-PLUS’ on outdoor and protected tomatoes is provided in the following tables. Outputs of the EFSA Calculator (Version: 30th March 2015, EFSA 2014 Guidance) and online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance) are presented in Appendix 1 (Estimates 14 - 16).

The EFSA 2014 Guidance and associated EFSA Calculator does not consider resident exposure from indoor applications. Thus, only the proposed use of ‘PROBLAD-PLUS’ on outdoor tomatoes has been presented below.

In the absence of established and commonly accepted models for the risk assessment of resident exposure during indoor application, the 2022 EFSA Exposure Guidance considers that the risk assessment approach for residents for outdoor application is suitable to use as a first tier approach for short term resident exposure to indoor applications of plant protection products. However, the re-entry into treated areas pathway is not considered as it is not deemed an appropriate/realistic scenario.

Table B.6.4.2-1: EFSA Calculator estimate of resident (short term) exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* from the proposed uses of ‘PROBLAD-PLUS’ on outdoor tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | |
|--|------------------|---------------------------------------|--|
| Model data | Exposure Pathway | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| Scenario: Vehicle mounted boom spray application (downwards) to low vegetables (tomatoes) Environment: Outdoors Buffer Zone: 2-3 m Drift Reduction Technology: No DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | |

| | | | |
|--------------------------------------|-----------------------------------|----------------------|-----|
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Resident Child Body weight: 10 kg | Drift (75 th perc.) | 0.0543 | 1 |
| | Vapour (75 th perc.) | 0.0011 | < 1 |
| | Deposits (75 th perc.) | 0.0362 | 1 |
| | Re-entry (75 th perc.) | 0.2691 | 5 |
| | Sum (Mean) | 0.2721 | 5 |
| Resident Adult Body weight: 10 kg | Drift (75 th perc.) | 0.0129 | < 1 |
| | Vapour (75 th perc.) | 0.0002 | < 1 |
| | Deposits (75 th perc.) | 0.0109 | < 1 |
| | Re-entry (75 th perc.) | 0.1495 | 3 |
| | Sum (Mean) | 0.1335 | 3 |

Based on the EFSA Calculator (EFSA 2014 Guidance), for the proposed uses of 'PROBLAD PLUS' on tomatoes grown outdoors, the predicted short term systemic exposure to a child and adult resident is within acceptable limits for all exposure pathways, with the (mean) sum of all pathways equivalent to 5% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 3% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident.

The short term exposure of bystanders is covered by the resident exposure assessment.

Table B.6.4.2-2: Online EFSA OPEX Model estimate of resident (short term) exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* from the proposed uses of 'PROBLAD PLUS' on outdoor and protected tomatoes and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | |
|--|-----------------------------------|------------------------------------|-------------------------------------|
| Model data | Exposure Pathway | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| Scenario: Vehicle mounted boom spray application (downwards) to low vegetables (tomatoes) Environment: Outdoors Buffer Zone: 2-3 m Drift Reduction Technology: No DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Resident Child Body weight: 10 kg | Drift (75 th perc.) | 0.05 | 1.1 |
| | Vapour (75 th perc.) | 0.0008 | 0.02 |
| | Deposits (75 th perc.) | 0.04 | 0.7 |
| | Re-entry (75 th perc.) | 0.3 | 5.4 |
| | Sum (Mean) | 0.3 | 5.4 |
| Resident Adult Body weight: 10 kg | Drift (75 th perc.) | 0.01 | 0.3 |
| | Vapour (75 th perc.) | 0.0003 | 0.005 |
| | Deposits (75 th perc.) | 0.01 | 0.2 |
| | Re-entry (75 th perc.) | 0.1 | 3.0 |
| | Sum (Mean) | 0.1 | 2.7 |
| Scenario: Handheld manual (tank and lance) spray application (upwards) to high vegetables (tomatoes) Environment: Protected Environment Buffer Zone: 5 m Drift Reduction Technology: No DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Resident Child Body weight: 10 kg | Drift (75 th perc.) | 0.3 | 5.6 |
| | Vapour (75 th perc.) | 0.0008 | 0.02 |
| | Deposits (75 th perc.) | 0.02 | 0.4 |

| | | | |
|--------------------------------------|-----------------------------------|--------|-------|
| | Re-entry (75 th perc.) | N/A | N/A |
| | Sum (Mean) | 0.2 | 4.0 |
| Resident Adult Body weight: 10 kg | Drift (75 th perc.) | 0.2 | 3.1 |
| | Vapour (75 th perc.) | 0.0003 | 0.005 |
| | Deposits (75 th perc.) | 0.006 | 0.1 |
| | Re-entry (75 th perc.) | N/A | N/A |
| | Sum (Mean) | 0.1 | 2.1 |

Based on the online EFSA OPEX Model (EFSA 2022 Guidance), for the proposed uses of 'PROBLAD-PLUS' on outdoor and protected tomatoes, the predicted short term systemic exposure to a child and adult resident is within acceptable limits for all exposure pathways, with the (mean) sum of all pathways equivalent to:

- 5.4% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 2.7% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident for the proposed application to tomatoes grown outdoors.
- 4.0% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 2.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident for the proposed application to tomatoes grown in protected environments.

The short term exposure of bystanders is covered by the resident exposure assessment.

Bystander (Acute) Exposure

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

B.6.4.3 Worker exposure

A Tier 1 estimate of worker exposure is presented based on the highest application rate and the highest dermal absorption values (worst-case scenario). A summary of the estimated short term worker exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for the proposed uses of 'PROBLAD-PLUS' is provided in the following tables. Outputs of the EFSA Calculator (Version: 30th March 2015, 2014 EFSA Guidance) and online EFSA OPEX Model (Version 1.0.2, 2022 EFSA Guidance) are presented in Appendix 1 (Estimates 17 - 23).

Table B.6.4.3-1: EFSA Calculator estimate of short term worker exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* from the proposed uses of 'PROBLAD PLUS' on outdoor and protected tomatoes and strawberries and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | |
|--|---|--|--|
| Model data | Level of PPE | Total absorbed dose at day 0 (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) |
| Worker re-entry activity: Reaching/picking (tomatoes) Environment: Outdoors Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Body weight: 60 kg | Workwear (covering arms, body and legs) TC: 2500 cm ² /person/h | 1.5947 | 32 |
| Worker re-entry activity: Reaching/picking (strawberries) Environment: Outdoors Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 450 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Body weight: 60 kg | Workwear (covering arms, body and legs) TC: 3000 cm ² /person/h | 1.9136 | 38 |
| Worker re-entry activity: Reaching/picking (tomatoes) Environment: Protected Environment Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Body weight: 60 kg | Potential TC Value (No workwear) TC: 5800 cm ² /person/h | 3.7000 | 74 |
| Worker re-entry activity: Reaching/picking (strawberries) Environment: Protected Environment Work Rate: 8 hours/day | | | |

| | | | |
|--|---|-----------------------------|-----------|
| DT₅₀: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 450 L/ha | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | |
| Body weight: 60 kg | Potential TC Value (No workwear) TC: 5800 cm²/person/h | 3.7000 | 74 |

Based on the EFSA Calculator (EFSA 2014 Guidance), the predicted short term systemic worker exposure is calculated to be equivalent to:

- 32% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in tomato crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 38% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in strawberry crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 74% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting reaching/picking activities in tomato and strawberry crops grown indoors that have been previously treated with 'PROBLAD-PLUS'.

This is within acceptable limits.

For the worker exposure assessment using the online EFSA OPEX Model (below), HSE considers that, at the time of the non-dietary exposure assessment, the online EFSA OPEX Model (Version 1.0.2) uses incorrect Transfer Coefficient (TC) values for workers in protected environments conducting searching, reaching and picking activities in treated strawberry crops. The EFSA 2022 Guidance (EFSA Journal 2022;20(1):7032), uses TC values for orchard crops as a surrogate for indoor strawberries due to the potential for higher body exposure for strawberries grown on tables/racks indoors in comparison to outdoor strawberries grown in the ground. Table 10 of the EFSA guidance document details two sets of TC values for orchards based on maintenance/thinning tasks and search/reach/pick tasks. The online EFSA OPEX Model uses a TC value of 22,500 cm²/person/h for potential worker exposure and a TC value of 4500 cm²/person/h for a worker wearing workwear (covering the arms, body and legs) based on the orchards maintenance/thinning tasks as a surrogate for searching, reaching and picking indoor strawberries. However, HSE considers that the TC values for search/reach/pick re-entry activities in orchards (12,500 cm²/person/h for potential worker exposure and 3500 cm²/person/h for a worker wearing workwear covering the arms, body and legs) are a more appropriate surrogate for manual harvest activities in protected strawberries. Thus, the assessment below for the proposed use of 'PROBLAD-PLUS' on

protected strawberries has been performed outside of the online EFSA OPEX Model, using the HSE Decline Model (Estimate 24).

Table B.6.4.3-2: Online EFSA OPEX and HSE Decline Model estimates of short term worker exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* from the proposed uses of 'PROBLAD-PLUS' on outdoor and protected tomatoes and strawberries and comparison with AOEL

| Active Substance: Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | | | | |
|--|---|--|--|--------------------------------------|
| Model data | Level of PPE | Total absorbed dose at day 0 (mg/kg bw/day) | % of systemic AOEL (5 mg/kg bw/day) | Safe re-entry interval (Days) |
| Worker re-entry activity: Reaching/picking (tomatoes) Environment: Outdoors Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | | |
| Body weight: 60 kg | Workwear (covering arms, body and legs) TC: 2500 cm ² /person/h | 1.6 | 31.9 | 0 |
| Worker re-entry activity: Reaching/picking (strawberries) Environment: Outdoors Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 450 L/ha | | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | | |
| Body weight: 60 kg | Workwear (covering arms, body and legs) TC: 3000 cm ² /person/h | 1.9 | 38.3 | 0 |
| Worker re-entry activity: Reaching/picking (tomatoes) Environment: Protected Environment Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 200 L/ha | | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | | |
| Body weight: 60 kg | Potential TC Value (No workwear) TC: 5800 cm ² /person/h | 3.8 | 75.1 | 0 |

| | | | | |
|---|--|----------------------|---------------|------------|
| Worker re-entry activity: Searching, reaching and picking (strawberries) Environment: Protected Environment Work Rate: 8 hours/day DT₅₀: 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 8 days Minimum Water Volume: 450 L/ha | | | | |
| Application rate: | | 6 x 4.016 kg a.s./ha | | |
| Body weight: 60 kg | Potential TC Value (No workwear) TC: 12500 cm ² /person/h | 8.03* | 160.5* | 21* |
| Body weight: 60 kg | Workwear (covering arms, body and legs) TC: 3500 cm ² /person/h | 2.29* | 45.7* | 0* |

*Assessment performed outside of the online EFSA OPEX Model, using the HSE Decline Model

Based on the online EFSA OPEX Model and HSE Decline Model (EFSA 2022 Guidance), the predicted short term systemic worker exposure is calculated to be equivalent to:

- 31.9% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in tomato crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 38.3% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in strawberry crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 75.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting reaching/picking activities in tomato crops grown indoors that have been previously treated with 'PROBLAD PLUS'.
- 161% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting searching, reaching and picking activities in strawberry crops grown indoors that have been previously treated with 'PROBLAD-PLUS'.

The proposed uses of 'PROBLAD-PLUS' on outdoor tomatoes, protected tomatoes and outdoor strawberries is within acceptable limits. However, the proposed use of 'PROBLAD PLUS' on protected strawberries is above acceptable limits.

At the first tier, for application of products in protected/indoor environments, HSE considers that workers may not wear full length clothing due to elevated temperatures. However, as a refined assessment, HSE considers that it is practical for workers to use workwear (covering

the arms, body and legs) when carrying out re-entry activities in protected environments, provided that employers monitor for heat stress.

Therefore, using a TC value of 3500 cm²/hr (corresponding to the use of workwear covering the arms, body and legs in treated strawberry crops), worker exposure equivalent to 46% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* is predicted for a re-entry worker. The predicted exposure is within acceptable limits.

Indoor workers – Protection duration (Protected Strawberries)

Based on the HSE Decline Model that utilises data from the EFSA 2022 guidance (EFSA Journal 2022;20(1):7032), worker exposure to the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* is calculated to be equivalent to 98.8% of the AOEL for a worker without the use of workwear (covering the arms, body and legs) 21 days (expressed as 3 weeks) post-application to protected strawberries (see Appendix 1, Estimate 25).

Consideration of thermal comfort and heat stress

Although there are no defined maximum temperatures for UK workplaces, employers have a duty of care to ensure workers are comfortable and safe in their working environment. The HSE has published guidance for employers on thermal comfort and heat stress. As a consequence of this risk assessment, a level of clothing beyond what workers may normally wear for comfort is necessary to ensure exposure is adequately controlled. Employers will be expected to carry out a thermal comfort checklist (see – <http://www.hse.gov.uk/temperature/assets/docs/thermal-comfort-checklist.pdf>) prior to worker re-entry tasks (including hand harvesting). A consequence of completing the thermal comfort checklist may be to complete a more detailed heat stress checklist and associated risk assessment (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>), records for which would need to be retained to demonstrate compliance with the product's authorisation conditions.

The temperature and humidity inside tunnels/greenhouses should be monitored when workers are carrying out re-entry tasks (including hand harvesting) throughout the day. If conditions become such that there is a risk of heat related illness, or if workers complain of ill effects, then work must cease until the conditions become such that the risk is reduced. It is not acceptable for workers to remove clothing and continue working.

The following restriction phrase is required:

- Managers must carry out a thermal comfort checklist (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>) prior to worker re-entry tasks. If needed, an additional heat stress check list and associated risk assessment must be undertaken (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>) and the records retained. Temperature and humidity inside tunnels should be monitored during re-entry tasks. If conditions become such that there is a risk of heat related

illness, or workers complain of ill effects, then work must cease until the risk is reduced. It is not acceptable for workers to remove clothing and continue working.

Worker Exposure Conclusions (EFSA 2014 Guidance)

No worker protection or restriction phrases are required for the authorisation of 'PROBLAD PLUS' on protected tomatoes and strawberries.

Worker Exposure Conclusions (EFSA 2022 Guidance)

The following worker protection and restriction phrases are required for the authorisation of 'PROBLAD-PLUS' on protected tomatoes and strawberries:

Worker protection phrases for the proposed maximum application rate of 4.016 kg a.s./ha to protected strawberries:

- Workers must wear suitable protective clothing in which arms, body and legs are fully covered when re-entering protected treated areas or handling protected strawberry crops or contaminated surfaces for 3 weeks post-treatment.

Other specific restrictions:

- Managers must carry out a thermal comfort checklist (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>) prior to worker re-entry tasks. If needed, an additional heat stress check list and associated risk assessment must be undertaken (see- <http://www.hse.gov.uk/temperature/assets/docs/heat-stress-checklist.pdf>) and the records retained. Temperature and humidity inside tunnels should be monitored during re-entry tasks. If conditions become such that there is a risk of heat related illness, or workers complain of ill effects, then work must cease until the risk is reduced. It is not acceptable for workers to remove clothing and continue working.

B.6.5. Exposure and risk assessment

B.6.5.1. Operator exposure

Estimates of operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor and protected tomatoes and strawberries have been calculated using the EFSA Calculator (Version: 30th March 2015, EFSA 2014 Guidance), EUROPOEM and the online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance). The results are summarised in the tables below:

Table B.6.5.1-1: Summary of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor tomatoes and strawberries. Model: EFSA Calculator

| Application Equipment | PPE Requirements | % of systemic AOEL |
|--|-------------------|--------------------|
| Vehicle mounted boom sprayer | Workwear (No PPE) | 11 |
| Manual-handheld (tank and lance) sprayer | Workwear (No PPE) | 5 |
| Handheld knapsack | Workwear (No PPE) | 2 |

Table B.6.5.1-2: Summary of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor tomatoes and strawberries. Model: Online EFSA OPEX Model

| Application Equipment | PPE Requirements | % of systemic AOEL |
|--|-------------------|--------------------|
| Vehicle mounted boom sprayer | Workwear (No PPE) | 9.6 |
| Manual-handheld (tank and lance) sprayer | Workwear (No PPE) | 5.5 |
| Handheld knapsack | Workwear (No PPE) | 1.8 |

Table B.6.5.1-3: Summary of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to protected tomatoes and strawberries. Model: EFSA Calculator and EUROPOEM

| Application Equipment | Crop culture | PPE Requirements | % of systemic AOEL |
|---|----------------|-------------------|--------------------|
| Manual-handheld (tank and lance) sprayer* | Not Applicable | Workwear (No PPE) | 12 |
| Handheld knapsack* | Not Applicable | Workwear (No PPE) | 13 |

*Calculated using EUROPOEM Database.

Table B.6.5.1-4: Summary of short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to protected tomatoes and strawberries. Model: Online EFSA OPEX Model

| Application Equipment | Crop culture | PPE Requirements | % of systemic AOEL |
|--|--------------|-------------------|--------------------|
| Manual-handheld (tank and lance) sprayer | Normal | Workwear (No PPE) | 6.1 |
| Handheld knapsack | Normal | Workwear (No PPE) | 6.3 |
| Manual trolley sprayer | Normal | Workwear (No PPE) | 2.4 |
| Manual-handheld (tank and lance) sprayer | Dense | Workwear (No PPE) | 95.9 |
| Handheld knapsack | Dense | Workwear (No PPE) | 96.1 |

The predicted short term operator exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor and protected tomatoes and strawberries is calculated to be within acceptable limits.

It is considered that application to protected crops via vehicle mounted equipment is likely to be within acceptable limits with the following additional operator protection phases:

- Broadcast air-assisted sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* during application in protected situations.

*Closed cabin meeting at least EN 15695 category 3.

- Vehicle-mounted or trailed horizontal or vertical boom sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* or suitable respiratory protective equipment** must be worn during application in protected situations.

*Closed cabin meeting at least EN 15695 category 3

**Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

The product 'PROBLAD-PLUS' is not classified for human health effects. Thus, there are no additional PPE requirements.

B.6.5.2 Bystander and resident exposure

For the proposed uses of 'PROBLAD-PLUS' on tomatoes and strawberries grown outdoors, estimates of resident exposure using the EFSA Calculator (Version: 30th March 2015) predict that short term exposure to a child and adult is within acceptable limits for all exposure pathways, with the (mean) sum for all pathways equivalent to 5% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 3% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident.

Note: The EFSA 2014 guidance and associated EFSA Calculator does not consider resident exposure from indoor applications.

The short term exposure of bystanders is covered by the resident exposure assessment.

For the proposed uses of 'PROBLAD-PLUS' on tomatoes and strawberries grown in outdoor and protected environments, estimates of resident exposure using the online EFSA OPEX Model (Version 1.0.2) predict that short term exposure to a child and adult is within acceptable limits for all exposure pathways, with the (mean) sum for all pathways equivalent to:

- 5.4% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 2.7% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident for the proposed application to tomatoes and strawberries grown outdoors.
- 4% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a child resident and 2.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for an adult resident for the proposed application to tomatoes and strawberries grown in protected environments.

The short term exposure of bystanders is covered by the resident exposure assessment.

B.6.5.3 Worker exposure

For the proposed uses of 'PROBLAD-PLUS' on outdoor and protected tomatoes and strawberries, estimates of worker exposure using the EFSA Calculator (Version: 30th March 2015) predict that short term exposure is equivalent to:

- 32% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in tomato crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 38% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in strawberry crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.

- 74% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting reaching/picking activities in tomato and strawberry crops grown indoors that have been previously treated with 'PROBLAD-PLUS'.

The predicted short term worker exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor and protected tomatoes and strawberries at an application rate of 6 x 4.016 kg a.s./ha is calculated to be within acceptable limits.

For the proposed uses of 'PROBLAD-PLUS' on outdoor and protected tomatoes and strawberries, estimates of worker exposure using the online EFSA OPEX Model (Version 1.0.2) and HSE Decline Model predict that short term exposure is equivalent to:

- 31.9% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in tomato crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 38.3% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) whilst conducting reaching/picking activities in strawberry crops grown outdoors that have been previously treated with 'PROBLAD-PLUS'.
- 75.1% of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting reaching/picking activities in tomato crops grown indoors that have been previously treated with 'PROBLAD PLUS'.
- 161%* of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker without workwear conducting searching, reaching and picking activities in strawberry crops grown indoors that have been previously treated with 'PROBLAD-PLUS'.
- 46%* of the AOEL of aqueous extract from the germinated seeds of sweet *Lupinus albus* for a re-entry worker wearing workwear (covering the arms, body and legs) conducting searching, reaching and picking activities 21 days (expressed as 3 weeks) post application in strawberry crops grown indoors that have been previously treated with 'PROBLAD-PLUS'.

*Calculated using the HSE Decline Model.

Therefore, the predicted short term worker exposure to aqueous extract from the germinated seeds of sweet *Lupinus albus* for application of 'PROBLAD-PLUS' to outdoor and protected tomatoes and strawberries at an application rate of 6 x 4.016 kg a.s./ha is calculated to be within acceptable limits.

B.6.6. APPENDIX 1: EXPOSURE CALCULATIONS**Inputs into the EFSA Calculator (Version 30th March 2015, EFSA 2014 Guidance)**

| | | |
|--|---|--------------------------------------|
| Substance name | Aqueous extract from the germinated seeds of sweet Lupinus albus | |
| Product name | PROBLAD PLUS | |
| Reference value non acutely toxic active substance (RVNAS) | 5 | mg/kg bw/day |
| Reference value acutely toxic active substance (RVAAS) | | mg/kg bw/day |
| Crop type | Fruiting vegetables | |
| Substance properties | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | |
| Minimum volume water for application (liquids) | 200 | L/ha |
| Maximum application rate of active substance | 4.016 | kg a.s. /ha |
| 50% Dissipation Time DT50 | 30 | days |
| Initial Dislodgeable Foliar Residue | 3 | µg/cm2 of foliage/kg a.s. applied/ha |
| Dermal absorption of product | 10.00% | |
| Dermal absorption of in-use dilution | 10.00% | |
| Oral absorption of active substance | 100.00% | |
| Inhalation absorption of active substance | 100.00% | |
| Vapour pressure of active substance | low volatile substances having a vapour pressure of <5*10-3Pa | |
| Scenario | | |
| Indoor or Outdoor application | Outdoor | |
| Application method | Downward spraying | |
| Application equipment | Vehicle-mounted | |
| Buffer strip | 2-3 | m |
| Number of applications | 6 | |
| Interval between multiple applications | 8 | days |
| Season (upward spraying orchards only) | not relevant | |

| | | |
|--|---|--------------------------------------|
| Substance name | Aqueous extract from the germinated seeds of sweet Lupinus albus | |
| Product name | PROBLAD PLUS | |
| Reference value non acutely toxic active substance (RVNAS) | 5 | mg/kg bw/day |
| Reference value acutely toxic active substance (RVAAS) | | mg/kg bw/day |
| Crop type | Low berries and other small fruits | |
| Substance properties | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | |
| Minimum volume water for application (liquids) | 450 | L/ha |
| Maximum application rate of active substance | 4.016 | kg a.s. /ha |
| 50% Dissipation Time DT50 | 30 | days |
| Initial Dislodgeable Foliar Residue | 3 | µg/cm2 of foliage/kg a.s. applied/ha |
| Dermal absorption of product | 10.00% | |
| Dermal absorption of in-use dilution | 10.00% | |
| Oral absorption of active substance | 100.00% | |
| Inhalation absorption of active substance | 100.00% | |
| Vapour pressure of active substance | low volatile substances having a vapour pressure of <5*10-3Pa | |
| Scenario | | |
| Indoor or Outdoor application | Outdoor | |
| Application method | Downward spraying | |
| Application equipment | Vehicle-mounted | |
| Buffer strip | 2-3 | m |
| Number of applications | 6 | |
| Interval between multiple applications | 8 | days |
| Season (upward spraying orchards only) | not relevant | |

Inputs into the Online EFSA OPEX Model (Version 1.0.2, EFSA 2022 Guidance)

1. Information on product and active substance(s)

| | |
|--|---|
| Product name | PROBLAD PLUS |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. |
| Product category | Other |
| Name of active substance | Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> |
| Concentration of active substance [g a.s./l or kg] | 1255 |
| AOEL [mg/kg bw/day] | 5 |
| AAOEL [mg/kg bw] | |
| Inhalation absorption [%] | 100 |
| Oral absorption [%] | 100 |
| Dermal absorption [%] (concentrate) | 10 |

2. Assessed uses

| Use | Crops | Max. application rate of the product [l or kg/ha] | Unit | Max. no. of applications | Interval between multiple applications [days] | Min. volume water [l/ha] | Max. volume water [l/ha] | Indoor/outdoor | Application method | Type of cultivation | Application technique | Buffer strip [m] | Drift reduction [%] |
|-------|----------------------|---|------|--------------------------|---|--------------------------|--------------------------|----------------|--------------------|---------------------|-----------------------|------------------|---------------------|
| Use 1 | Strawberry (outdoor) | 3.2 | l/ha | 6 | 8 | 450 | 1000 | Outdoor | Downward spraying | Normal | Vehicle-mounted | 2-3 | 0 |
| Use 2 | Low vegetables | 3.2 | l/ha | 6 | 8 | 200 | 1000 | Outdoor | Downward spraying | Normal | Vehicle-mounted | 2-3 | 0 |
| Use 3 | Strawberry (indoor) | 3.2 | l/ha | 6 | 8 | 450 | 1000 | Indoor | Upward spraying | Normal | Manual-hand held | 5 | 0 |
| Use 3 | Strawberry (indoor) | 3.2 | l/ha | 6 | 8 | 450 | 1000 | Indoor | Upward spraying | Dense | Manual-hand held | 5 | 0 |
| Use 4 | High vegetables | 3.2 | l/ha | 6 | 8 | 200 | 1000 | Indoor | Upward spraying | Normal | Manual-hand held | 5 | 0 |
| Use 4 | High vegetables | 3.2 | l/ha | 6 | 8 | 200 | 1000 | Indoor | Upward spraying | Dense | Manual-hand held | 5 | 0 |

Estimate 1: EFSA Calculator (Version: 30th March 2015) – Short term operator exposure for application of 'PROBLAD-PLUS' via vehicle mounted boom sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

| Operator exposure for PROBLAD PLUS outdoor spray applications | | | | | |
|--|---|--|--------------------------|--------------------------------------|------------------------------|
| Application rate of active substance | | 4.016 kg a.s./ha | | i_AppRate | |
| Assumed area treated | | 50 ha/day | | d_AreaTreated | |
| Amount of active substance applied | | 200.8 kg a.s./day | | i_AmountAS | |
| Dermal absorption of the product | | 10.00% | | i_AbsorpProduct | |
| Dermal absorption of in-use dilution | | 10.00% | | i_AbsorInuse | |
| Formulation type | | Soluble concentrates, emulsifiable concentrate, etc. | | | |
| Indoor or Outdoor application | | Outdoor | | | |
| Application method | | Downward spraying | | | |
| Application equipment | | Vehicle-mounted | | | |
| Season | | not relevant | | | |
| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 287804 | 1105086 | AOEM | |
| | Body | 148256 | 336114 | AOEM | |
| | Head | 10418 | 57139 | AOEM | |
| | Protected hands (gloves) | 1086 | 39772 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 2613 | 29367 | AOEM | |
| | Protected head (hood and face shield) | 167 | 3235 | AOEM | |
| | Inhalation | 18 | 33 | 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 | 29783 | 111362 | AOEM | |
| | Body | 16653 | 85845 | AOEM | |
| | Head | 787 | 2374 | AOEM | |
| | Protected hands (gloves) | 754 | 6185 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 457 | 1120 | AOEM | |
| | Inhalation | 15 | 61 | AOEM | |
| | Protective Equipment | Select for inclusion | | Penetration 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) | | 49.4028032 | | 33.2188875 | |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | | 0.8233801 | | 0.5536481 | |
| % of RVNAS | | 16.47% | | 11.07% | |

Estimate 2: EFSA Calculator (Version: 30th March 2015) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld manual (tank and lance) sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

| Operator exposure for PROBLAD PLUS outdoor spray applications | | | | | | |
|--|---|--|--------------------------|--------------------------------------|------------------------------|------------------------------|
| Application rate of active substance | | 4.016 kg a.s./ha | | i_AppRate | | |
| Assumed area treated | | 4 ha/day | | d_AreaTreated | | |
| Amount of active substance applied | | 16.064 kg a.s./day | | i_AmountAS | | |
| Dermal absorption of the product | | 10.00% | | i_AbsorpProduct | | |
| Dermal absorption of in-use dilution | | 10.00% | | i_AbsorInuse | | |
| Formulation type | | Soluble concentrates, emulsifiable concentrate, etc. | | | | |
| Indoor or Outdoor application | | Outdoor | | | | |
| Application method | | Downward spraying | | | | |
| Application equipment | | Manual-Hand held | | | | |
| Season | | not relevant | | | | |
| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment | |
| | | 75 th centile | 95 th centile | | | |
| | Hands | 41178 | 154625 | AOEM | | |
| | Body | 25117 | 161363 | AOEM | | |
| | Head | 833 | 4571 | AOEM | | |
| | Protected hands (gloves) | 210 | 3182 | AOEM | | |
| | Protected body (workwear or protective garment and sturdy footwear) | 278 | 2349 | AOEM | | |
| | Protected head (hood and face shield) | 13 | 259 | AOEM | | |
| | Inhalation | 8 | 31 | 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 | 16535 | 45118 | AOEM | | |
| | Body | 951717 | 1467254 | AOEM | | |
| | Head | 129 | 910 | AOEM | | |
| | Protected hands (gloves) | 54 | 236 | AOEM | | |
| | Protected body (workwear or protective garment and sturdy footwear) | 95345 | 670726 | AOEM | | |
| | Inhalation | 278 | 278 | 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) | | 103.8377540 | | 15.7167604 | | |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | | 1.7306292 | | 0.2619460 | | |
| % of RVNAS | | 34.61% | | 5.24% | | |

Estimate 3: EFSA Calculator (Version: 30th March 2015) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld knapsack sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

| Operator exposure for PROBLAD PLUS outdoor spray applications | | | | | |
|--|---|--|--------------------------|--------------------------------------|------------------------------|
| Application rate of active substance | | 4.016 kg a.s./ha | | i_AppRate | |
| Assumed area treated | | 1 ha/day | | d_AreaTreated | |
| Amount of active substance applied | | 4.016 kg a.s./day | | i_AmountAS | |
| Dermal absorption of the product | | 10.00% | | i_AbsorpProduct | |
| Dermal absorption of in-use dilution | | 10.00% | | i_AbsorInuse | |
| Formulation type | | Soluble concentrates, emulsifiable concentrate, etc. | | | |
| Indoor or Outdoor application | | Outdoor | | | |
| Application method | | Downward spraying | | | |
| Application equipment | | Manual-Knapsack | | | |
| Season | | not relevant | | | |
| | | OutdoorSoluble concentrates, emulsifiable concentrate, etc. Downward sprayingManual-Knapsack | | | |
| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment |
| | | 75 th centile | 95 th centile | | |
| | Hands | 25421 | 68224 | AOEM | |
| | Body | 2150 | 7462 | AOEM | |
| | Head | 13 | 29 | AOEM | |
| | Protected hands (gloves) | 48 | 439 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 67 | 276 | AOEM | |
| | Protected head (hood and face shield) | 13 | 29 | AOEM | |
| | Inhalation | 67 | 70 | 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 | 4134 | 11280 | AOEM | |
| | Body | 237929 | 366813 | AOEM | |
| | Head | 32 | 228 | AOEM | |
| | Protected hands (gloves) | 13 | 59 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 23836 | 167681 | AOEM | |
| | Inhalation | 70 | 70 | 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) | | 27.1045195 | | 5.4869269 | |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | | 0.4517420 | | 0.0914488 | |
| % of RVNAS | | 9.03% | | 1.83% | |

Estimate 4: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via vehicle mounted boom sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

3.3.1. Scenario 1 : Outdoor, normal, downward spraying, vehicle-mounted

3.3.1.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of syst emic AOE L |
|---|---|--|----------------------|
| Low vegetables/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.5 | 9.6 |

Estimate 5: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld manual (tank and lance) sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

3.3.2. Scenario 2 : Outdoor, normal, downward spraying, manual-hand held

3.3.2.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of syst emic AOE L |
|--|---|--|----------------------|
| Low vegetables/Outdoor/Downward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.3 | 5.5 |

Estimate 6: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld knapsack sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

3.3.3. Scenario 3 : Outdoor, normal, downward spraying, manual-knapsack

3.3.3.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|---|---|--|---------------------|
| Low vegetables/Outdoor/Downward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.09 | 1.8 |

Estimate 7: EUROPOEM Model – Short term operator exposure for application of 'PROBLAD PLUS' via handheld manual (tank and lance) sprayer to high vegetables (tomatoes) grown in protected environments.

PPE: None

Crop Density: Not applicable

| EUROPOEM (75th percentile values) | | | | | | | | | | |
|--|---------|---|-----------------|---|--------------|----------------|-----------|-------------------------------|-----------------------------------|--------------------------------|
| Hand-held sprayers (indoor use). Combined mixer/loader/appliquer values. | | | | | | | | | | |
| Application rate (product) | | 3.2 l/ha | | Dermal absorption for the concentrate and spray solution* | | 10 % | | | | |
| a.s. content | | 1255 g/l | | AOEL | | 5 mg/kg bw/day | | | | |
| Work rate | | 1 ha/day | | | | | | | | |
| Amount of a.s. handled/applied | | 4.016 kg/day | | | | | | | | |
| | | | | | | | | | | |
| | | Component | kg a.s. handled | Exposure mg/kg a.s. | % absorption | mg/person/day | % of AOEL | Total dermal mg/person/day | Total inhalation mg/person/day | Total Systemic mg/kg bw/day |
| No PPE | PIE | = | 4.016 x | 0.153 | 100 = | 0.614448 | 0% | 34.4754 | 0.6144 | 0.5848 |
| | PDE (b) | = | 4.016 x | 28.701 | 10 = | 11.5263216 | 4% | | | |
| | PDE (h) | = | 4.016 x | 57.144 | 10 = | 22.9490304 | 8% | | | |
| | Total | | | | | 35.0898 | 12% | | | |
| Gloves only | PIE | = | 4.016 x | 0.153 | 100 = | 0.614448 | 0% | 13.8211 | 0.6144 | 0.2406 |
| | PDE (b) | = | 4.016 x | 28.701 | 10 = | 11.5263216 | 4% | | | |
| | ADE (h) | = | 4.016 x | 5.714 | 10 = | 2.2947424 | 1% | | | |
| | Total | | | | | 14.435512 | 5% | | | |
| Coveralls and gloves | PIE | = | 4.016 x | 0.153 | 100 = | 0.614448 | 0% | 2.6333 | 0.6144 | 0.0541 |
| | ADE (b) | = | 4.016 x | 0.843 | 10 = | 0.3385488 | 0% | | | |
| | ADE (h) | = | 4.016 x | 5.714 | 10 = | 2.2947424 | 1% | | | |
| | Total | | | | | 3.2477392 | 1% | | | |
| | | | | | | | | | | |
| * | | When different dermal absorption values are available for the concentrate and the spray solution, the higher value is used | | | | | | | | |
| PIE | | Potential inhalation exposure (mix/load/apply) | | | | | | | | |
| PDE (b) | | Potential body exposure less hands, feet and head (mix/load/apply) from sum of outer and inner body dosimeter measurements | | | | | | | | |
| PDE (h) | | Potential hand exposure (mix/load/apply) from sampling glove measurements (no protective gloves worn) | | | | | | | | |
| ADE (b) | | Actual body exposure less hands, feet and head (mix/load/apply) from inner body dosimeter measurements | | | | | | | | |
| ADE (h) | | Actual hand exposure (mix/load/apply) assuming that protective gloves are worn providing 90% protection from penetration/transfer | | | | | | | | |
| % of AOEL | | Assuming a body weight of 60 kg | | | | | | | | |

Estimate 8: EFSA Calculator (Version: 30th March 2015) – Short term operator exposure during mixing/loading 'PROBLAD-PLUS' in a handheld knapsack sprayer prior to application to high vegetables (tomatoes) grown in protected environments.

PPE: None

Crop Density: Not applicable

| Operator exposure for PROBLAD PLUS outdoor spray applications | | | | | |
|---|--|------------------------|--|--|--|
| Application rate of active substance | 4.016 kg a.s./ha | <i>i_AppRate</i> | | | |
| Assumed area treated | 1 ha/day | <i>d_AreaTreated</i> | | | |
| Amount of active substance applied | 4.016 kg a.s./day | <i>i_AmountAS</i> | | | |
| Dermal absorption of the product | 10.00% | <i>i_AbsorpProduct</i> | | | |
| Dermal absorption of in-use dilution | 10.00% | <i>i_AbsorpInuse</i> | | | |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | | | |
| Indoor or Outdoor application | Outdoor | | | | |
| Application method | Downward spraying | | | | |
| Application equipment | Manual-Knapsack | | | | |
| Season | not relevant | | | | |

| Mixing and loading | Exposure values | µg exposure/day mixed and loaded | | Reference | Comment |
|--------------------|---|---|--------------------------|---------------------|------------------------------|
| | | 75 th centile | 95 th centile | | |
| | Hands | 25421 | 68224 | AOEM | |
| | Body | 2150 | 7462 | AOEM | |
| | Head | 13 | 29 | AOEM | |
| | Protected hands (gloves) | 48 | 439 | AOEM | |
| | Protected body (workwear or protective garment and sturdy footwear) | 67 | 276 | AOEM | |
| | Protected head (hood and face shield) | 13 | 29 | AOEM | |
| | Inhalation | 67 | 70 | 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 | |

| 2. Longer term exposure | | | |
|----------------------------------|----------------------------------|---------------------------------------|--|
| 2.1 Mixing and loading | | | |
| | Systemic exposure [µg a.s. /day] | Systemic exposure [µg a.s./kg bw/day] | Formula |
| Without RPE/PPE | | | |
| Hands | 2542.1280000 | 42.3688000 | $D15 * i_AbsorpProduct$ |
| Body | 214.9898667 | 3.5831644 | $D16 * i_AbsorpProduct$ |
| Head | 1.3386667 | 0.0223111 | $D17 * i_AbsorpProduct$ |
| Inhalation | 66.9333333 | 1.1155556 | $D21 * i_AbsorpInhalation$ |
| Sum | 2825.3898667 | 47.0898311 | |
| With RPE/PPE (as selected above) | | | |
| Hands | 2542.1280000 | 42.3688000 | $D18 * i_AbsorpProduct$ |
| Body | 6.6933333 | 0.1115556 | $D19 * i_AbsorpProduct$ or $D15 * i_AbsorpProduct * F24$ |
| Head | 1.3386667 | 0.0223111 | $D20 * i_AbsorpProduct$ or $D17 * i_AbsorpProduct * F25$ |
| Inhalation | 66.9333333 | 1.1155556 | $D21 * i_AbsorpInhalation * G25$ |
| Sum | 2617.0933333 | 43.6182222 | |
| Water soluble bag | 2617.0933333 | 43.6182222 | $C70 * F26$ |

Estimate 9: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld manual (tank and lance) sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

Crop Density: 'Normal'

3.4.1. Scenario 1 : Indoor, normal, upward spraying, manual-hand held

3.4.1.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|--|---|--|---------------------|
| High vegetables/Indoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.3 | 6.1 |

Estimate 10: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld knapsack sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

Crop Density: 'Normal'

3.4.2. Scenario 2 : Indoor, normal, upward spraying, manual-knapsack

3.4.2.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|---|---|--|---------------------|
| High vegetables/Indoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.3 | 6.3 |

Estimate 11: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via manual trolley sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

Crop Density: 'Normal'

3.4.3. Scenario 3 : Indoor, normal, upward spraying, manual-trolley

3.4.3.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|--|---|--|---------------------|
| High vegetables/Indoor/Upward spraying/Manual-trolley/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 0.1 | 2.4 |

Estimate 12: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld manual (tank and lance) sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

Crop Density: 'Dense'

3.4.4. Scenario 4 : Indoor, dense, upward spraying, manual-hand held

3.4.4.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|---|---|--|---------------------|
| High vegetables/Indoor/Upward spraying/Manual-hand held/Drift reduction: 0 %/75th percentile Crop density: Dense | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 4.8 | 95.9 |

Estimate 13: Online EFSA OPEX Model (Version 1.0.2) – Short term operator exposure for application of 'PROBLAD-PLUS' via handheld knapsack sprayer to low vegetables (tomatoes) grown outdoors.

PPE: None.

Crop Density: 'Dense'

3.4.5. Scenario 5 : Indoor, dense, upward spraying, manual-knapsack

3.4.5.1. Summary data - Short term exposure

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOE L |
|--|---|--|---------------------|
| High vegetables/Indoor/Upward spraying/Manual-knapsack/Drift reduction: 0 %/75th percentile Crop density: Dense | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption (concentrate): 10 % | | |
| | Dermal absorption (in-use dilution): 10 % | | |
| | M/L: Workwear App: Workwear | 4.8 | 96.1 |

Aqueous extract from the germinated seeds of sweet *Lupinus albus*

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Estimate 14: EFSA Calculator (Version: 30th March 2015) – Child and adult resident (short term) exposure for application of 'PROBLAD-PLUS' via vehicle mounted boom sprayer to low vegetables (tomatoes) grown outdoors.

| Resident exposure for PROBLAD PLUS | | | | | |
|---|--|--------------------------|--|--|---------------------|
| Croptype | Fruiting vegetables | | | | |
| Application method | Downward spraying | | | | |
| Application equipment | Vehicle-mounted | | | | L_AppEquip |
| Formulation type | Soluble concentrates, emulsifiable concentrate, etc. | | | | L_FormVal |
| Buffer strip | 2-3 m | | | | L_Buffer |
| Application rate of the product | 4.016 kg a.s./ha | | | | L_AppRate |
| Concentration of active substance (in-use dilution for liquid applications) | 20.08 g a.s./l | | | | d_ConcAS |
| Dermal absorption of product | 10.00% | | | | L_AbsorpProduct |
| Dermal absorption of in-use dilution | 10.00% | | | | L_Absorpinuse |
| Oral absorption | 100.00% | | | | L_AbsorpOrallnuse |
| Dislodgeable foliar residue (L_AppRate*1_DFR) | 12.048 µg a.s./cm ² | | | | d_DFR |
| Vapour pressure of in-use dilution | low volatile substances having a vapour pressure of <5*10 ⁻³ Pa | | | | L_Volat |
| Concentration in air | 0.001 mg/m ³ | | | | d_AirCon |
| Resident dermal spray drift exposure 75th percentile - adult | 0.47 ml spray dilution/person | | | | |
| Resident dermal spray drift exposure 75th percentile - child | 0.327 ml spray dilution/person | | | | |
| Resident inhal. spray drift exposure 75th percentile - adult | 0.00010 ml spray dilution/person | | | | |
| Resident inhal. spray drift exposure 75th percentile - child | 0.00022 ml spray dilution/person | | | | |
| Resident dermal spray drift exposure mean - adult | 0.22318 ml spray dilution/person | | | | |
| Resident dermal spray drift exposure mean - child | 0.18 ml spray dilution/person | | | | |
| Resident inhal. spray drift exposure mean - adult | 0.00009 ml spray dilution/person | | | | |
| Resident inhal. spray drift exposure mean - child | 0.00017 ml spray dilution/person | | | | |
| Exposure duration dermal | 2 hours | | | | d_ReExpDur |
| Exposure duration inhalation | 24 hours | | | | d_ReExpDurinhal |
| Exposure duration entry into treated crops | 0.25 hours | | | | d_ExpDurTreatCrop |
| Light clothing adjustment factor | 18.0% | | | | d_ClothAF |
| Breathing rate adult | 0.23 m ³ /day/kg | | | | d_BreathRAd |
| Breathing rate child (1-3 year old) | 1.07 m ³ /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 cm ² /hour | | | | d_ReTCAd |
| Transfer coeff. of surface deposits-child (1-3 year old) | 2600 cm ² /hour | | | | d_ReTCCh |
| Saliva extraction percentage | 50.00% | | | | d_SolExt |
| Surface area of hands mouthed | 20 cm ² | | | | d_AreaHM |
| Frequency of hand to mouth activity | 9.5 events/hour | | | | d_ReFreqHM |
| Ingestion rate for mouthing of grass per day | 25 cm ² | | | | d_MouthGrass |
| Dislodgeable residues percentage transferability for object to mouth | 20.00% | | | | d_DRP |
| Transfer coefficient for entry into treated crops (75th percentile) - adult | 7500 cm ² /h | | | | d_TcEntryAd |
| Transfer coefficient for entry into treated crops (75th percentile) - child | 2250 cm ² /h | | | | d_TcEntryCh |
| Transfer coefficient for entry into treated crops (mean) - adult | 5980 cm ² /h | | | | d_TcEntryAd |
| Transfer coefficient for entry into treated crops (mean) - child | 1794 cm ² /h | | | | d_TcEntryCh |
| 1. Total | | | | | |
| 1.1 1-3 year old child | | | | | |
| Spray drift (75th percentile) | | Vapour (75th percentile) | | Entry into treated crops (75th percentile) | All pathways (mean) |
| Total systemic exposure (mg a.s./day) | 0.5428427 | 0.0107000 | | 2.6910210 | 2.7209316 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 0.0542843 | 0.0010700 | | 0.2691021 | 0.2720932 |
| % of RVNAS | 1.09% | 0.02% | | 5.38% | 5.44% |
| 1.2 Adult | | | | | |
| Spray drift | | Vapour | | Entry into treated crops | All pathways (mean) |
| Total systemic exposure (mg a.s./day) | 0.7758912 | 0.0138000 | | 8.9700701 | 8.0125098 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 0.0129315 | 0.0002300 | | 0.1495012 | 0.1335418 |
| % of RVNAS | 0.26% | 0.00% | | 2.99% | 2.67% |

Estimate 15: Online EFSA OPEX Model (Version 1.0.2) – Child and adult resident (short term) exposure for application of 'PROBLAD-PLUS' via vehicle mounted boom sprayer to low vegetables (tomatoes) grown outdoors.

5.3. Use 3 : Low vegetables

5.3.1. Scenario 1 : Outdoor, season not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|---|--|--------------------|
| Season: Not relevant Buffer zone: 2-3 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 200 l | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4,016 kg a.s./ha | | |
| | Dermal absorption: 10 % | | |
| | DFR: 3 µg/cm ² foliage per kg a.s./ha | | |
| | DT50: 30 days | | |
| | Drift (75th perc.) | 0.05 | 1.1 |
| | Vapour (75th perc.) | 0.0008 | 0.02 |
| Resident child Body weight: 10 kg | Deposits (75th perc.) | 0.04 | 0.7 |
| | Re-entry (75th perc.) | 0.3 | 5.4 |
| | Sum (mean) | 0.3 | 5.4 |
| | Drift (75th perc.) | 0.01 | 0.3 |
| Resident adult Body weight: 60 kg | Vapour (75th perc.) | 0.0003 | 0.005 |
| | Deposits (75th perc.) | 0.01 | 0.2 |
| | Re-entry (75th perc.) | 0.1 | 3 |
| | Sum (mean) | 0.1 | 2.7 |

Estimate 16: Online EFSA OPEX Model (Version 1.0.2) – Child and adult resident (short term) exposure for application of 'PROBLAD-PLUS' via handheld manual (tank and lance) sprayer to high vegetables (tomatoes) grown in protected environments.

5.4. Use 4 : High vegetables

5.4.1. Scenario 1 : Indoor, season not relevant

| Model data | Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL |
|--|---|--|--------------------|
| Season: Not relevant Buffer zone: 5 m Drift reduction technology: 0 % Interval between treatments: 8 days Minimum volume of water: 200 l | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | Number of applications and application rate: 6 x 4.016 kg a.s./ha | | |
| | Dermal absorption: 10 % | | |
| | DFR: 3 µg/cm² foliage per kg a.s./ha | | |
| | DT50: 30 days | | |
| | | | |
| Resident child Body weight: 10 kg | Drift (75th perc.) | 0.3 | 5.6 |
| | Vapour (75th perc.) | 0.0008 | 0.02 |
| | Deposits (75th perc.) | 0.02 | 0.4 |
| | Re-entry (75th perc.) | | |
| | Sum (mean) | 0.2 | 4 |
| Resident adult Body weight: 60 kg | Drift (75th perc.) | 0.2 | 3.1 |
| | Vapour (75th perc.) | 0.0003 | 0.005 |
| | Deposits (75th perc.) | 0.006 | 0.1 |
| | Re-entry (75th perc.) | | |
| | Sum (mean) | 0.1 | 2.1 |

Estimate 17: EFSA Calculator (Version: 30th March 2015) – Worker exposure for reaching and picking activities in tomatoes grown outdoors that have previously been treated with 'PROBLAD-PLUS'

| Worker exposure from residues on foliage for PROBLAD PLUS | | | |
|--|-----------------------------|---|-------------------------|
| Crop type | Fruiting vegetables | | |
| Indoor or outdoor | Outdoor | | |
| Application method | Downward spraying | | |
| Application equipment | Vehicle-mounted | | |
| Worker's task | Reaching, picking | | |
| Main body parts in contact with foliage | Hand and body | | |
| Application rate of active substance | 4.016 kg a.s./ha | | |
| Number of applications | 6 | | |
| Interval between multiple applications | 8 days | | |
| Half-life of active substance | 30 days | | |
| Multiple application factor | 4.0 | | |
| Dermal absorption of the product | 10.00% | | |
| Dermal absorption of the in-use dilution | 10.00% | | |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 12.048 µg a.s./cm² | | |
| Working hours | 8 hr | | |
| Dermal transfer coefficient - Total potential exposure | 5800 cm²/hr | | |
| Dermal transfer coefficient - arms, body and legs covered | 2500 cm²/hr | | |
| Dermal transfer coefficient - hands, arms, body and legs covered | 580 cm²/hr | | |
| Inhalation transfer coefficient for automated applications | NA ha/hr*10 ⁽⁻³⁾ | | |
| Inhalation transfer coefficient for cutting ornamentals | NA ha/hr*10 ⁽⁻³⁾ | | |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA ha/hr*10 ⁽⁻³⁾ | | |
| 1. Total | | | |
| | Potential exposure | Work wear - arms, body and legs covered | Working wear and gloves |
| Total systemic exposure (mg a.s./day) | 221.9793356 | 95.6807481 | 22.1979336 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 3.6996556 | 1.5946791 | 0.3699656 |
| % of RVNAS | 73.99% | 31.89% | 7.40% |

Estimate 18: EFSA Calculator (Version: 30th March 2015) – Worker exposure for reaching and picking activities in low berries (strawberries) grown outdoors that have previously been treated with 'PROBLAD-PLUS'.

| Worker exposure from residues on foliage for PROBLAD PLUS | | | |
|--|------------------------------------|---|-------------------------|
| Crop type | Low berries and other small fruits | | |
| Indoor or outdoor | Outdoor | | |
| Application method | Downward spraying | | |
| Application equipment | Vehicle-mounted | | |
| Worker's task | Reaching, picking | | |
| Main body parts in contact with foliage | Hand and forearm | | |
| Application rate of active substance | 4.016 kg a.s./ha | | |
| Number of applications | 6 | | |
| Interval between multiple applications | 8 days | | |
| Half-life of active substance | 30 days | | |
| Multiple application factor | 4.0 | | |
| Dermal absorption of the product | 10.00% | | |
| Dermal absorption of the in-use dilution | 10.00% | | |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 12.048 µg a.s./cm ² | | |
| Working hours | 8 hr | | |
| Dermal transfer coefficient - Total potential exposure | 5800 cm ² /hr | | |
| Dermal transfer coefficient - arms, body and legs covered | 3000 cm ² /hr | | |
| Dermal transfer coefficient - hands, arms, body and legs covered | 750 cm ² /hr | | |
| Inhalation transfer coefficient for automated applications | NA ha/hr*10 ^{^(-3)} | | |
| Inhalation transfer coefficient for cutting ornamentals | NA ha/hr*10 ^{^(-3)} | | |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA ha/hr*10 ^{^(-3)} | | |
| 1. Total | | | |
| | Potential exposure | Work wear - arms, body and legs covered | Working wear and gloves |
| Total systemic exposure (mg a.s./day) | 221.9793356 | 114.8168977 | 28.7042244 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 3.6996556 | 1.9136150 | 0.4784037 |
| % of RVNAS | 73.99% | 38.27% | 9.57% |

Estimate 19: EFSA Calculator (Version: 30th March 2015) – Worker exposure for reaching and picking activities in tomatoes grown indoors that have previously been treated with 'PROBLAD-PLUS'.

| Worker exposure from residues on foliage for PROBLAD PLUS | | | |
|--|--------------------------------|---|-------------------------|
| Crop type | Fruiting vegetables | | |
| Indoor or outdoor | Indoor | | |
| Application method | Spray application | | |
| Application equipment | Vehicle-mounted | | |
| Worker's task | Reaching, picking | | |
| Main body parts in contact with foliage | Hand and body | | |
| Application rate of active substance | 4.016 kg a.s./ha | | |
| Number of applications | 6 | | |
| Interval between multiple applications | 8 days | | |
| Half-life of active substance | 30 days | | |
| Multiple application factor | 4.0 | | |
| Dermal absorption of the product | 10.00% | | |
| Dermal absorption of the in-use dilution | 10.00% | | |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 12.048 µg a.s./cm ² | | |
| Working hours | 8 hr | | |
| Dermal transfer coefficient - Total potential exposure | 5800 cm ² /hr | | |
| Dermal transfer coefficient - arms, body and legs covered | 2500 cm ² /hr | | |
| Dermal transfer coefficient - hands, arms, body and legs covered | 580 cm ² /hr | | |
| Inhalation transfer coefficient for automated applications | NA ha/hr*10 ^{^(-3)} | | |
| Inhalation transfer coefficient for cutting ornamentals | NA ha/hr*10 ^{^(-3)} | | |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA ha/hr*10 ^{^(-3)} | | |
| 1. Total | | | |
| | Potential exposure | Work wear - arms, body and legs covered | Working wear and gloves |
| Total systemic exposure (mg a.s./day) | 221.9793356 | 95.6807481 | 22.1979336 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 3.6996556 | 1.5946791 | 0.3699656 |
| % of RVNAS | 73.99% | 31.89% | 7.40% |

Estimate 20: EFSA Calculator (Version: 30th March 2015) – Worker exposure for reaching and picking activities in low berries (strawberries) grown indoors that have previously been treated with 'PROBLAD-PLUS'.

| Worker exposure from residues on foliage for PROBLAD PLUS | | | |
|--|------------------------------------|---|-------------------------|
| Crop type | Low berries and other small fruits | | |
| Indoor or outdoor | Indoor | | |
| Application method | Spray application | | |
| Application equipment | Vehicle-mounted | | |
| Worker's task | Reaching, picking | | |
| Main body parts in contact with foliage | Hand and forearm | | |
| Application rate of active substance | 4.016 kg a.s./ha | | |
| Number of applications | 6 | | |
| Interval between multiple applications | 8 days | | |
| Half-life of active substance | 30 days | | |
| Multiple application factor | 4.0 | | |
| Dermal absorption of the product | 10.00% | | |
| Dermal absorption of the in-use dilution | 10.00% | | |
| Dislodgeable foliar residue (i_AppRate*i_DFR) | 12.048 µg a.s./cm² | | |
| Working hours | 8 hr | | |
| Dermal transfer coefficient - Total potential exposure | 5800 cm²/hr | | |
| Dermal transfer coefficient - arms, body and legs covered | 3000 cm²/hr | | |
| Dermal transfer coefficient - hands, arms, body and legs covered | 750 cm²/hr | | |
| Inhalation transfer coefficient for automated applications | NA ha/hr*10^(-3) | | |
| Inhalation transfer coefficient for cutting ornamentals | NA ha/hr*10^(-3) | | |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA ha/hr*10^(-3) | | |
| | | | |
| 1. Total | | | |
| | Potential exposure | Work wear - arms, body and legs covered | Working wear and gloves |
| Total systemic exposure (mg a.s./day) | 221.9793356 | 114.8168977 | 28.7042244 |
| Total systemic exposure per kg body weight (mg/kg bw/day) | 3.6996556 | 1.9136150 | 0.4784037 |
| % of RVNAS | 73.99% | 38.27% | 9.57% |

Estimate 21: Online EFSA OPEX Model (Version 1.0.2) – Worker exposure for reaching and picking activities in tomatoes grown outdoors that have previously been treated with 'PROBLAD-PLUS'.

4.3. Use 3 : Low vegetables

4.3.1. Scenario 1 : Outdoor, normal

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|---|-----------------------------|
| Reaching, picking (all except Brassica) / Outdoor Work rate: 8 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | | Number of applications & application rate: 6 x 4.016 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | |
| Potential | 3.7 | 74 | 0 |
| Workwear | 1.6 | 31.9 | 0 |
| Workwear and gloves | 0.4 | 7.4 | 0 |
| Hands covered, no workwear | | | |

Estimate 22: Online EFSA OPEX Model (Version 1.0.2) - Worker exposure for reaching and picking activities in strawberries grown outdoors that have previously been treated with 'PROBLAD-PLUS'.

4.1. Use 1 : Strawberry (outdoor)

4.1.1. Scenario 1 : Outdoor, normal

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|--|--|---|-----------------------------|
| Reaching, picking / Outdoor Work rate: 8 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 3000 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 750 cm ² /h TC (gloves): NA cm ² /h | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> | | Number of applications & application rate: 6 x 4.016 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | |
| Potential | 3.7 | 74 | 0 |
| Workwear | 1.9 | 38.3 | 0 |
| Workwear and gloves | 0.5 | 9.6 | 0 |
| Hands covered, no workwear | | | |

Estimate 23: Online EFSA OPEX Model (Version 1.0.2) – Worker exposure for reaching and picking activities in tomatoes grown indoors that have previously been treated with 'PROBLAD-PLUS'.

4.4. Use 4 : High vegetables

4.4.1. Scenario 1 : Indoor, normal

| Level of PPE | Total absorbed dose [mg/kg bw per day] | % of systemic AOEL | Re-entry restriction [days] |
|---|--|--------------------|-----------------------------|
| Reaching, picking / Harvesting, including cutting and bundling / Indoor Work rate: 8 hours/day Interval: 8 days Body weight: 60 kg TC (potential): 5800 cm ² /h TC (workwear (arms, body and legs covered)): 2500 cm ² /h TC (workwear (arms, body and legs covered) and gloves): 580 cm ² /h TC (gloves): NA cm ² /h TSF: 0.1 mg a.s./h / kg a.s./ha | | | |
| Aqueous extract from the germinated seeds of sweet <i>lupinus albus</i> Number of applications & application rate: 6 x 4.016 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm ² foliage per kg a.s./ha DT50: 30 days | | | |
| Potential | 3.8 | 75.1 | 0 |
| Workwear | 1.6 | 33 | 0 |
| Workwear and gloves | 0.4 | 8.5 | 0 |
| Hands covered, no workwear | | | |

Estimate 24: HSE Decline Model – Worker exposure for searching, reaching and picking activities in strawberries grown indoors that have previously been treated with 'PROBLAD PLUS'.

| | | |
|---|---|--------------------------------------|
| Product Name | PROBLAD PLUS | |
| Number of Applications* | 6 | Per year |
| Interval Between Applications | 8 | Days |
| Exclusion Period/Pre-harvest Interval (PHI) | 0 | Days |
| Active Substance Name | aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | |
| Half-life (Foliar) | 30 | Days |
| Half-life (Air) | 30 | Days |
| Dislodgeable Foliar Residue (DFR) | 3 | µg/cm² of foliage/kg a.s. applied/ha |
| Application rate | 4.016 | kg a.s./ha |
| Dermal Absorption Value | 10.0% | |
| AOEL | 5 | mg/kg bw/day |
| Vapour Pressure** | Low Volatility (< 0.005 Pa) | Pa |
| Molecular Weight** | | g/mol |
| Crop | Strawberries (High Crop) | |
| Worker Re-entry Activity | Searching, reaching and picking | |
| Task Specific Factor | Harvesting (including cutting and bundling) | |
| Working Time (Hours) | 8 | |
| Transfer Coefficient (Potential Exposure) | 12500 | cm²/person/hour |
| Transfer Coefficient (Potential Body Exposure & Gloves) | N/A | cm²/person/hour |
| Transfer Coefficient (Workwear) | 3500 | cm²/person/hour |
| Transfer Coefficient (Workwear and Gloves) | N/A | cm²/person/hour |

| | | |
|---|---|--------------|
| Searching, reaching and picking | aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | |
| Potential Exposure (% of AOEL) | 160.5% | |
| Potential Exposure - Systemic Exposure | 8.0271 | mg/kg bw/day |
| Potential Exposure - Dermal Exposure | 4784.0374 | mg/day |
| Potential Exposure - Inhalation (Foliar) Exposure | 3.2128 | mg/day |
| Potential Exposure - Inhalation (Vapour) Exposure | 0.0100 | mg/day |
| Potential Body Exposure & Gloves (% of AOEL) | 0.0% | |
| Potential Body Exposure & Gloves - Systemic Exposure | 0.0000 | mg/kg bw/day |
| Potential Body Exposure & Gloves - Dermal Exposure | 0.0000 | mg/day |
| Potential Body Exposure & Gloves - Inhalation (Foliar) Exposure | 3.2128 | mg/day |
| Potential Body Exposure & Gloves - Inhalation (Vapour) Exposure | 0.0100 | mg/day |
| Workwear (% of AOEL) | 45.7% | |
| Workwear - Systemic Exposure | 2.2863 | mg/kg bw/day |
| Workwear - Dermal Exposure | 1339.5305 | mg/day |
| Workwear - Inhalation (Foliar) Exposure | 3.2128 | mg/day |
| Workwear - Inhalation (Vapour) Exposure | 0.0100 | mg/day |
| Workwear and Gloves (% of AOEL) | 0.0% | |
| Workwear and Gloves - Systemic Exposure | 0.0000 | mg/kg bw/day |
| Workwear and Gloves - Dermal Exposure | 0.0000 | mg/day |
| Workwear and Gloves - Inhalation (Foliar) Exposure | 3.2128 | mg/day |
| Workwear and Gloves - Inhalation (Vapour) Exposure | 0.0100 | mg/day |

*Model accurate for up to 20 uses.

**If vapour pressure is entered, ensure molecular weight is also entered. If molecular weight is unavailable, use default value.

Estimate 25: HSE Decline Model – Worker exposure for searching, reaching and picking activities in strawberries grown indoors that have previously been treated with 'PROBLAD PLUS'.

Worker Protection Duration: 21 days

| | | |
|---|---|--------------------------------------|
| Product Name | PROBLAD PLUS | |
| Number of Applications* | 6 | Per year |
| Interval Between Applications | 8 | Days |
| Exclusion Period/Pre-harvest Interval (PHI) | 21 | Days |
| Active Substance Name | aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | |
| Half-life (Foliar) | 30 | Days |
| Half-life (Air) | 30 | Days |
| Dislodgeable Foliar Residue (DFR) | 3 | µg/cm² of foliage/kg a.s. applied/ha |
| Application rate | 4.016 | kg a.s./ha |
| Dermal Absorption Value | 10.0% | |
| AOEL | 5 | mg/kg bw/day |
| Vapour Pressure** | Low Volatility (< 0.005 Pa) | Pa |
| Molecular Weight** | | g/mol |
| Crop | Strawberries (High Crop) | |
| Worker Re-entry Activity | Searching, reaching and picking | |
| Task Specific Factor | Harvesting (including cutting and bundling) | |
| Working Time (Hours) | 8 | |
| Transfer Coefficient (Potential Exposure) | 12500 | cm²/person/hour |
| Transfer Coefficient (Potential Body Exposure & Gloves) | N/A | cm²/person/hour |
| Transfer Coefficient (Workwear) | 3500 | cm²/person/hour |
| Transfer Coefficient (Workwear and Gloves) | N/A | cm²/person/hour |

| | | |
|---|---|--------------|
| Searching, reaching and picking | aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> | |
| Potential Exposure (% of AOEL) | 98.8% | |
| Potential Exposure - Systemic Exposure | 4.9413 | mg/kg bw/day |
| Potential Exposure - Dermal Exposure | 2944.9205 | mg/day |
| Potential Exposure - Inhalation (Foliar) Exposure | 1.9777 | mg/day |
| Potential Exposure - Inhalation (Vapour) Exposure | 0.0062 | mg/day |
| Potential Body Exposure & Gloves (% of AOEL) | 0.0% | |
| Potential Body Exposure & Gloves - Systemic Exposure | 0.0000 | mg/kg bw/day |
| Potential Body Exposure & Gloves - Dermal Exposure | 0.0000 | mg/day |
| Potential Body Exposure & Gloves - Inhalation (Foliar) Exposure | 1.9777 | mg/day |
| Potential Body Exposure & Gloves - Inhalation (Vapour) Exposure | 0.0062 | mg/day |
| Workwear (% of AOEL) | 28.1% | |
| Workwear - Systemic Exposure | 1.4074 | mg/kg bw/day |
| Workwear - Dermal Exposure | 824.5777 | mg/day |
| Workwear - Inhalation (Foliar) Exposure | 1.9777 | mg/day |
| Workwear - Inhalation (Vapour) Exposure | 0.0062 | mg/day |
| Workwear and Gloves (% of AOEL) | 0.0% | |
| Workwear and Gloves - Systemic Exposure | 0.0000 | mg/kg bw/day |
| Workwear and Gloves - Dermal Exposure | 0.0000 | mg/day |
| Workwear and Gloves - Inhalation (Foliar) Exposure | 1.9777 | mg/day |
| Workwear and Gloves - Inhalation (Vapour) Exposure | 0.0062 | mg/day |

*Model accurate for up to 20 uses.

**If vapour pressure is entered, ensure molecular weight is also entered. If molecular weight is unavailable, use default value.

B.6.7. APPENDIX 2: APPLICATION VIA VEHICLE MOUNTED EQUIPMENT INDOORS

It is understood that a range of horizontal or variable geometry boom spraying equipment and broadcast air-assisted sprayers with multiple nozzles are used in polytunnels and greenhouses reflecting the need in commercial operations to achieve higher work rates than would be the case with hand held application with a single nozzle. This equipment can range from pedestrian controlled trolley sprayers which are manually pushed or pulled through the crop, robotic sprayers which run along the heating pipes between rows (either manually or automatically transported between rows), vehicle mounted/trailed boom sprayers and vehicle mounted/trailed broadcast air-assisted sprayers. A variety of crop heights can be targeted with horizontal and variable geometry boom sprayers and broadcast air-assisted sprayers.

The most up-to-date exposure model for assessing operator exposure for indoor application is the online EFSA OPEX model associated with the 2022 EFSA Exposure Guidance⁴. This model only contains data for application via hand-held application techniques (tank and lance/spray gun and knapsack sprayers), and for manual trolley sprayers for application to high crops with a normal crop culture. Therefore, there is uncertainty regarding operator exposure for application via other types of vehicle-mounted equipment in enclosed spaces.

Application via Pedestrian Trolley Sprayers

The 2022 EFSA Exposure Guidance includes the Greenhouse Agricultural Operator Exposure Model (Greenhouse AOEM) assessment approach for indoor spray application developed by the German Regulatory Authority BfR in 2015⁵ and updated in 2020⁶. The 2020 update considers two new studies conducted in France and Spain which contain data for trolley sprayer application to high crops in greenhouses. In the French study, the trolley sprayers (connected via a hose to a static tank) were pushed during spraying while in the Spanish study, the trolley sprayers were pulled during spraying leaving a spray cloud behind the trolley, and avoiding contact of the operator with treated foliage. BfR excluded the data for two operators of the French study using trolley sprayers as the application scenario differed from that of the Spanish trolley sprayer data where they were pulled instead of pushed. Contact to

⁴ EFSA 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. European Food Safety Authority. EFSA Journal 2022;20(1):7032.

⁵ BfR (Bundesinstitut für Risikobewertung, German Federal Institute for Risk Assess), 2015. Joint development of a new Greenhouse Agricultural Operator Exposure Model for handheld application. BfR, Berlin.

⁶ BfR (Bundesinstitut für Risikobewertung, German Federal Institute for Risk Assess), 2020. Update of the Greenhouse Agricultural Operator Exposure Model – Amendment to Project Report 01/2016. BfR, Berlin.

treated foliage was avoided in the Spanish study because the operator pushed the trolley to the end of each row where the trolley was switched on and the operator pulled it spraying towards the main corridor. At the main corridor, the operator switched off the trolley, turned around and started again. The EFSA OPEX model includes calculations for operator exposure for application via trolley sprayer based on the Spanish study only, where the operators pulled the trolley during spraying leaving a spray cloud behind the trolley, and avoiding contact of the operator with treated foliage.

The EFSA working group considered that it is generally impractical for trolley equipment to be used to spray of the outside rows, therefore the outside rows or other areas where the trolley cannot be driven into have to be sprayed by other means, e.g. lance sprayers, and these areas represent 10% of the total treated area. Operator exposure for application via trolley sprayer using the online EFSA OPEX Model is therefore calculated from two separate exposure estimates using the model for handheld application with 10% of the total amount of active substance applied and the model for trolley application with 90% of the total amount of active substance applied. These two estimates are summed to obtain the overall exposure estimate for trolley application. The tank mixing and loading estimates are used to calculate exposure during mixing and loading before trolley application. Since the operators in the Spanish study avoided contact with the treated crop, the exposure estimates are only for a normal crop culture scenario.

The EFSA default work rate for application via manual hand-held equipment indoors is 1 ha/day. This default is also assumed for application via manual trolley sprayers. Given the treatment areas in the Spanish study (0.64–0.98 ha), and the assumption that part of the crop is treated with hand-held equipment, the default of a 1 ha/day treatment rate for application via trolley sprayers is considered a reasonable assumption until more data is available to confirm treatment rates.

As the operators pulled the trolley equipment backwards through the crop therefore avoiding contact with the treated crop or the spray cloud, exposure is likely to be lower than where an operator pushes equipment through the crop. Therefore, the following Other Specific Restriction (OSR) is required on the notice of authorisation:

- When applying with a pedestrian controlled trolley sprayer only apply by pulling equipment backwards and not pushing equipment forwards through the crop.

The operator exposure data for application via trolley sprayer in the EFSA OPEX Model is only for application to high crops with a normal crop culture using a vertical boom. It is considered that this would also cover exposure for application to low crops via a trolley sprayer with a horizontal boom where there is no contact with treated crops i.e. where the equipment is pulled backwards.

Application via vehicle mounted/trailed boom sprayers / broadcast air assisted sprayers

As the EFSA OPEX model only considers exposure for application via handheld equipment and trolley sprayers, there is uncertainty regarding operator exposure for application via other types of vehicle-mounted equipment with multiple nozzles in enclosed spaces. It is considered that a greater work rate can be achieved with application via vehicle mounted/trailed boom spraying equipment or broadcast assisted sprayers indoors than the default 1 ha/day work rate for handheld/trolley sprayer application. The default work rate of 4 ha/day for outdoor manual (tank and lance) application is considered a more realistic reflection of the likely area that would be treated daily by vehicle mounted/trailed horizontal and variable geometry boom sprayers and broadcast air-assisted sprayers in a commercial polytunnel or greenhouse operation in the UK, until more data is available to confirm treatment rates.

The most precautionary approach to calculating operator exposure during application via vehicle mounted equipment indoors would be to use the EFSA OPEX Model for application via hand-held equipment and to scale up the model estimate by an appropriate factor for application via vehicle mounted/trailed boom/broadcast air assisted equipment to account for the higher work rate. This approach assumes that exposure from hand-held equipment per kg applied will exceed that from vehicular/pedestrian controlled boom/broadcast air assisted equipment. Therefore, consideration has been given as to the relative exposures that may occur during application via different equipment.

Comparison of relative exposure based on Greenhouse AOEM studies

As the exposure estimates for application via trolley sprayer in the EFSA OPEX model assume that 10% of total amount of active substance is applied via hand-held equipment rather than a trolley sprayer, it is not possible to compare the relative exposure between the different application equipment directly from the EFSA OPEX model results. Instead the Greenhouse AOEM regression modelling equations for application via trolley sprayer (pulled backwards through the crop) and manual hand-held equipment have been used to compare the relative exposure between these application techniques. The table below summarises the reduction in dermal exposure during application via a trolley sprayer compared to manual handheld equipment.

| Clothing / PPE | Total Active Applied | | | | | |
|--------------------|----------------------|--------|------|------|------|------|
| | 0.1 kg | 0.5 kg | 1 kg | 2 kg | 3 kg | 4 kg |
| Potential Exposure | 6.1 | 6.2 | 6.2 | 6.3 | 6.3 | 6.3 |
| Workwear | 5.0 | 5.6 | 5.8 | 6.0 | 6.1 | 6.2 |

| | | | | | | |
|---------------------|-----|------|------|------|------|------|
| Workwear and gloves | 8.6 | 13.1 | 14.5 | 15.5 | 15.9 | 16.1 |
|---------------------|-----|------|------|------|------|------|

It is calculated that there is between a 5 and 16 fold reduction in dermal exposure when applying via a trolley sprayer pulled backwards through the crop in comparison to application via manual hand-held equipment, both scenarios assuming a normal crop culture. Inhalation exposure is reduced by a factor of 1.55 when applying via a trolley sprayer in comparison to application via manual hand-held equipment, and this does not vary with the total amount of active applied.

Comparison of relative exposure based on European Crop Protection Association study

A study was undertaken by the European Crop Protection Association (ECPA) and the Belgium Agricultural Research Centre (CLO-DVL) which compared the relative dermal exposure for different application techniques in a protected situation. The results of the study are presented in a paper, by Nuyttens, D. et al 2003⁷. The study monitored comparative dermal exposure for operators using 4 different types of spraying equipment:

- Standard short spray gun – used as a reference
- Spray lance – monitored with operators walking forwards and the operators walking backwards.
- Manually pulled trolley with 2 vertical booms.
- Self-propelled vehicle (Fumimatic) with the operator sitting in an open cab at the front of the vehicle and the tank located between the operator and 2 vertical booms at the back of the vehicle.

The study monitored dermal exposure using mineral chelates collected on patch dosimeters attached to the operators' coveralls and also on cotton gloves. The experiments were performed under field conditions in two pepper greenhouses in Spain. The average exposure for application with the short spray gun was given a nominal exposure of 100% with the other techniques compared to this. The highest dermal exposure was received by the operators walking forwards with the spray lance (216%), then the spray gun (100%), the spray lance backwards (32%), manual trolley sprayer (4%) and the self-propelled vehicle (1%). The higher relative exposure for the spray lance walking forwards in comparison to the spray lance walking backwards is likely to be due to the operator walking into the spray cloud and also

⁷ 'Comparison of operator exposure for 5 different greenhouse spraying applications' Nuyttens, D. et al 2003.

potentially coming into contact with sprayed foliage when walking forwards which is less likely to occur when walking backwards.

The operators using the vertical boom application techniques (manual trolley and self-propelled vehicle) received significantly less dermal exposure than the three single nozzle manual application techniques (spray lance forwards and backwards and spray gun). A comparison of the reduction in relative dermal exposure for the vertical boom application techniques compared to the three single nozzle manual application scenarios is provided below.

| Vertical boom application | Single nozzle manual application technique | | |
|---------------------------|--|----------------------|-----------------------|
| | Spray Gun | Spray Lance forwards | Spray lance backwards |
| Manual trolley | 25 | 54 | 8 |
| Self-propelled vehicle | 100 | 216 | 32 |

This comparative study indicates that the relative dermal exposure from the vertical boom application techniques of the manually trolley and self-propelled vehicle was significantly less than the single nozzle manual application techniques, with a minimum of an 8 fold reduction in exposure.

Comparison of relative exposure conclusions

Based on the Greenhouse AOEM studies the relative reduction in dermal exposure for application via trolley sprayer compared to manual hand-held equipment is 5-16 fold. Based on the ECPA study the relative reduction in dermal exposure for application via manual trolley sprayer and self-propelled vehicle in comparison to manual hand-held equipment is 8-54 fold reduction and 32-216 fold reduction respectively. It is therefore considered that the EFSA OPEX model dermal exposure estimates for application via manual hand-held equipment are likely to be protective for dermal exposure during application via a vehicle mounted/trailed boom sprayer, even when accounting for the assumption of a 4 ha/day work rate in comparison to the default work rate of 1 ha/day for handheld equipment.

However, for certain application scenarios, the difference in relative dermal exposure to manual application techniques is still unknown. For example, there is no data on the relative dermal exposure for the use of broadcast air-assisted sprayers in a protected situation. Therefore, to address this uncertainty it is recommended that a closed cab is used for application via a broadcast air-assisted sprayer in protected situations.

Whilst the estimated exposure using the Greenhouse AOEM model for manual hand-held equipment is expected to be protective with regards to the dermal route for the majority of application scenarios, this is not necessarily the case with regards to inhalation for which greater volumes of spray would be generated from equipment with multiple nozzles compared to hand held application with a single nozzle. The reduction in inhalation exposure using trolley sprayers rather than manual hand-held equipment based on the Greenhouse AOEM studies is 1.55 fold and there is no data on inhalation exposure in the ECPA study.

For tractor mounted/trailed sprayers the driver would be moving away from the spray as it leaves the nozzle but with reduced ventilation and dispersion in polytunnels/greenhouses airborne droplets may remain in the breathing zone during the return pass / passes. In an addition the daily treatment rate achievable with tractor mounted/trailed sprayers will be higher than manual hand-held equipment. It is therefore not known whether the relative inhalation exposure is likely to be higher or lower compared to handheld application with single nozzle equipment where the output and daily treatment rate is lower, but the operator is more likely to walk directly into the spray cloud. To address this uncertainty of inhalation exposure with vehicle mounted/trailed equipment, the use of RPE during application is recommended or alternatively, a vehicle with closed cab and suitable filtration system.

The operator protection phases to mitigate dermal and inhalation exposure to operators during indoor application via horizontal or variable geometry boom spraying equipment and broadcast air-assisted sprayers are as follows:

- Broadcast air-assisted sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* during application in protected situations.
*Closed cabin meeting at least EN 15695 category 3.
- Vehicle-mounted or trailed horizontal or vertical boom sprayers must only be used where the operator's normal working position is within a closed cab with a suitable in-cab filtration system* or suitable respiratory protective equipment** must be worn during application in protected situations.
*Closed cabin meeting at least EN 15695 category 3
**Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

B.6.8. References relied on

See Volume 3 CA B6 for list of references applicable to the representative product.