

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 3: Mammalian Toxicology**

#### **Detailed summary of the risk assessment**

**Product code: TOTO 75/ TYTAN 75/ HERKULES 75**

**Active Substance: Thifensulfuron-methyl – 68.2%**

**Metsulfuron-methyl – 6.8%**

**All Zones**

**Zonal Rapporteur Member State: N/A**

**CORE ASSESSMENT- renewal of  
authorisation**

**Applicant: Innvigo Sp z o.o.**

**Date: January, 2019**

**July 2021**

**October 2022**

## Version history

| When         | What                          |
|--------------|-------------------------------|
| July 2021    | ZRMs evaluated submitted dRR. |
| October 2022 | Final Registration Report     |
|              |                               |
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## III A 7 TOXICOLOGICAL STUDIES

|                          |   |
|--------------------------|---|
| <p>Comments of zRMS:</p> | <p>The toxicological data on the formulation TOTO 75/ TYTAN 75/ HERKULES 75 was evaluated during previous authorisation. Since the summary of the methodology and conclusions regarding the end points do not raise any objections, data contained in the revised dRR are sufficient in this renewal. Therefore, the acute toxicity tests were not re-assessed.</p> <p>The new data on acute inhalation toxicity performed using calculation method has been assessed during this evaluation.</p> <p>Taking into account the toxicological data (study results and the <b>classification</b> of the formulation TOTO 75/ TYTAN 75/ HERKULES 75 is as follows:</p> <p><b>Eye Irrit. 2, H319 Causes serious eye irritation</b><br/><b>STOT SE3, H335: May cause respiratory irritation</b> (for details, see. dRR, part C)</p> <p><b>Labelling:</b><br/>Warning section of the label (first page):<br/><b>P280:</b> Wear eye/face protection.<br/><b>P305+P351+P338:</b> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/><b>P261:</b> Avoid breathing dust/fume/gas/mist/vapours/spray<br/><b>P271:</b> Use only outdoors</p> <p>Other section of the label:<br/><b>P270:</b> Do not eat, drink or smoke when using this product.<br/><b>P264:</b> Wash hands thoroughly after handling.<br/><b>P403+P233:</b> Store in a well-ventilated place. Keep container tightly closed.<br/><b>P405:</b> Store locked up.<br/><b>P501:</b> Dispose of contents/container to....</p> <p>and P280 as follows:<br/>„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.”<br/>“Wear protective gloves, eye/face protection and work wear (coverall) during mixing and loading and application.”</p> <p><b>P305+P351+P338:</b> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/><b>P337+P313:</b> If eye irritation persists: Get medical advice/ attention.<br/><b>P304+P340:</b> IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.<br/><b>P312:</b> Call a POISON CENTER or doctor/physician if you feel unwell.</p> |
|--------------------------|---|

This document reviews the toxicological studies for the product TOTO 75 SG containing the active substance metsulfuron-methyl which was included into Annex I of Directive 91/414 by Commission Directive 2000/49/EC of 26 July 2000 and has been renewed by Commission Implementing Regulation (EU) 2016/139 of 2 February 2016. A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for operators, workers and bystanders.

This active substance thifensulfuron-methyl was included on Annex I of Directive 91/414/EEC on 1 July 2002 under Inclusion Directive 2001/99/EC of 20 November 2001 and has been renewed by Commission Implementing Regulation (EU) 2016/1424 of 25 August 2016.

This active substance metsulfuron-methyl was included on Annex I of Directive 91/414/EEC on 1 July 2001 under Inclusion Directive 2000/49/EC of 26 July 2000.

The SANTE document for metsulfuron methyl (SANTE/10319/2015 Rev 3) are considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

The SANTE document for thifensulfuron methyl (SANTE/10150/2016 rev. 2) are considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

**Agreed EU End-points for the active substance metsulfuron-methyl**  
(7593/VI/97-final – 14 August 2000)

| End-Point          | Active Substance     |
|--------------------|----------------------|
| Dermal penetration | Spray dilutions: 10% |
| AOEL systemic      | 0.7 mg/kg/bw/d       |
| AOEL dermal        | 20 mg/kg/bw/d        |

**Agreed EU End-points for the active substance metsulfuron methyl**  
(SANTE/10319/2015 Rev 3 and EFSA Journal 2015;13(1):3936)

| End-Point                             | Active Substance                                 |
|---------------------------------------|--|
| Dermal absorption<br>(default values) | 25% for the concentrate<br>75% for the dilutions |
| AOEL                                  | 0.25 mg/kg bw per day,                           |

**Agreed EU End-points for the active substance thifensulfuron-methyl**  
(7577/VI/97-final 12 December 2001)

| End-Point          | Active Substance              |
|--------------------|-------------------------------|
| Dermal penetration | Spray dilutions: 10%          |
| AOEL systemic      | 0.07 mg/kg/bw/d               |
| AOEL dermal        | not allocated (not necessary) |

**Agreed EU End-points for the active substance thifensulfuron methyl**  
(SANTE/10150/2016 rev. 2 and EFSA Journal 2015;13(7):4201)

| End-Point                             | Active Substance                                 |
|---------------------------------------|--|
| Dermal absorption<br>(default values) | 25% for the concentrate<br>75% for the dilutions |
| AOEL                                  | 0.07 mg/kg bw per day,                           |

The Commission Implementing Regulation for metsulfuron-methyl 2016/139 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their renewal of authorisation and by the MS prior to granting a renewal of authorisation.

The Commission Implementing Regulation for thifensulfuron-methyl 2016/1424 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their renewal of authorisation and by the MS prior to granting a renewal of authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the metsulfuron-methyl and in particular Appendices I and II thereof, as finalised in the COMMISSION STAFF WORKING DOCUMENT (SANTE/10319/2015 Rev 3) on 11 December 2015 shall be taken into account. In this overall assessment:

Member States may pay particular attention to the:

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of consumers,
- the protection of groundwater,
- the protection of non-target terrestrial plants.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the thifensulfuron-methyl and in particular Appendices I and II thereof, as finalised in the COMMISSION STAFF WORKING DOCUMENT (SANTE/10150/2016 rev. 2) 12 July 2016 shall be taken into account. In this overall assessment:

Member States may pay particular attention to the:

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- the protection of groundwater,
- the protection of non-target plants and aquatic organisms.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

**Any changes made by Applicant in November 2020 were highlighted on blue.**

### IIIA 7.1 Acute Toxicity

A battery of tests was conducted to determine the acute toxicity, irritation, and sensitisation potential of Toto 75 SG:

| Type of study | Species | Toto 75 SG | CLP/GHS |
|---------------|---------|------------|---------|
|---------------|---------|------------|---------|

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

|                         |            |   |                         |
|-------------------------|------------|---|-------------------------|
| Oral acute              | Rat        | LD50 >2000 mg/kg bw   | NA                      |
| Dermal route            | Rat        | LD50 >2000 mg/kg bw   | NA                      |
| Inhalation (4 hrs)      | Rat        | LC <sub>50</sub> >5.0 mg/L (metsulfuron-methyl)<br>LC <sub>50</sub> >7,9 mg/L (thifensulfuron-methyl) | NA                      |
| Primary skin irritation | Rabbit     | Non irritating  | NA                      |
| Eye irritation          | Rabbit     | Irritates eyes  | R 39/Eye irrit. 2; H319 |
| Skin sensitisation      | Guinea pig | Not sensitising   | NA                      |

**OECD IIIA 7.1.1 Acute oral toxicity**

**Report:** Annex IIIA. 7.1.1/01 xxx, xxx, xxx, xxx, (2008) Study Code OS-11/08 Part I: TOTO 75 WG - acute oral toxicity study on rats

**Material and Methods:**

The test material at a single dose of 2000 mg/kg b.w. was administered to one female (the sighting study) and then to further four females (the main study). The test material was administered to the females in the form of aqueous suspension as a single dose of 0.5 mL per 100 g of body weight, with the aid of a ball-ended feeding needle affixed to the top of the syringe. Evaluation of general condition of animals, i.e. observation of all animals for morbidity and mortality was conducted twice a day or once a day (during weekend) for 14 days of observation period. Body weight of animals was individually determined for each animal directly before administration of test material (day 0) and then on 7th and 14th day – before termination of experiment. All animals which were euthanized after 14-day observation period, were dissected and subjected to gross necropsy.

**Table 7.1.1-1: Acute oral toxicity in rats of <TOTO 75SG>**

| Dose (mg/kg) | Toxicological results* | Duration of signs | Time of death | LD <sub>50</sub> (mg/kg) (14 days) |
|--------------|------------------------|-------------------|---------------|------------------------------------|
| female rats  |                        |                   |               |                                    |
| 2000         | 0/0/5                  | -                 | -             | > 2000                             |

\*Number of animals which died/number of animals with clinical signs/number of animals used

**Findings:**

All females survived 14-day period of observation. No mortalities occurred at 2000 mg/kg/bw, the only dose level. No signs of toxicity were observed. No pathological changes were observed. Following the administration of the test material all animals gained weight normally. No pathological changes in animals were stated at gross necropsy.

**Conclusion/endpoint:**

On the ground of study one may state that the median oral acute dose (LD<sub>50</sub>) for TOTO 75 WG plant protection product is greater than 2000 mg/kg b.w. The test material – TOTO 75 WG plant protection product – can be classified to: - category 5/unclassified – according to the Globally Harmonized System (GHS) - category U – according to the EU Scheme for transition period for full implementation of the Globally Harmonized System (GHS).

**OECD IIIA 7.1.2 Acute precutaneous (dermal) toxicity**



**Report:** Annex IIIA. 7.1.2/01 xxx, xxx, xxx, Poland, (2008) Study Code OS-11/08 Part II: TOTO 75 WG - acute dermal toxicity study on rats

### Material and Methods:

The undiluted test material at a single dose of 2000 mg/kg b.w. was applied to the dorsal skin (6 cm<sup>2</sup>) of 5 female and 5 male rats. After 24 hours the band and gauze patches were taken off and the residual test material was removed using water. The rats were observed for clinical signs, body weight effects, dermal effects, and mortality for 14 days following application. Observations for dermal irritation were made daily (weekends excluded). Dermal effects were scored according to the Draize Scale. All animals were examined for gross pathological changes. Body weight were recorded pretest, weekly and at death or termination in the survivors. All animals were examined for gross pathology.

**Table 7.1.2-1: Acute percutaneous (dermal) toxicity of <TOTO 75SG>**

| Dose (mg/kg) | Toxicological results* | Duration of signs | Time of death | LD50 (mg/kg) (14 days) |
|--------------|------------------------|-------------------|---------------|------------------------|
| male rats    |                        |                   |               |                        |
| 2000         | 0/5/5                  | 1-2 day           | --            | > 2000                 |
| female rats  |                        |                   |               |                        |
| 2000         | 0/5/5                  | 2-12 day          | --            | >2000                  |

\* Number of animals which died/number of animals with clinical signs/number of animals used

### Findings:

Following application of the test material, changes on treated area of skin in form of erythema were stated in all males, and changes in form of dryness of epidermis were stated in four males. Changes on treated area of skin in form of erythema, scabs, dryness and desquamation of epidermis were stated in all females. These changes were transient.

No mortalities occurred at 2000 mg/kg/bw, the only dose level. Body weight loss in one male with inflammatory changes in lungs (unconnected to the test material) and one female (at the first week of the experiment) were confirmed. No other pathological changes were observed.

### Conclusion/endpoint:

On the ground of study one may state that median dermal acute dose (LD50) for TOTO 75 WG plant protection product is greater than 2000 mg/kg b.w.

### OECD IIIA 7.1.3 Acute inhalation toxicity to rats

|                   |   |
|-------------------|---|
| Comments of zRMS: | Taking into account the composition of the formulation TOTO 75/ TYTAN 75/ HERKULES 75 and the provisions of EC Regulation 1272/2008, <b>the classification regarding the acute inhalation toxicity is not required.</b> |
|-------------------|---|

Each type of hazard is considered separately, taking into account the sum of the components posing a hazard. We use the summation method using the formula:

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_i}}$$

Table 3.1.2

Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for classification for the respective routes of exposure.

| Exposure routes           | Classification Category or experimentally obtained acute toxicity range estimate   | Converted acute toxicity point estimate (see Note 1) |
|---------------------------|--|--|
| Oral (mg/kg bodyweight)   | $0 < \text{Category 1} \leq 5$<br>$5 < \text{Category 2} \leq 50$<br>$50 < \text{Category 3} \leq 300$<br>$300 < \text{Category 4} \leq 2\,000$              | 0,5<br>5<br>100<br>500                               |
| Dermal (mg/kg bodyweight) | $0 < \text{Category 1} \leq 50$<br>$50 < \text{Category 2} \leq 200$<br>$200 < \text{Category 3} \leq 1\,000$<br>$1\,000 < \text{Category 4} \leq 2\,000$    | 5<br>50<br>300<br>1\,100                             |
| Gases (ppmV)              | $0 < \text{Category 1} \leq 100$<br>$100 < \text{Category 2} \leq 500$<br>$500 < \text{Category 3} \leq 2\,500$<br>$2\,500 < \text{Category 4} \leq 20\,000$ | 10<br>100<br>700<br>4\,500                           |
| Vapours (mg/l)            | $0 < \text{Category 1} \leq 0,5$<br>$0,5 < \text{Category 2} \leq 2,0$<br>$2,0 < \text{Category 3} \leq 10,0$<br>$10,0 < \text{Category 4} \leq 20,0$        | 0,05<br>0,5<br>3<br>11                               |
| Dust/mist (mg/l)          | $0 < \text{Category 1} \leq 0,05$<br>$0,05 < \text{Category 2} \leq 0,5$<br>$0,5 < \text{Category 3} \leq 1,0$<br>$1,0 < \text{Category 4} \leq 5,0$         | 0,005<br>0,05<br>0,5<br>1,5                          |

## Note 1

These values are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results.

## 1.1. By inhalation (Acute Tox. 4, H332)

Only one ingredient is classified in this hazard class.

- 3.496 % (Acute Tox. 4, H332)

LD<sub>50</sub> is not known. Therefore the estimated values were used to calculation.

$$ATE_{mix} = \frac{100}{\sum_{i=1}^n \frac{C_i}{ATE_{mix}}} = \frac{100}{\frac{3.496}{11}} = 315$$

## Conclusion:

According to the table 3.1.2, the result (315 mg/L >> 20.0 mg/L) does not classify the whole formulation as Acute Tox. 4, H332.

#### OECD IIIA 7.1.4 Skin irritation

**Report:** Annex IIIA 7.1.4/01 xxxxxx, xxx, xxx, Poland, (2008) Study Code OS-11/08 Part III: TOTO 75 WG - acute skin irritation/skin corrosion study on rabbits

#### Material and Methods:

The study was performed with white rabbits of New Zealand strain. The triturated test material, 0.5 g, was applied to shaved skin of one rabbit and covered (No. 1). The skin area treated was 6 cm<sup>2</sup>. After 4 hours of exposure the band and gauze patches were taken away and the residual test material was removed using water. Following evaluation of the treated skin area and to confirm the obtained results the test material was applied on skin of rabbit No 2 and 3 for 4 hours. Test sites were evaluated by Draize (1959) for signs of dermal irritation 1, 24, 48, and 72 hours after test substance removal. The rabbits were weighed directly before the beginning of experiment, on day of test material administration, and then on the last day of experiment.

**Table 7.1.4-1 Skin irritation <TOTO 75SG>**

| Number of animal | Sex | The degree of reaction E/O* for several hours and days |     |     |     |  | Individual mean values after 24, 48 and 72 hours |
|------------------|-----|--|-----|-----|-----|--|--|
|                  |     | 1h   | 24h | 48h | 72h |  |  |
| 1                | M   | 1/0  | 1/0 | 0/0 | 0/0 |  | 0.3/0  |
| 2                | M   | 1/0  | 1/0 | 0/0 | 0/0 |  | 0.3/0  |
| 3                | M   | 2/0  | 1/0 | 1/0 | 0/0 |  | 0.7/0  |

#### Findings:

During reading after 1 hour since the end of exposure, very slight (barely perceptible) erythema was observed on treated area of skin of rabbit No 1 and 2 and well defined erythema on treated area of skin of rabbit No 3. No oedema was observed on treated area of skin of rabbits. During reading after 24 hours since the end of exposure, very slight (barely perceptible) erythema was observed on treated area of skin of all rabbits. During reading after 48 hours since the end of exposure, very slight (barely perceptible) erythema was observed only on treated area of skin of rabbit No 3. No pathological changes were observed on treated area of skin of the rest of rabbits. During reading after 72 hours since the end of exposure, no pathological changes were observed on treated area of skin of any rabbit.

#### Conclusion/endpoint:

Taking into account the obtained results and according to Annex to Decree of Ministry of Health of September 2, 2003 (Acts Daily No 171, Position 1666) one may state that **TOTO 75 SG** plant protection product does not irritate skin.

#### OECD IIIA 7.1.5 Eye irritation

**Report:** Annex IIIA 7.1.5/01 xxx, xxx, xxx, Poland, (2008) Study Code OS-11/08 Part IV: TOTO 75 WG – acute eye irritation study on rabbits

#### Material and Methods:

The study was performed with white rabbits of New Zealand strain. The test material in amount of 0,07 g (the amount was the equivalent of volume of 0,1 ml) was administered to conjunctival sack of eye of two rabbits. Condition of cornea, iris and conjunctiva was evaluated after 1, 24, 48, 72 hours as well as after 7 and 14 days since administration of test material.

Changes in cornea, iris and conjunctiva of rabbits' eyes were noticed during readings after administration of test material.

The rabbits were weighed directly before the experiment, on day of test material administration and then on the last day of experiment.

**Table 7.1.5-1: Eye irritation of <TOTO 75SG>**

| Observation time            | Corneal opacity | Iris damages | Conjunctivae redness | Conjunctiva swelling |
|-----------------------------|-----------------|--------------|----------------------|----------------------|
| Animals no: 1, 2            |                 |              |                      |                      |
| 1 h                         | 0/0             | 1/0          | 3/2                  | 2/2                  |
| 24 h                        | 1/0             | 1/1          | 3/3                  | 2/2                  |
| 48 h                        | 1/0             | 1/1          | 3/3                  | 2/2                  |
| 72 h                        | 0/0             | 0/0          | 2/3                  | 1/1                  |
| 7d                          | 0/0             | 0/0          | 1/1                  | 1/0                  |
| 14d                         | 0/0             | 0/0          | 0/0                  | 0/0                  |
| Average after: 24, 48h, 72h | 0.7/0           | 0.7/0.7      | 2.7/3                | 1.7/1.7              |

#### Findings:

Pathological changes in cornea, iris and conjunctiva of rabbits' eyes were stated during readings after administration of test material.

There were no body weight effects or clinical signs noted.

#### Conclusion/endpoint:

Taking into account the obtained results, one may state that TOTO 75 WG plant protection product does irritate eyes.

#### OECD IIIA 7.1.6

#### Skin sensitization

**Report:** Annex IIIA 7.1.6/01 xxxy, xxxx xxx, Poland, , (2008) Study Code AI-48/08: TOTO 75 WG – Skin sensitization

#### OECD III A 7.1.7

#### Supplementary studies for combinations of plant protection products

Applicant (**PUH Chemirol Sp z o.o.**) Evaluator s see Appendix 3 National Institute of Public Health – National Institute of Hygiene

#### Material and Methods:

The experiment was conducted on guinea pigs according to maximization method of Magnusson and Kligman. 11 animals in treated group and 6 animals in control group were used in the main study. Concentrations of test item used in the main study were determined in the pilot study.

The main study comprised two parts: induction and challenge. Induction was performed in two steps. In the first step the animals were given 2% aqueous suspension of test item with Freund's Complete Adjuvant (FCA). In the second step, the 50% aqueous suspension of test item was applied to skin on sites of intradermal injections. During period of induction group of control animals was subjected to sham treatment – it was given water (medium) instead of test item. In order to challenge sensitization the 50% aqueous suspension of test item (challenge dose) was applied to right flank of treated and control animals. Distilled water (medium) was applied to left flank. Following induction, skin reaction of treated and control animals was evaluated after 24, 48 and 72 hours since the end of exposure. During readings no allergic skin reactions were stated in animals of treated group. No pathological changes were stated on skin of animals of control group. The animals were weighed directly before start of experiment, on day of intradermal injections (day 0) and on day of termination of experiment (day 25).

**Table 7.1.6-1: Skin sensitization <TOTO 75SG>**  
(Evaluation of skin reactions according to grading scale of Magnusson and Kligman)

| Sex     | Animal No | Evaluation after hours |             |            |             |            |             |
|---------|-----------|------------------------|-------------|------------|-------------|------------|-------------|
|         |           | 24                     |             | 48         |             | 72         |             |
|         |           | Left flank             | Right flank | Left flank | Right flank | Left flank | Right flank |
| Males   | 1         | 0                      | 0           | 0          | 0           | 0          | 0           |
|         | 2         | 0                      | 0           | 0          | 0           | 0          | 0           |
|         | 3         | 0                      | 0           | 0          | 0           | 0          | 0           |
|         | 4         | 0                      | 0           | 0          | 0           | 0          | 0           |
| Females | 5         | 0                      | 0           | 0          | 0           | 0          | 0           |
|         | 6         | 0                      | 0           | 0          | 0           | 0          | 0           |

#### Findings:

During readings after 24, 48 and 72 hours since the end of exposure, no pathological changes were stated on skin of control animals in the site of test item application. No pathological changes were stated also on skin in the site of medium application.

During readings after 24, 48 and 72 hours since the end of exposure, no pathological changes were stated on skin of animals of treated group in the site of test item application. No pathological changes on skin were stated also in the site of medium application.

On the ground of obtained results one may state that no allergic skin reactions occurred in animals of treated group.

During experiment no distinct differences in body weight gain were stated between animals of control and treated group.

During experiment no changes in behavior were observed in animals of control and treated group. No clinical signs were stated in animals of both control and treated group.

#### Conclusion/endpoint:

On the ground of the study one may state that TOTO 75 WG plant protection product may be included to agents not causing sensitization

#### IIIA 7.1.7 Supplementary studies for combinations of plant protection products

No supplementary studies have been carried out as the product is not proposed for use in combination with other products.

### IIIA 7.2 Short-Term Toxicity Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

### IIIA 7.3 Operator Exposure

|                  |   |            |
|------------------|---|------------|
| <b>Reference</b> | <b>IIIA 7.3/01</b> xxx, xxxx, Estimation of operator exposure using the German models – TOTO 75 | and the UK |
|------------------|---|------------|

Estimations of potential operator exposure were compared to proposed/EU agreed data for **TOTO 75 SG**

Exposure estimates were calculated separately for each crop use scenario. The estimates of total **TOTO 75 SG** exposure (expressed as the systemically absorbed dose) predicted by the German model and UK model were calculated as a proportion of the proposed systemic AOEL and are summarised in the tables below.

**Table 7.3-1: Short-term AOELs compared with exposure levels for operators following use of (GERMAN MODEL)**

| Active substance          | Short-term systemic<br>AOEL<br>mg/kg bw/day<br>(source: Review<br>reports for the active<br>substance<br>thifensulfuron-<br>methyl and<br>metsulfuron-methyl) | Predicted systemic<br>exposure<br>mg/kg bw/day<br>(no PPE) | Predicted exposure<br>as % of short-term<br>systemic AOEL |
|---------------------------|---|--|---|
| Thifensulfuron-<br>methyl | 0.07  | 0.00724284   | 10.3%   |
| Metsulfuron-methyl        | 0.7   | 0.00072216   | 0.1%  |
|                           |   | TOTAL =<br>0.0079655                                       | TOTAL = 10.4%   |

## CONCLUSION:

**The sum of the fractions is  $\leq 1$  (or  $\leq 100\%$ ) and therefore exposure of the operator is acceptable** (worst case assessment = no PPE)

**Table 7.3-2: Short-term AOELs compared with exposure levels for operators following use of TOTO 75 SG (UK MODEL)**

| Active substance | Short-term systemic<br>AOEL<br>mg/kg bw/day<br>(source: Review<br>reports for the active | Predicted systemic<br>exposure<br>mg/kg bw/day<br>(no PPE) | Predicted exposure<br>as % of short-term<br>systemic AOEL |
|------------------|--|--|---|
|------------------|--|--|---|

|                                   |   |                              |                      |
|-----------------------------------|---|------------------------------|----------------------|
|                                   | substance<br>thifensulfuron-<br>methyl and<br>metsulfuron-methyl) |                              |                      |
| <b>Thifensulfuron-<br/>methyl</b> | <b>0.07</b>   | <b>0.007189133</b>           | <b>10%</b>           |
| <b>Metsulfuron-methyl</b>         | <b>0.7</b>  | <b>0.000716805</b>           | <b>0.1%</b>          |
|                                   |   | <b>TOTAL =<br/>0.0079059</b> | <b>TOTAL = 10.1%</b> |

**CONCLUSION:**

**The sum of the fractions is  $\leq 1$  (or  $\leq 100\%$ ) and therefore exposure of the operator is acceptable**

**Conclusions:**

According to Annex III, point 7, Risk Quotation is obtained by dividing operator exposure by AOEL. The results of the calculations using the two recognized models, the UK POEM and the German model show that RQ for operator exposure is well below 1, hence TOTO 75 poses no undue risk to the operator. Exposure to **TOTO 75 SG** during mixing, loading, and spraying does not involve a significant risk to the health of operators assuming personal protective equipment is not used.

**IIIA 7.3 Operator Exposure**

**Reference**      **IIIA 7.3/01**    xxx\_Operator exposure (acc. to the German model)\_TOTO 75 SG\_met

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| Estimation of operator exposure (acc. to the German model)   |  |                            |                   |                          |
|--|--|----------------------------|-------------------|--------------------------|
| Active substance (a.s.)  | Metsulfuron methyl                       |                            |                   |                          |
| Product  | TOTO 75 SG/ HESRKULES 75 SG /TYTAN 75 SG |                            |                   |                          |
| Intended use(s)  | e.g. cereals                             |                            |                   |                          |
| Type of preparation  | Field Crops, Tractor Mounted (FCTM)      |                            |                   |                          |
| Type of preparation  | Liquid                                   |                            |                   |                          |
| Application rate (AR)  | 0.0062                                   | kg a.s./ha                 |                   |                          |
| Treated area per day (A)   | 20                                       | ha/d                       |                   |                          |
| Systemic AOEL  | 0.25                                     | mg/kg bw/d                 |                   |                          |
| Dermal absorption (DA)   | 25                                       | % for mixing/loading (m/l) |                   |                          |
|  | 75                                       | % for application (appl.)  |                   |                          |
| Inhalation absorption (IA)   | 100                                      | %                          |                   |                          |
| Body weight (BW)   | 70                                       | kg                         |                   |                          |
| Personal protective equipment:   | BVL code                                 | Reduction factor           | to lower:         |                          |
| Particle filtering half mask (m/l) <sup>1)</sup>   | ST1102                                   | 0.08                       | I <sub>M</sub>    | <input type="checkbox"/> |
| Half mask with combined filter (m/l) <sup>1)</sup>   | ST2102                                   | 0.02                       | I <sub>M</sub>    | <input type="checkbox"/> |
| Particle filtering half mask (appl.) <sup>1)</sup>   | ST1203                                   | 0.08                       | I <sub>A</sub>    | <input type="checkbox"/> |
|  |  | 0.8                        | D <sub>A(C)</sub> |                          |
| Half mask with combined filter (appl.) <sup>1)</sup>   | ST2202                                   | 0.02                       | I <sub>A</sub>    | <input type="checkbox"/> |
|  |  | 0.8                        | D <sub>A(C)</sub> |                          |
| Protective gloves (m/l) <sup>2)</sup>  | SS110                                    | 0.01                       | D <sub>M(H)</sub> | <input type="checkbox"/> |
| Protective gloves (appl.) <sup>2)</sup>  | SS120                                    | 0.01                       | D <sub>A(H)</sub> | <input type="checkbox"/> |
| Protective garment + sturdy footwear (appl.) <sup>2)</sup>   | SS2202                                   | 0.05                       | D <sub>A(B)</sub> | <input type="checkbox"/> |
| Broad-brimmed headgear (appl.) <sup>2)</sup>   | SS420                                    | 0.5                        | D <sub>A(C)</sub> | <input type="checkbox"/> |
| Hood and visor (appl.) <sup>2)</sup>   | SS520                                    | 0.05                       | D <sub>A(C)</sub> | <input type="checkbox"/> |
| <sup>1)</sup> DIN EN 149 (2001), <sup>2)</sup> BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection |  |                            |                   |                          |
| Estimated inhalation exposure:   | Personal protective equipment (PPE)      |                            | Factor            |                          |
| I <sub>M</sub>   | no PPE                                   |                            | 1                 |                          |
| I <sub>A</sub>   | no PPE                                   |                            | 1                 |                          |



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| Estimated dermal exposure: | Personal protective equipment (PPE) | Factor |
|----------------------------|-------------------------------------|--------|
| $D_{M(H)}$                 | no PPE                              | 1      |
| $D_{A(H)}$                 | no PPE                              | 1      |
| $D_{A(C)}$                 | no PPE                              | 1      |
| $D_{A(B)}$                 | no PPE                              | 1      |

**Estimation of operator exposure: German model**

Input parameters considered for the estimation of operator exposure:

| Formulation type:           | Liquid           | Application technique:             | Field Crops, Tractor Mounted (FCTM) |
|-----------------------------|------------------|------------------------------------|-------------------------------------|
| Application rate (AR):      | 0.0062 kg        |                                    |                                     |
| Area treated per day (A):   | 20 ha            | Dermal hands m/l ( $D_{M(H)}$ ):   | 2.4 mg/person/kg a.s.               |
| Dermal absorption (DA):     | 25 % (concentr.) | Dermal hands appl. ( $D_{A(H)}$ ): | 0.38 mg/person/kg a.s.              |
|                             | 75 % (dilution)  | Dermal body appl. ( $D_{A(B)}$ ):  | 1.6 mg/person/kg a.s.               |
| Inhalation absorption (IA): | 100 %            | Dermal head appl. ( $D_{A(C)}$ ):  | 0.06 mg/person/kg a.s.              |
| Body weight (BW):           | 70 kg/person     | Inhalation m/l ( $I_A$ ):          | 0.0006 mg/person/kg a.s.            |
| AOEL                        | 0.25 mg/kg bw/d  | Inhalation appl. ( $I_A$ ):        | 0.001 mg/person/kg a.s.             |

**Operator exposure towards Metsulfuron methyl**

| Without PPE   |           |            | With PPE  |           |            |
|---|-----------|------------|---|-----------|------------|
| Operators: Systemic dermal exposure after application in e.g. cereals |           |            |   |           |            |
| Dermal exposure during mixing/loading                                 |           |            |   |           |            |
| Hands   |           |            | Hands   |           |            |
| $SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$          |           |            | $SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^1 \times DA) / BW$ |           |            |
| $(2.4 \times 0.0062 \times 20 \times 25\%) / 70$                      |           |            | $(2.4 \times 0.0062 \times 20 \times 1 \times 25\%) / 70$                 |           |            |
| External dermal exposure  | 0.2976    | mg/person  | External dermal exposure  | 0.2976    | mg/person  |
| External dermal exposure  | 0.0042514 | mg/kg bw/d | External dermal exposure  | 0.0042514 | mg/kg bw/d |
| Systemic dermal exposure  | 0.001063  | mg/kg bw/d | Systemic dermal exposure  | 0.001063  | mg/kg bw/d |
| Dermal exposure during application                                    |           |            |   |           |            |
| Hands   |           |            | Hands   |           |            |
| $SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$          |           |            | $SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE^1 \times DA) / BW$ |           |            |
| $(0.38 \times 0.0062 \times 20 \times 75\%) / 70$                     |           |            | $(0.38 \times 0.0062 \times 20 \times 1 \times 75\%) / 70$                |           |            |
| External dermal exposure  | 0.04712   | mg/person  | External dermal exposure  | 0.04712   | mg/person  |
| External dermal exposure  | 0.0006731 | mg/kg bw/d | External dermal exposure  | 0.0006731 | mg/kg bw/d |
| Systemic dermal exposure  | 0.000505  | mg/kg bw/d | Systemic dermal exposure  | 0.000505  | mg/kg bw/d |
| Body  |           |            | Body  |           |            |
| $SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$          |           |            | $SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE^2 \times DA) / BW$ |           |            |
| $(1.6 \times 0.0062 \times 20 \times 75\%) / 70$                      |           |            | $(1.6 \times 0.0062 \times 20 \times 1 \times 75\%) / 70$                 |           |            |
| External dermal exposure  | 0.1984    | mg/person  | External dermal exposure  | 0.1984    | mg/person  |
| External dermal exposure  | 0.0028343 | mg/kg bw/d | External dermal exposure  | 0.0028343 | mg/kg bw/d |
| Systemic dermal exposure  | 0.002126  | mg/kg bw/d | Systemic dermal exposure  | 0.002126  | mg/kg bw/d |

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| Head   |           |            | Head  |           |            |
|--|-----------|------------|---|-----------|------------|
| $SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$   |           |            | $SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE^3 \times DA) / BW$                       |           |            |
| $(0.06 \times 0.0062 \times 20 \times 75\%) / 70$  |           |            | $(0.06 \times 0.0062 \times 20 \times 1 \times 75\%) / 70$                                      |           |            |
| External dermal exposure   | 0.00744   | mg/person  | External dermal exposure  | 0.00744   | mg/person  |
| External dermal exposure   | 0.0001063 | mg/kg bw/d | External dermal exposure  | 0.0001063 | mg/kg bw/d |
| Systemic dermal exposure   | 0.000080  | mg/kg bw/d | Systemic dermal exposure  | 0.000080  | mg/kg bw/d |
| Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$  |           |            | Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$ |           |            |
| Total external dermal exposure   | 0.55056   | mg/person  | Total external dermal exposure  | 0.55056   | mg/person  |
| Total external dermal exposure   | 0.0078651 | mg/kg bw/d | Total external dermal exposure  | 0.0078651 | mg/kg bw/d |
| Total systemic dermal exposure   | 0.00377   | mg/kg bw/d | Total systemic dermal exposure  | 0.00377   | mg/kg bw/d |
| <b>Operators: Systemic inhalation exposure after application in e.g. cereals</b>   |           |            |   |           |            |
| Inhalation exposure during mixing/loading  |           |            |   |           |            |
| $SIE_{OM} = (I_M \times AR \times A \times IA) / BW$   |           |            | $SIE_{OM} = (I_M \times AR \times A \times PPE^4 \times IA) / BW$                               |           |            |
| $(0.0006 \times 0.0062 \times 20 \times 100\%) / 70$   |           |            | $(0.0006 \times 0.0062 \times 20 \times 1 \times 100\%) / 70$                                   |           |            |
| External inhalation exposure   | 0.0000744 | mg/person  | External inhalation exposure  | 0.0000744 | mg/person  |
| External inhalation exposure   | 1.063E-06 | mg/kg bw/d | External inhalation exposure  | 1.063E-06 | mg/kg bw/d |
| Systemic inhalation exposure   | 0.000001  | mg/kg bw/d | Systemic inhalation exposure  | 0.000001  | mg/kg bw/d |
| Inhalation exposure during application   |           |            |   |           |            |
| $SIE_{OA} = (I_A \times AR \times A \times IA) / BW$   |           |            | $SIE_{OA} = (I_A \times AR \times A \times PPE^4 \times IA) / BW$                               |           |            |
| $(0.001 \times 0.0062 \times 20 \times 100\%) / 70$  |           |            | $(0.001 \times 0.0062 \times 20 \times 1 \times 100\%) / 70$                                    |           |            |
| External inhalation exposure   | 0.000124  | mg/person  | External inhalation exposure  | 0.000124  | mg/person  |
| External inhalation exposure   | 1.771E-06 | mg/kg bw/d | External inhalation exposure  | 1.771E-06 | mg/kg bw/d |
| Systemic inhalation exposure   | 0.000002  | mg/kg bw/d | Systemic inhalation exposure  | 0.000002  | mg/kg bw/d |
| Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$  |           |            | Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$                               |           |            |
| Total external inhalation exposure   | 0.000198  | mg/person  | Total external inhalation exposure  | 0.000198  | mg/person  |
| Total external inhalation exposure   | 0.000003  | mg/kg bw/d | Total external inhalation exposure  | 0.000003  | mg/kg bw/d |
| Total systemic inhalation exposure   | 0.000003  | mg/kg bw/d | Total systemic inhalation exposure  | 0.000003  | mg/kg bw/d |
| Total systemic exposure: $SE_O = SDE_O + SIE_O$  |           |            | Total systemic exposure: $SE_O = SDE_O + SIE_O$   |           |            |
| Total systemic exposure  | 0.26432   | mg/person  | Total systemic exposure   | 0.26432   | mg/person  |
| Total systemic exposure  | 0.003776  | mg/kg bw/d | Total systemic exposure   | 0.003776  | mg/kg bw/d |
| % of AOEL  | 1.5       | %          | % of AOEL   | 1.5       | %          |
| <sup>1)</sup> reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications), resp.<br><sup>2)</sup> reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden appl.), resp.<br><sup>3)</sup> reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional appl.)<br><sup>4)</sup> reduction factor for RPE is 0.08 (particle filter) and 0.02 (combined vapour and particle filter), resp. (prof. appl.) |           |            |   |           |            |

**Reference** IIIA 7.3/02 xxx\_Operator exposure (acc. to the German model)\_TOTO 75 SG\_thifen

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| Estimation of operator exposure (acc. to the German model)   |   |                            |                   |                          |
|--|---|----------------------------|-------------------|--------------------------|
| Active substance (a.s.)  | Thifensulfuron methyl                   |                            |                   |                          |
| Product  | TOTO 75 SG/ HESKULES 75 SG /TYTAN 75 SG |                            |                   |                          |
| Intended use(s)  | e.g. cereals                            |                            |                   |                          |
| Type of preparation  | Field Crops, Tractor Mounted (FCTM)     |                            |                   |                          |
| Application rate (AR)  | 0.062                                   | kg a.s./ha                 |                   |                          |
| Treated area per day (A)   | 20                                      | ha/d                       |                   |                          |
| Systemic AOEL  | 0.07                                    | mg/kg bw/d                 |                   |                          |
| Dermal absorption (DA)   | 25                                      | % for mixing/loading (m/l) |                   |                          |
|  | 75                                      | % for application (appl.)  |                   |                          |
| Inhalation absorption (IA)   | 100                                     | %                          |                   |                          |
| Body weight (BW)   | 70                                      | kg                         |                   |                          |
| Personal protective equipment:   | BVL code                                | Reduction factor           | to lower:         |                          |
| Particle filtering half mask (m/l) <sup>1)</sup>   | ST1102                                  | 0.08                       | I <sub>h</sub>    | <input type="checkbox"/> |
| Half mask with combined filter (m/l) <sup>1)</sup>   | ST2102                                  | 0.02                       | I <sub>h</sub>    | <input type="checkbox"/> |
| Particle filtering half mask (appl.) <sup>1)</sup>   | ST1203                                  | 0.08                       | I <sub>a</sub>    | <input type="checkbox"/> |
|  |   | 0.8                        | D <sub>A(C)</sub> | <input type="checkbox"/> |
| Half mask with combined filter (appl.) <sup>1)</sup>   | ST2202                                  | 0.02                       | I <sub>a</sub>    | <input type="checkbox"/> |
|  |   | 0.8                        | D <sub>A(C)</sub> | <input type="checkbox"/> |
| Protective gloves (m/l) <sup>2)</sup>  | SS110                                   | 0.01                       | D <sub>M(H)</sub> | <input type="checkbox"/> |
| Protective gloves (appl.) <sup>2)</sup>  | SS120                                   | 0.01                       | D <sub>A(H)</sub> | <input type="checkbox"/> |
| Protective garment + sturdy footwear (appl.) <sup>2)</sup>   | SS2202                                  | 0.05                       | D <sub>A(B)</sub> | <input type="checkbox"/> |
| Broad-brimmed headgear (appl.) <sup>2)</sup>   | SS420                                   | 0.5                        | D <sub>A(C)</sub> | <input type="checkbox"/> |
| Hood and visor (appl.) <sup>2)</sup>   | SS520                                   | 0.05                       | D <sub>A(C)</sub> | <input type="checkbox"/> |
| <sup>1)</sup> DIN EN 149 (2001), <sup>2)</sup> BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection |   |                            |                   |                          |
| Estimated inhalation exposure:   | Personal protective equipment (PPE)     |                            | Factor            |                          |
| I <sub>h</sub>   | no PPE                                  |                            | 1                 |                          |
| I <sub>a</sub>   | no PPE                                  |                            | 1                 |                          |
| II   |   |                            |                   |                          |
| Estimated dermal exposure:   | Personal protective equipment (PPE)     |                            | Factor            |                          |
| D <sub>M(H)</sub>  | no PPE                                  |                            | 1                 |                          |
| D <sub>A(H)</sub>  | no PPE                                  |                            | 1                 |                          |
| D <sub>A(C)</sub>  | no PPE                                  |                            | 1                 |                          |
| D <sub>A(B)</sub>  | no PPE                                  |                            | 1                 |                          |

|   |  |                                     |                                     |  |
|---|--|-------------------------------------|-------------------------------------|--|
| 1 Estimation of operator exposure: German model   |  |                                     |                                     |  |
| 2   |  |                                     |                                     |  |
| 3 Input parameters considered for the estimation of operator exposure:                            |  |                                     |                                     |  |
| 4 Formulation type:   | Liquid   | Application technique:              | Field Crops, Tractor Mounted (FCTM) |  |
| 5 Application rate (AR):  | 0.062 kg   | Dermal hands m/l                    | 2.4 mg/person/kg                    |  |
| 6 Area treated per day  | 20 ha  | Dermal hands appl.                  | 0.38 mg/person/kg                   |  |
| 7 Dermal absorption   | 25 % (concentr.)   | Dermal body appl.                   | 1.6 mg/person/kg                    |  |
| 8 (DA):   | 75 % (dilution)  | Dermal head appl.                   | 0.06 mg/person/kg                   |  |
| 9 Inhalation absorption (IA)  | 100 %  | Inhalation m/l (I <sub>h</sub> ):   | 0.0006 mg/person/kg                 |  |
| 0 Body weight (BW):   | 70 kg/person   | Inhalation appl. (I <sub>a</sub> ): | 0.001 mg/person/kg                  |  |
| 1 AOEL  | 0.07 mg/kg bw/d  |                                     |                                     |  |
| 2   |  |                                     |                                     |  |
| 3 Operator exposure towards Thifensulfuron methyl   |  |                                     |                                     |  |
| 4 Without PPE With PPE  |  |                                     |                                     |  |
| 5 Operators: Systemic dermal exposure after application in e.g. cereals                           |  |                                     |                                     |  |
| 6 Dermal exposure during mixing/loading   |  |                                     |                                     |  |
| 7 Hands   | Hands  |                                     |                                     |  |
| 8 $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times DA) / BW$                                    | $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times PPE^{-1} \times DA) / BW$ |                                     |                                     |  |
| 9 $(2.4 \times 0.062 \times 20 \times 25\%) / 70$   | $(2.4 \times 0.062 \times 20 \times 1 \times 25\%) / 70$                     |                                     |                                     |  |
| 0 External dermal exposure  | 2.976 mg/person  | External dermal exposure            | 2.976 mg/person                     |  |
| 1 External dermal exposure  | 0.04251 mg/kg bw/d   | External dermal exposure            | 0.04251 mg/kg bw/d                  |  |
| 2 Systemic dermal   | ##### mg/kg bw/d   | Systemic dermal                     | ##### mg/kg bw/d                    |  |
| 3 Dermal exposure during application  |  |                                     |                                     |  |
| 4 Hands   | Hands  |                                     |                                     |  |
| 5 $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times DA) / BW$                                    | $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times PPE^{-1} \times DA) / BW$ |                                     |                                     |  |
| 6 $(0.38 \times 0.062 \times 20 \times 75\%) / 70$  | $(0.38 \times 0.062 \times 20 \times 1 \times 75\%) / 70$                    |                                     |                                     |  |
| 7 External dermal exposure  | 0.4712 mg/person   | External dermal exposure            | 0.4712 mg/person                    |  |
| 8 External dermal exposure  | 0.00673 mg/kg bw/d   | External dermal exposure            | 0.00673 mg/kg bw/d                  |  |
| 9 Systemic dermal   | ##### mg/kg bw/d   | Systemic dermal                     | ##### mg/kg bw/d                    |  |
| 0 Body  | Body   |                                     |                                     |  |
| 1 $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times DA) / BW$                                    | $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times PPE^{-1} \times DA) / BW$ |                                     |                                     |  |
| 2 $(1.6 \times 0.062 \times 20 \times 75\%) / 70$   | $(1.6 \times 0.062 \times 20 \times 1 \times 75\%) / 70$                     |                                     |                                     |  |
| 3 External dermal exposure  | 1.984 mg/person  | External dermal exposure            | 1.984 mg/person                     |  |
| 4 External dermal exposure  | 0.02834 mg/kg bw/d   | External dermal exposure            | 0.02834 mg/kg bw/d                  |  |
| 5 Systemic dermal   | ##### mg/kg bw/d   | Systemic dermal                     | ##### mg/kg bw/d                    |  |
| 6 Head  | Head   |                                     |                                     |  |
| 7 $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times DA) / BW$                                    | $SDE_{DA(2)} = (D_{A(2)} \times AR \times A \times PPE^{-1} \times DA) / BW$ |                                     |                                     |  |
| 8 $(0.06 \times 0.062 \times 20 \times 75\%) / 70$  | $(0.06 \times 0.062 \times 20 \times 1 \times 75\%) / 70$                    |                                     |                                     |  |
| 9 External dermal exposure  | 0.0744 mg/person   | External dermal exposure            | 0.0744 mg/person                    |  |
| 0 External dermal exposure  | 0.00106 mg/kg bw/d   | External dermal exposure            | 0.00106 mg/kg bw/d                  |  |
| 1 Systemic dermal   | ##### mg/kg bw/d   | Systemic dermal                     | ##### mg/kg bw/d                    |  |
| 2 Total systemic dermal exposure: $SDE_o = SDE_{DA(2)} + SDE_{DA(2)} + SDE_{DA(2)} + SDE_{DA(2)}$ |  |                                     |                                     |  |
| 3 Total external dermal exposure  |  |                                     |                                     |  |
| 4 Total external dermal exposure  | 5.5056 mg/person   | Total external dermal exposure      | 5.5056 mg/person                    |  |
| 5 Total external dermal exposure  | 0.07865 mg/kg bw/d   | Total external dermal exposure      | 0.07865 mg/kg bw/d                  |  |
| 6 Total systemic dermal exposure  | 0.03773 mg/kg bw/d   | Total systemic dermal exposure      | 0.03773 mg/kg bw/d                  |  |
| 7 Operators: Systemic inhalation exposure after application in e.g. cereals                       |  |                                     |                                     |  |
| 8 Inhalation exposure during mixing/loading   |  |                                     |                                     |  |

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| A   | B       | C  | D                                  | E       | F          |
|---|---------|--|------------------------------------|---------|------------|
| Total systemic dermal exposure  | 0.03773 | mg/kg bw/d   | Total systemic dermal exposure     | 0.03773 | mg/kg bw/d |
| Operators: Systemic inhalation exposure after application in e.g. cereals   |         |  |                                    |         |            |
| Inhalation exposure during mixing/loading   |         |  |                                    |         |            |
| $SI_{O_{M}} = (I_{M} \times AR \times A \times IA) / BW$  |         | $SI_{O_{M}} = (I_{M} \times AR \times A \times PPE^{-0.4} \times IA) / BW$ |                                    |         |            |
| $(0.0006 \times 0.062 \times 20 \times 100\%) / 70$   |         | $(0.0006 \times 0.062 \times 20 \times 1 \times 100\%) / 70$               |                                    |         |            |
| External inhalation   | 0.00074 | mg/person  | External inhalation                | 0.00074 | mg/person  |
| External inhalation   | 1.1E-05 | mg/kg bw/d   | External inhalation                | 1.1E-05 | mg/kg bw/d |
| Systemic inhalation   | #####   | mg/kg bw/d   | Systemic inhalation                | #####   | mg/kg bw/d |
| Inhalation exposure during application  |         |  |                                    |         |            |
| $SI_{O_{A}} = (I_{A} \times AR \times A \times IA) / BW$  |         | $SI_{O_{A}} = (I_{A} \times AR \times A \times PPE^{-0.4} \times IA) / BW$ |                                    |         |            |
| $(0.001 \times 0.062 \times 20 \times 100\%) / 70$  |         | $(0.001 \times 0.062 \times 20 \times 1 \times 100\%) / 70$                |                                    |         |            |
| External inhalation   | 0.00124 | mg/person  | External inhalation                | 0.00124 | mg/person  |
| External inhalation   | 1.8E-05 | mg/kg bw/d   | External inhalation                | 1.8E-05 | mg/kg bw/d |
| Systemic inhalation   | #####   | mg/kg bw/d   | Systemic inhalation                | #####   | mg/kg bw/d |
| Total systemic inhalation exposure: $SI_{O_{S}} = SI_{O_{M}} + SI_{O_{A}}$  |         | Total systemic inhalation exposure: $SI_{O_{S}} = SI_{O_{M}} + SI_{O_{A}}$ |                                    |         |            |
| Total external inhalation exposure  | #####   | mg/person  | Total external inhalation exposure | #####   | mg/person  |
| Total external inhalation exposure  | #####   | mg/kg bw/d   | Total external inhalation exposure | #####   | mg/kg bw/d |
| Total systemic inhalation exposure  | #####   | mg/kg bw/d   | Total systemic inhalation exposure | #####   | mg/kg bw/d |
| Total systemic exposure: $SE_{O_{S}} = SDE_{O_{S}} + SI_{O_{S}}$  |         | Total systemic exposure: $SE_{O_{S}} = SDE_{O_{S}} + SI_{O_{S}}$           |                                    |         |            |
| Total systemic exposure   | 2.64318 | mg/person  | Total systemic exposure            | 2.64318 | mg/person  |
| Total systemic exposure   | #####   | mg/kg bw/d   | Total systemic exposure            | #####   | mg/kg bw/d |
| % of AOEL   | 53.9    | %  | % of AOEL                          | 53.9    | %          |
| <sup>1)</sup> reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications),               |         |  |                                    |         |            |
| <sup>2)</sup> reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden)                     |         |  |                                    |         |            |
| <sup>3)</sup> reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional)                 |         |  |                                    |         |            |
| <sup>4)</sup> reduction factor for RPE is 0.03 (particulate filter) and 0.02 (combined vapour and particulate filter) <i>reson. (nonf</i> |         |  |                                    |         |            |

Table 7.3-1: Short-term AOELs compared with exposure levels for operators following use of TOTO 75 SG (GERMAN MODEL)

| Active substance      | Short-term systemic AOEL<br>mg/kg bw/day<br>(source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl) | Predicted systemic exposure<br>mg/kg bw/day<br>(no PPE) | Predicted exposure as % of short-term systemic AOEL |
|-----------------------|--|---|---|
| Thifensulfuron-methyl | 0.07   | 0.037760  | 53.9%   |
| Metsulfuron-methyl    | 0.25   | 0.003776  | 1.5   |
|                       |  | TOTAL = 0.011   | TOTAL = 11.8%                                       |

## CONCLUSION:

The values of predicted exposure for metsulfuron methyl and thifensulfuron methyl are below 100% of short-term systemic AOEL and therefore exposure of the operator is acceptable (worst case assessment = no PPE)

Reference IIIA 7.3/02 xxx\_Operator exposure (acc. to the UK model) \_TOTO 75 SG\_met

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| THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE) |   |                              |                    |
|--|---|------------------------------|--------------------|
| Application method   | Tractor-mounted/trailed boom sprayer: hydraulic nozzles                     |                              |                    |
| Product  | TOTO 75 SG  | Active substance             | Metsulfuron methyl |
| Formulation type   | WG or SG  | a.s. concentration           | 68 mg/g            |
| Dermal absorption from product   | 25 %  | Dermal absorption from spray | 75 %               |
| PPE during mix/loading   | None  | PPE during application       | None               |
| Dose   | 0.09 kg product/ha  | Work rate/day                | 50 ha              |
| Application volume   | 200 l/ha  | Duration of spraying         | 6 h                |
| DERMAL EXPOSURE DURING MIXING AND LOADING  |   |                              |                    |
| Hand contamination/kg a.s.   | 5.72 mg/kg a.s.   |                              |                    |
| Hand contamination/day   | 1.75032 mg/day  |                              |                    |
| Protective clothing  | None  |                              |                    |
| Transmission to skin   | 100 %   |                              |                    |
| Dermal exposure to a.s.  | 1.75032 mg/day  |                              |                    |
| INHALATION EXPOSURE DURING MIXING AND LOADING  |   |                              |                    |
| Inhalation exposure/kg a.s.  | 0.0358 mg/kg a.s.   |                              |                    |
| Inhalation exposure/day  | 0.0109548 mg/day  |                              |                    |
| RPE  | None  |                              |                    |
| Transmission through RPE   | 100 %   |                              |                    |
| Inhalation exposure to a.s.  | 0.0109548 mg/day  |                              |                    |
| DERMAL EXPOSURE DURING SPRAY APPLICATION   |   |                              |                    |
| Application technique  | Tractor-mounted/trailed boom sprayer: hydraulic nozzles                     |                              |                    |
| Application volume   | 200 spray/ha  |                              |                    |
| Volume of surface contamination  | 10 ml/h   |                              |                    |
| Distribution   | Hands Trunk Legs  |                              |                    |
|  | 65% 10% 25%   |                              |                    |
| Clothing   | None Permeable  |                              | Permeable          |
| Penetration  | 100% 5%   |                              | 15%                |
| Dermal exposure  | 6.5 0.05  |                              | 0.375 ml/h         |
| Duration of exposure   | 6 h   |                              |                    |
| Total dermal exposure to spray   | 41.55 ml/day  |                              |                    |
| Concentration of a.s. in spray solution  | 0.0306 mg/ml  |                              |                    |
| Dermal exposure to a.s.  | 1.27143 mg/day  |                              |                    |
| INHALATION EXPOSURE DURING SPRAYING  |   |                              |                    |
| Inhalation exposure to spray   | 0.01 ml/h   |                              |                    |
| Duration of exposure   | 6 h   |                              |                    |
| Concentration of a.s. in spray   | 0.0306 mg/ml  |                              |                    |
| Inhalation exposure to a.s.  | 0.001836 mg/day   |                              |                    |
| Percent absorbed   | 100 %   |                              |                    |
| Absorbed dose  | 0.001836 mg/day   |                              |                    |
| ABSORBED DOSE  |   |                              |                    |
|  | Mix/load  | Application                  |                    |
| Dermal exposure to a.s.  | 1.75032 mg/day  | 1.27143 mg/day               |                    |
| Percent absorbed   | 25 %  | 75 %                         |                    |
| Absorbed dose (dermal route)   | 0.43758 mg/day  | 0.9535725 mg/day             |                    |
| Inhalation exposure to a.s.  | 0.0109548 mg/day  | 0.001836 mg/day              |                    |
| Absorbed dose  | 0.4485348 mg/day  | 0.9554085 mg/day             |                    |
| PREDICTED EXPOSURE   |   |                              |                    |
| Total absorbed dose  | 1.4039433 mg/day  |                              |                    |
| Operator body weight   | 60 kg   |                              |                    |
| Operator exposure  | 0.023399055 mg/kg bw/day  |                              |                    |
| Reference  | IIIA 7.3/02 Xxx_Operator exposure (acc. to the UK model) _TOTO 75 SG_thifen |                              |                    |

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## THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

|                                |   |                              |                       |
|--------------------------------|---|------------------------------|-----------------------|
| Application method             | Tractor-mounted/trailed boom sprayer: hydraulic nozzles |                              |                       |
| Product                        | TOTO 75 SG  | Active substance             | Thifensulfuron methyl |
| Formulation type               | WG or SG  | a.s. concentration           | 682 mg/g              |
| Dermal absorption from product | 25 %  | Dermal absorption from spray | 75 %                  |
| PPE during mix/loading         | Gloves and RPE (FFP2)                                   | PPE during application       | Gloves                |
| Dose                           | 0.09 kg product/ha                                      | Work rate/day                | 50 ha                 |
| Application volume             | 200 l/ha  | Duration of spraying         | 6 h                   |

## DERMAL EXPOSURE DURING MIXING AND LOADING

|                            |                  |
|----------------------------|------------------|
| Hand contamination/kg a.s. | 5.72 mg/kg a.s.  |
| Hand contamination/day     | 17.55468 mg/day  |
| Protective clothing        | Gloves           |
| Transmission to skin       | 1 %              |
| Dermal exposure to a.s.    | 0.1755468 mg/day |

## INHALATION EXPOSURE DURING MIXING AND LOADING

|                             |                   |
|-----------------------------|-------------------|
| Inhalation exposure/kg a.s. | 0.0358 mg/kg a.s. |
| Inhalation exposure/day     | 0.1098702 mg/day  |
| RPE                         | RPE (FFP2)        |
| Transmission through RPE    | 10 %              |
| Inhalation exposure to a.s. | 0.01098702 mg/day |

## DERMAL EXPOSURE DURING SPRAY APPLICATION

|                                 |   |           |            |
|---------------------------------|---|-----------|------------|
| Application technique           | Tractor-mounted/trailed boom sprayer: hydraulic nozzles |           |            |
| Application volume              | 200 spray/ha  |           |            |
| Volume of surface contamination | 10 ml/h   |           |            |
| Distribution                    | Hands   | Trunk     | Legs       |
|                                 | 65%   | 10%       | 25%        |
| Clothing                        | Gloves  | Permeable | Permeable  |
| Penetration                     | 10%   | 5%        | 15%        |
| Dermal exposure                 | 0.65  | 0.05      | 0.375 ml/h |
| Duration of exposure            | 6 h   |           |            |

|   |                 |
|---|-----------------|
| Total dermal exposure to spray          | 6.45 ml/day     |
| Concentration of a.s. in spray solution | 0.3069 mg/ml    |
| Dermal exposure to a.s.                 | 1.979505 mg/day |

## INHALATION EXPOSURE DURING SPRAYING

|                                |                 |
|--------------------------------|-----------------|
| Inhalation exposure to spray   | 0.01 ml/h       |
| Duration of exposure           | 6 h             |
| Concentration of a.s. in spray | 0.3069 mg/ml    |
| Inhalation exposure to a.s.    | 0.018414 mg/day |
| Percent absorbed               | 100 %           |
| Absorbed dose                  | 0.018414 mg/day |

## ABSORBED DOSE

|                              | Mix/load          | Application       |
|------------------------------|-------------------|-------------------|
| Dermal exposure to a.s.      | 0.1755468 mg/day  | 1.979505 mg/day   |
| Percent absorbed             | 25 %              | 75 %              |
| Absorbed dose (dermal route) | 0.0438867 mg/day  | 1.48462875 mg/day |
| Inhalation exposure to a.s.  | 0.01098702 mg/day | 0.018414 mg/day   |
| Absorbed dose                | 0.05487372 mg/day | 1.50304275 mg/day |

## PREDICTED EXPOSURE

|                      |                          |
|----------------------|--------------------------|
| Total absorbed dose  | 1.55791647 mg/day        |
| Operator body weight | 60 kg                    |
| Operator exposure    | 0.025965275 mg/kg bw/day |

Table 7.3-2: Short-term AOELs compared with exposure levels for operators following use of TOTO 75 SG (UK MODEL)

| Active substance | Short-term systemic AOEL mg/kg bw/day (source: Review reports for the active substance thifensulfuron- | Predicted systemic exposure mg/kg bw/day (no PPE) | Predicted systemic exposure mg/kg bw/day (Gloves and RPE) | Predicted exposure as % of short-term systemic AOEL |
|------------------|--|---|---|---|
|------------------|--|---|---|---|



|                                   | methyl and<br>metsulfuron-<br>methyl) |                 | (FFP2)-<br>during<br>mix/loading<br>and gloves<br>during<br>application) |              |
|-----------------------------------|---------------------------------------|-----------------|--|--------------|
| <b>Thifensulfuron-<br/>methyl</b> | <b>0.07</b>                           | <b>0.2346</b>   | <b>0.0259</b>  | <b>37%</b>   |
| <b>Metsulfuron-<br/>methyl</b>    | <b>0.25</b>                           | <b>0.023399</b> | <b>-</b>   | <b>9.36%</b> |

#### CONCLUSION:

The values of predicted exposure for metsulfuron and thifensulfuron are below 100% of short-term systemic AOEL and therefore exposure of the operator is acceptable (worst case assessment = no PPE for metsulfuron methyl and worst case assessment- with PPE (gloves and RPE (FFP2)- during mix/loading and gloves during application) for thifensulfuron methyl )

#### Conclusions:

According to Annex III, point 7, Risk Assessment is obtained by dividing operator exposure by AOEL. The results of the calculations using the two recognized models, the UK POEM and the German model show that values of predicted exposure for metsulfuron methyl and thifensulfuron methyl are below 100% for operator exposure, hence TOTO 75 poses no undue risk to the operator.

Exposure to **TOTO 75 SG** during mixing, loading, and spraying does not involve a significant risk to the health of operators assuming personal protective equipment is used (gloves and RPE (FFP2)- during mix/loading and gloves during application).

**Reference** IIIA 7.3/03 Xxx\_Operator exposure (acc. to the EFSA\_model)\_TOTO 75 SG\_met

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| Operator exposure for TOTO 75 SG outdoor spray applications                                    |   |   |                             |                                      |                              |
|--|---|---|-----------------------------|--------------------------------------|------------------------------|
| Application rate of active substance   | 0,0052  | kg a.s./ha                              | U <sub>AppRate</sub>        |                                      |                              |
| Assumed area treated   | 50  | ha/day                                  | U <sub>AreaTreated</sub>    |                                      |                              |
| Amount of active substance applied   | 0,31  | kg a.s./day                             | U <sub>Amount</sub>         |                                      |                              |
| Dermal absorption of the product   | 25,00%  |   | U <sub>AbsorpProduct</sub>  |                                      |                              |
| Dermal absorption of in-use dilution   | 75,00%  |   | U <sub>AbsorpDilution</sub> |                                      |                              |
| Formulation type   | Wettable granules, soluble granules                                 |   |                             |                                      |                              |
| Indoor or Outdoor application  | Outdoor   |   |                             |                                      |                              |
| Application method   | Downward spraying   |   |                             |                                      |                              |
| Application equipment  | Vehicle-mounted-Drift Reduction                                     |   |                             |                                      |                              |
| Season   | not relevant  |   |                             |                                      |                              |
| Mixing and loading   | Exposure values   | µg exposure/day mixed and loaded        |                             | Reference                            | Comment                      |
|  |   | 75 <sup>th</sup> centile                | 95 <sup>th</sup> centile    |                                      |                              |
|  | Hands   | 532                                     | 2512                        | ACIEM                                |                              |
|  | Body  | 542                                     | 11436                       | ACIEM                                |                              |
|  | Head  | 2                                       | 28                          | ACIEM                                |                              |
|  | Protected hands (gloves)  | 8                                       | 10                          | ACIEM                                |                              |
|  | Protected body (workwear or protective garment and sturdy footwear) | 7                                       | 19                          | ACIEM                                |                              |
|  | Protected head (hood and face shield)                               | 0                                       | 2                           | ACIEM                                |                              |
|  | Inhalation  | 26                                      | 252                         | ACIEM                                |                              |
|  | Protective Equipment  | Select for inclusion                    |                             | Penetration factor                   | Inhalation Protection factor |
|  | Gloves  | No                                      |                             |                                      |                              |
|  | Clothing  | Work wear - arms, body and legs covered |                             | Incl. in ACIEM model                 |                              |
| Application  | Head and respiratory PPE  | None                                    |                             | 1                                    | 1                            |
|  | Water soluble bag   | No                                      |                             | 1                                    |                              |
|  | Exposure values   | µg exposure/day applied                 |                             | Reference                            | Comment                      |
|  |   | 75 <sup>th</sup> centile                | 95 <sup>th</sup> centile    |                                      |                              |
|  | Hands   | 19                                      | 238                         | ACIEM                                |                              |
|  | Body  | 4                                       | 4                           | ACIEM                                |                              |
|  | Head  | 0                                       | 0                           | ACIEM                                |                              |
|  | Protected hands (gloves)  | 2                                       | 47                          | ACIEM                                |                              |
|  | Protected body (workwear or protective garment and sturdy footwear) | 0                                       | 0                           | ACIEM                                |                              |
|  | Inhalation  | 1                                       | 1                           | ACIEM                                |                              |
|  | Protective Equipment  | Select for inclusion                    |                             | Penetration factor                   | Inhalation Protection factor |
|  | Gloves  | No                                      |                             |                                      |                              |
|  | Clothing  | Work wear - arms, body and legs covered |                             | Incl. in ACIEM model                 |                              |
|  | Head and respiratory PPE  | None                                    |                             | 1                                    | 1                            |
|  | Closed cab  | No                                      |                             | vehicle mounted upward spraying only |                              |
| 1. Total   |   |   |                             |                                      |                              |
|  |   | Without RPE/PPE                         |                             | With RPE/PPE                         |                              |
| Longer term  |   |   |                             |                                      |                              |
| Total systemic exposure from mixing, loading and application (mg a.s./day)                     |   | 0,3137105                               |                             | 0,1769171                            |                              |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) |   | 0,0052385                               |                             | 0,0029486                            |                              |
| % of RVNAG   |   | 2,09%                                   |                             | 1,18%                                |                              |
| Acute  |   |   |                             |                                      |                              |
| Total systemic exposure from mixing, loading and application (mg a.s./day)                     |   | 3,9285138                               |                             | 1,0715074                            |                              |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) |   | 0,0654752                               |                             | 0,0178585                            |                              |
| % of RVNAG   |   | 40,7163 / 01                            |                             | 40,7163 / 01                         |                              |

Reference IIIA 7.3/04 Xxx\_Operator exposure (acc. to the EFSA model)\_TOTO 75 SG\_thifen



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|                                      |                                     |                 |
|--------------------------------------|-------------------------------------|-----------------|
| Application rate of active substance | 0,062 kg a.s./ha                    | U_AppRate       |
| Assumed area treated                 | 50 ha/day                           | U_AreaTreated   |
| Amount of active substance applied   | 3,1 kg a.s./day                     | U_Amount        |
| Dermal absorption of the product     | 25,00%                              | U_AbsorpProduct |
| Dermal absorption of in-use dilution | 75,00%                              | U_AbsorpUse     |
| Formulation type                     | Wettable granules, soluble granules |                 |
| Indoor or Outdoor application        | Outdoor                             |                 |
| Application method                   | Downward spraying                   |                 |
| Application equipment                | Vehicle-mounted-Drift Reduction     |                 |
| Season                               | not relevant                        |                 |

  

| Mixing and loading | Exposure values   | µg exposure/day mixed and loaded        |                          | Reference            | Comment                      |
|--------------------|---|---|--------------------------|----------------------|------------------------------|
|                    |   | 75 <sup>th</sup> centile                | 95 <sup>th</sup> centile |                      |                              |
|                    |   |   |                          |                      |                              |
|                    | Hands   | 3132                                    | 15087                    | ACIEM                |                              |
|                    | Body  | 2796                                    | 22325                    | ACIEM                |                              |
|                    | Head  | 20                                      | 278                      | ACIEM                |                              |
|                    | Protected hands (gloves)  | 35                                      | 98                       | ACIEM                |                              |
|                    | Protected body (workwear or protective garment and sturdy footwear) | 51                                      | 183                      | ACIEM                |                              |
|                    | Protected head (hood and face shield)                               | 0                                       | 16                       | ACIEM                |                              |
|                    | Inhalation  | 52                                      | 267                      | ACIEM                |                              |
|                    | Protective Equipment  | Select for inclusion                    |                          | Penetration Factor   | Inhalation Protection factor |
|                    | Gloves  | Yes                                     |                          | Incl. in ACIEM model |                              |
|                    | Clothing  | Work wear - arms, body and legs covered |                          | Incl. in ACIEM model |                              |
|                    | Head and respiratory PPE  | None                                    |                          | 1                    | 1                            |
|                    | Water soluble bag   | No                                      |                          | 1                    |                              |

  

| Application | Exposure values   | µg exposure/day applied                 |                          | Reference                            | Comment                      |
|-------------|---|---|--------------------------|--------------------------------------|------------------------------|
|             |   | 75 <sup>th</sup> centile                | 95 <sup>th</sup> centile |                                      |                              |
|             |   |   |                          |                                      |                              |
|             | Hands   | 195                                     | 1285                     | ACIEM                                |                              |
|             | Body  | 40                                      | 41                       | ACIEM                                |                              |
|             | Head  | 2                                       | 3                        | ACIEM                                |                              |
|             | Protected hands (gloves)  | 6                                       | 61                       | ACIEM                                |                              |
|             | Protected body (workwear or protective garment and sturdy footwear) | 1                                       | 2                        | ACIEM                                |                              |
|             | Inhalation  | 2                                       | 3                        | ACIEM                                |                              |
|             | Protective Equipment  | Select for inclusion                    |                          | Penetration factor                   | Inhalation Protection factor |
|             | Gloves  | Yes                                     |                          | Incl. in ACIEM model                 |                              |
|             | Clothing  | Work wear - arms, body and legs covered |                          | Incl. in ACIEM 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)                     | 1,7031911       | 0,0872508    |  |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | 0,0383805       | 0,0014543    |  |
| % of RIVAS   | 405,52%         | 20,78%       |  |
| Acute  |                 |              |  |
| Total systemic exposure from mixing, loading and application (mg a.s./day)                     | 10,6879810      | 0,4609024    |  |
| Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day) | 0,1781330       | 0,0076820    |  |
| % of RIVAS   | 463161,10%      | 463161,10%   |  |

**Table 7.3-3: Short-term AOELs compared with exposure levels for operators following use of TOTO 75 SG (EFSA MODEL)**

| Active substance      | Short-term systemic AOEL mg/kg bw/day (source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl) | Predicted systemic exposure mg/kg bw/day (no PPE) | Predicted exposure as % of short-term systemic AOEL | Predicted systemic exposure mg/kg bw/day (Gloves during mix/loading and gloves during application) | Predicted exposure as % of short-term systemic AOEL |
|-----------------------|--|---|---|--|---|
| Thifensulfuron-methyl | 0.07   | 0.02834   | 405.53%   | 0.00145  | 20.78%  |
| Metsulfuron-methyl    | 0.25   | 0.00523   | 2.09%   | -  | 2.09%   |

**CONCLUSION:**

The values of predicted exposure for metsulfuron and thifensulfuron are below 100% of short-term systemic AOEL and therefore exposure of the operator is acceptable (worst case assessment = no PPE for metsulfuron methyl and worst case assessment- with PPE (gloves during mix/loading and gloves during application) for thifensulfuron methyl )

**Conclusions:**

According to Annex III, point 7, Risk Assessment is obtained by dividing operator exposure by AOEL. The results of the calculations using the three recognized models, the UK POEM, the German model and EFSA model show that values of predicted exposure for metsulfuron methyl and thifensulfuron methyl are below 100% for operator exposure, hence TOTO 75 poses no undue risk to the operator.

Exposure to **TOTO 75 SG** during mixing, loading, and spraying does not involve a significant risk to the health of operators assuming personal protective equipment is used (gloves during mix/loading and gloves during application).

|                   |   |
|-------------------|---|
| Comments of zRMS: | <p>The results of operator exposure estimation to thifensulfuron-methyl and metsulfuron-methyl contained in the product TOTO 75/ TYTAN 75/ HERKULES 75 presented by the applicant are not accepted. Acc. to <i>EFSA Journal 2017;15(6):4873</i>, the default values of dermal absorption for solid formulation amount to 10% and 50% for concentrate and dilution, respectively. Additionally, the AOEL value used for estimation of exposure to thifensulfuron-methyl is incorrect. The results of the calculations indicate that the value 0.007 mg/kg b.w. was used by the Applicant instead of 0.07 mg/kg b.w.</p> <p>The new calculation of operator exposure are presented below:<br/><u>Thifensulfuron-methyl:</u></p> |
|-------------------|---|

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

|  |   |   |  |                                 |   |
|--|---|---|--|---------------------------------|---|
| Substance  | Herkules  | Formulation = Wettable granules, soluble granules | Application rate-0,062 kg a.s. /ha                 | Spray dilution = 0,31 g a.s./l  | Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa |
| Scenario   | Cereals / Outdoor / Downward spraying / Vehicle-mounted |   |  | Buffer = 2-3                    | Number applications = 3, Application interval = 3 days                          |
| Percentage Absorption  | Dermal for product = 10                                 | Dermal for in use dilution = 50                   | Oral = 100   | Inhalation = 100                |   |
| RVNAS  | 0,07 mg/kg bw/day                                       |   | RVAAS  | mg/kg bw/day                    |   |
| DFR  | 3 µg a.s./cm2 per kg a.s./ha                            |   | DT50   | 30 days                         |   |
| Operator Model Mixing, loading and application AOEM  |   |   |  |                                 |   |
| Potential exposure   | Longer term systemic exposure mg/kg bw/day              |   | 0,0168   | % of RVNAS                      | 23,99%  |
|  | Acute systemic exposure mg/kg bw/day                    |   | 0,1224   | % of RVAAS                      |   |
| Mixing and Loading   | Gloves = Yes  |   | Clothing = Work wear - arms, body and legs covered | RPE = None                      | Soluble bags = No   |
| Application  | Gloves = Yes  |   | Clothing = Work wear - arms, body and legs covered | RPE = None                      | Closed cabin = Yes  |
| Exposure (including PPE options above)   | Longer term systemic exposure mg/kg bw/day              |   | 0,0019   | % of RVNAS                      | 2,70%   |
|  | Acute systemic exposure mg/kg bw/day                    |   | 0,0376   | % of RVAAS                      |   |
| Metsulfuron-methyl:  |   |   |  |                                 |   |
| Substance  | Herkules  | Formulation = Wettable granules, soluble granules | Application rate-0,0062 kg a.s. /ha                | Spray dilution = 0,031 g a.s./l | Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa |
| Scenario   | Cereals / Outdoor / Downward spraying / Vehicle-mounted |   |  | Buffer = 2-3                    | Number applications = 3, Application interval = 3 days                          |
| Percentage Absorption  | Dermal for product = 10                                 | Dermal for in use dilution = 50                   | Oral = 100   | Inhalation = 100                |   |
| RVNAS  | 0,25 mg/kg bw/day                                       |   | RVAAS  | mg/kg bw/day                    |   |
| DFR  | 3 µg a.s./cm2 per kg a.s./ha                            |   | DT50   | 30 days                         |   |
| Operator Model Mixing, loading and application AOEM  |   |   |  |                                 |   |
| Potential exposure   | Longer term systemic exposure mg/kg bw/day              |   | 0,0029   | % of RVNAS                      | 1,14%   |
|  | Acute systemic exposure mg/kg bw/day                    |   | 0,0368   | % of RVAAS                      |   |
| Mixing and Loading   | Gloves = Yes  |   | Clothing = Work wear - arms, body and legs covered | RPE = None                      | Soluble bags = No   |
| Application  | Gloves = Yes  |   | Clothing = Work wear - arms, body and legs covered | RPE = None                      | Closed cabin = Yes  |
| Exposure (including PPE options above)   | Longer term systemic exposure mg/kg bw/day              |   | 0,0007   | % of RVNAS                      | 0,27%   |
|  | Acute systemic exposure mg/kg bw/day                    |   | 0,0286   | % of RVAAS                      |   |
| Based on AOEM estimation and assuming the list of intended uses presented in GAP Table, the exposure of an <b>unprotected operator</b> to thifensulfuron-methyl and metsulfuron-methyl contained in the product TOTO 75/ TYTAN 75/ HERKULES 75 <b>causes no unacceptable health risk</b> because the calculated exposure to the active substances do not exceed AOEL values for the active substances. |   |   |  |                                 |   |
| Conclusions:   |   |   |  |                                 |   |

|  |  |
|--|--|
|  | <p>Taking into account the results of exposure estimation, the use of TOTO 75/ TYTAN 75/ HERKULES 75 causes acceptable exposure risk for an unprotected operator. However, bearing in minds the classification of the product (H319; <i>Causes serious eye irritation</i>) as well as the hygienic rules, it is necessary that the operator is equipped with the eyes/face protection and work wear during mixing and loading and application.</p> <p>Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the <b>section of precautions for the operators</b>:</p> <p>„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.”</p> <p>“Wear protective gloves, eye/face protection and work wear (coverall) during mixing and loading and application.”</p> |
|--|--|

### IIIA 7.3-2 Measurement of operator exposure (mixer/loader/applicator)

Since the risk assessment carried out indicated that the health-based limit value (AOEL) will not be exceeded under practical conditions of use, a study to provide a measure of operator

**III A 7.4 Bystander exposure**

|   |   |   |            |            |        |
|---|---|---|------------|------------|--------|
| Comments of zRMS:   | The results of bystander and resident exposure estimations to thifensulfuron-methyl and metsulfuron-methyl contained in the product TOTO 75/ TYTAN 75/ HERKULES 75 presented by the applicant are not accepted. Acc. to EFSA Journal 2017;15(6):4873, the default values of dermal absorption for solid formulation amount to 10% and 50% for concentrate and dilution, respectively. Additionally, the AOEL value used for the estimation of exposure to thifensulfuron-methyl is incorrect. The results of calculations indicate that the value 0.007 mg/kg b.w. was used by the Applicant instead of 0.07 mg/kg b.w. |   |            |            |        |
|   | The reference values acutely toxic active substance (RVAAS) for thifensulfuron-methyl and metsulfuron-methyl are not allocated. Consequently, it is assumed that the estimations of bystander exposure are covered by the calculations of resident exposure.  |   |            |            |        |
|   | The results of estimations are presented below:   |   |            |            |        |
|   | Thifensulfuron-methyl:  |   |            |            |        |
|   | Resident - child  | Spray drift (75th percentile) mg/kg bw/day              | 0,0042     | % of RVNAS | 5,95%  |
|   |   | Vapour (75th percentile) mg/kg bw/day                   | 0,0011     | % of RVNAS | 1,53%  |
|   |   | Surface deposits (75th percentile) mg/kg bw/day         | 0,0014     | % of RVNAS | 2,01%  |
|   |   | Entry into treated crops (75th percentile) mg/kg bw/day | 0,0147     | % of RVNAS | 20,95% |
|   |   | All pathways (mean) mg/kg bw/day                        | 0,0161     | % of RVNAS | 22,98% |
|   | Resident - adult  | Spray drift (75th percentile) mg/kg bw/day              | 0,0010     | % of RVNAS | 1,42%  |
| Vapour (75th percentile) mg/kg bw/day   |   | 0,0002  | % of RVNAS | 0,33%      |        |
| Surface deposits (75th percentile) mg/kg bw/day   |   | 0,0006  | % of RVNAS | 0,85%      |        |
| Entry into treated crops (75th percentile) mg/kg bw/day   |   | 0,0081  | % of RVNAS | 11,64%     |        |
| All pathways (mean) mg/kg bw/day  |   | 0,0076  | % of RVNAS | 10,90%     |        |
| Metsulfuron-methyl:   |   |   |            |            |        |
| Resident - child  | Spray drift (75th percentile) mg/kg bw/day  | 0,0002  | % of RVNAS | 0,08%      |        |
|   | Vapour (75th percentile) mg/kg bw/day   | 0,0011  | % of RVNAS | 0,43%      |        |
|   | Surface deposits (75th percentile) mg/kg bw/day   | 0,0000  | % of RVNAS | 0,01%      |        |
|   | Entry into treated crops (75th percentile) mg/kg bw/day   | 0,0005  | % of RVNAS | 0,21%      |        |
|   | All pathways (mean) mg/kg bw/day  | 0,0016  | % of RVNAS | 0,65%      |        |
| Resident - adult  | Spray drift (75th percentile) mg/kg bw/day  | 0,0000  | % of RVNAS | 0,02%      |        |
|   | Vapour (75th percentile) mg/kg bw/day   | 0,0002  | % of RVNAS | 0,09%      |        |
|   | Surface deposits (75th percentile) mg/kg bw/day   | 0,0000  | % of RVNAS | 0,00%      |        |
|   | Entry into treated crops (75th percentile) mg/kg bw/day   | 0,0003  | % of RVNAS | 0,12%      |        |
|   | All pathways (mean) mg/kg bw/day  | 0,0005  | % of RVNAS | 0,20%      |        |
| Summary and conclusions:  |   |   |            |            |        |
| The estimation performed according to AOEM indicates that the systemic exposure to thifensulfuron-methyl and metsulfuron-methyl contained in TOTO 75/ TYTAN 75/ HERKULES 75 does not exceed the value of AOEL for these active substances.          |   |   |            |            |        |
| The <b>incidental short-time exposure of bystander and resident (children and adult)</b> to TOTO 75/ TYTAN 75/ HERKULES 75 <b>causes no risk</b> to human health if the product is used in accordance to the intended uses listed in the GAP Table. |   |   |            |            |        |

**III A 7.4.1 Estimation of bystander exposure assuming personal protective equipment is not used**

**Reference** IIIA 7.4/01 Cross Reference to 7.3/01, xxxx, 2010, xxx, Bystander exposure assessment for TOTO 75, Dossier Documents K-III and L-III

Bystander exposure assessment for TOTO 75 was performed according to PSD Bystander Exposure Guidance [field crop (boom) sprayers – cereals] available at:

Based on a published UK study it is assumed that the average potential dermal exposure for a bystander, positioned 8 meters downwind from the sprayer and the average estimated amount of spray passing through the breathing zone are 0.1 and 0.006 ml spray/person, respectively. TOTO 75 SG is applied at max. dose of 0,09 kg/ha (equivalent to 61.38 g/ha of thifensulfuron and 6.12 g/ha of metsulfuron) in min. 200 liters water = 0.307 mg/ml for thifensulfuron and 0.036 mg/l for metsulfuron, respectively (no protection from clothing and 100% inhalation, retention and absorption of PIE is assumed).

The calculated systemic exposure for **thifensulfuron** is:

dermal                      inhalation

$$(0.1 \times 0.307 \times 17\%) + (0.006 \times 0.307 \times 100\%)/60 = 0.0001178 \text{ mg/kg bw/day}$$

The calculated systemic exposure for **metsulfuron** is:

dermal                      inhalation

$$(0.1 \times 0.036 \times 17\%) + (0.006 \times 0.036 \times 100\%)/60 = 0.0000138 \text{ mg/kg bw/day}$$

#### Short-term AOELs compared with exposure levels for bystander following use of TOTO 75

| Active substance      | Short-term systemic<br>AOEL<br>mg/kg bw/day<br><br>(source: Review reports<br>for the active substance<br>thifensulfuron-methyl<br>and metsulfuron-methyl) | Predicted systemic<br>exposure<br>mg/kg<br>bw/day | Predicted exposure as<br>% of short-term<br>systemic AOEL |
|-----------------------|--|---|---|
| Thifensulfuron-methyl | 0.07   | 0.0001178   | 0.17%   |
| Metsulfuron-methyl    | 0.7  | 0.0000138   | 0.002%  |
|                       |  | <b>TOTAL = 0.0001316</b>                          | <b>TOTAL = 0.172%</b>                                     |

#### CONCLUSION:

The sum of the fractions is  $\leq 1$  (or  $\leq 100\%$ ) and therefore exposure of the bystander is acceptable. The results of the calculations using the recognized PSD model, show exposure well below the AOEL value, hence TOTO 75 SG poses no undue risk to bystander.

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

## Reference IIIA 7.4/01 Cross Reference to 7.3/01, XXX\_EFSA\_TOTO 75 SG\_metsul

| Resident exposure for TOTO 75 SG  |   |                          |                                    |  |                     |
|---|---|--------------------------|------------------------------------|--|---------------------|
| Croptype  | Cereals   |                          |                                    |  |                     |
| Application method  | Downward spraying   |                          |                                    |  |                     |
| Application equipment   | Vehicle-mounted-Drift Reduction                               |                          |                                    |  |                     |
| Formulation type  | Wettable granules, soluble granules                           |                          |                                    |  |                     |
| Buffer strip  | 2-3 m   |                          |                                    |  |                     |
| Application rate of the product   | 0,0052 kg a.s./ha   |                          |                                    |  |                     |
| Concentration of active substance (in-use dilution for liquid applications) | 0,031 g a.s./l  |                          |                                    |  |                     |
| Dermal absorption of product  | 25,00%  |                          |                                    |  |                     |
| Dermal absorption of in-use dilution  | 75,00%  |                          |                                    |  |                     |
| Oral absorption   | 100,00%   |                          |                                    |  |                     |
| Dilodgeable foliar residue (L_AppRate*_GFR)                                 | 0,0186 µg a.s./cm <sup>2</sup>                                |                          |                                    |  |                     |
| Vapour pressure of in-use dilution  | low volatile substances having a vapour pressure of <5*10-3Pa |                          |                                    |  |                     |
| Concentration in air  | 0,001 mg/m <sup>3</sup>                                       |                          |                                    |  |                     |
| Resident dermal spray drift exposure 75th percentile - adult                | 0,47 ml spray dilution/person                                 |                          |                                    |  |                     |
| Resident dermal spray drift exposure 75th percentile - child                | 0,327 ml spray dilution/person                                |                          |                                    |  |                     |
| Resident inhal. spray drift exposure 75th percentile - adult                | 0,00010 ml spray dilution/person                              |                          |                                    |  |                     |
| Resident inhal. spray drift exposure 75th percentile - child                | 0,00022 ml spray dilution/person                              |                          |                                    |  |                     |
| Resident dermal spray drift exposure mean - adult                           | 0,22318 ml spray dilution/person                              |                          |                                    |  |                     |
| Resident dermal spray drift exposure mean - child                           | 0,18 ml spray dilution/person                                 |                          |                                    |  |                     |
| Resident inhal. spray drift exposure mean - adult                           | 0,00009 ml spray dilution/person                              |                          |                                    |  |                     |
| Resident inhal. spray drift exposure mean - child                           | 0,00017 ml spray dilution/person                              |                          |                                    |  |                     |
| Exposure duration dermal  | 2 hours   |                          |                                    |  |                     |
| Exposure duration inhalation  | 24 hours  |                          |                                    |  |                     |
| Exposure duration entry into treated crops                                  | 0,25 hours  |                          |                                    |  |                     |
| Light clothing adjustment factor  | 18,0%   |                          |                                    |  |                     |
| Breathing rate adult  | 0,23 m <sup>3</sup> /day/kg                                   |                          |                                    |  |                     |
| Breathing rate child (1-3 year old)   | 1,07 m <sup>3</sup> /day/kg                                   |                          |                                    |  |                     |
| Drift percentage on surface (75th percentile)                               | 5,60%   |                          |                                    |  |                     |
| Drift percentage on surface (mean)  | 4,10%   |                          |                                    |  |                     |
| Turf transferable residues percentage                                       | 5,00%   |                          |                                    |  |                     |
| Transfer coeff. of surface deposits-adult                                   | 7300 cm <sup>2</sup> /hour                                    |                          |                                    |  |                     |
| Transfer coeff. of surface deposits-child (1-3 year old)                    | 2500 cm <sup>2</sup> /hour                                    |                          |                                    |  |                     |
| Saliva extraction percentage  | 50,00%  |                          |                                    |  |                     |
| Surface area of hands mouthed   | 30 cm <sup>2</sup>  |                          |                                    |  |                     |
| Frequency of hand to mouth activity   | 9,5 events/hour   |                          |                                    |  |                     |
| Ingestion rate for mouthing of grass per day                                | 25 cm <sup>3</sup>  |                          |                                    |  |                     |
| Dilodgeable residues percentage transferability for object to mouth         | 20,00%  |                          |                                    |  |                     |
| Transfer coefficient for entry into treated crops (75th percentile) - adult | 7500 cm <sup>2</sup> /h                                       |                          |                                    |  |                     |
| Transfer coefficient for entry into treated crops (75th percentile) - child | 2250 cm <sup>2</sup> /h                                       |                          |                                    |  |                     |
| Transfer coefficient for entry into treated crops (mean) - adult            | 5980 cm <sup>2</sup> /h                                       |                          |                                    |  |                     |
| Transfer coefficient for entry into treated crops (mean) - child            | 1794 cm <sup>2</sup> /h                                       |                          |                                    |  |                     |
|   |   |                          |                                    |  |                     |
| I. Total  |   |                          |                                    |  |                     |
| I.1 1-3 year old child  |   |                          |                                    |  |                     |
|   | Spray drift (75th percentile)                                 | Vapour (75th percentile) | Surface deposits (75th percentile) | Entry into treated crops (75th percentile) | All pathways (mean) |
| Total systemic exposure (mg a.s./day)                                       | 0,0031205   | 0,0107000                | 0,0003637                          | 0,0079469                                  | 0,0189413           |
| Total systemic exposure per kg body weight (mg/kg)                          | 0,0003121   | 0,0010700                | 0,0000364                          | 0,0007947                                  | 0,0018941           |
| % of RIVAS  | 0,12%   | 0,42%                    | 0,01%                              | 0,31%                                      | 0,16%               |
| I.2 Adult   |   |                          |                                    |  |                     |
|   | Spray drift   | Vapour                   | Surface deposits                   | Entry into treated crops                   | All pathways (mean) |
| Total systemic exposure (mg a.s./day)                                       | 0,0044818   | 0,0138000                | 0,0009205                          | 0,0261563                                  | 0,0374800           |
| Total systemic exposure per kg body weight (mg/kg)                          | 0,0000747   | 0,0002300                | 0,0000158                          | 0,0004329                                  | 0,000247            |
| % of RIVAS  | 0,03%   | 0,09%                    | 0,01%                              | 0,17%                                      | 0,25%               |

## Reference IIIA 7.4/02 Cross Reference to 7.3/01, XXX\_EFSA\_TOTO 75 SG\_thifen

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

| Resident exposure for TOTO 75 SG  |  |                          |                                    |  |
|---|--|--------------------------|------------------------------------|--|
| Crop type   | Cereals  |                          |                                    |  |
| Application method  | Downward spraying  |                          |                                    |  |
| Application equipment   | Vehicle-mounted Drift Reduction  |                          |                                    |  |
| Formulation type  | Wettable granules, soluble granules  |                          |                                    |  |
| Buffer strip  | 2-3 m  |                          |                                    |  |
| Application rate of the product   | 0,002 kg a.s./ha   |                          |                                    |  |
| Concentration of active substance (in-use dilution for liquid applications) | 0,31 g a.s./l  |                          |                                    |  |
| Dermal absorption of product  | 25,00%   |                          |                                    |  |
| Dermal absorption of in-use dilution  | 75,00%   |                          |                                    |  |
| Oral absorption   | 100,00%  |                          |                                    |  |
| Dilutable foliar residue (L_AppRate*_DFR)                                   | 0,180 µg a.s./cm <sup>2</sup>  |                          |                                    |  |
| Vapour pressure of in-use dilution  | low volatile substances having a vapour pressure of <5*10 <sup>-3</sup> Pa |                          |                                    |  |
| Concentration in air  | 0,001 mg/m <sup>3</sup>  |                          |                                    |  |
| Resident dermal spray drift exposure 75th percentile - adult                | 0,47 ml spray dilution/person  |                          |                                    |  |
| Resident dermal spray drift exposure 75th percentile - child                | 0,327 ml spray dilution/person   |                          |                                    |  |
| Resident inhal. spray drift exposure 75th percentile - adult                | 0,00010 ml spray dilution/person   |                          |                                    |  |
| Resident inhal. spray drift exposure 75th percentile - child                | 0,00022 ml spray dilution/person   |                          |                                    |  |
| Resident dermal spray drift exposure mean - adult                           | 0,22318 ml spray dilution/person   |                          |                                    |  |
| Resident dermal spray drift exposure mean - child                           | 0,18 ml spray dilution/person  |                          |                                    |  |
| Resident inhal. spray drift exposure mean - adult                           | 0,00009 ml spray dilution/person   |                          |                                    |  |
| Resident inhal. spray drift exposure mean - child                           | 0,00017 ml spray dilution/person   |                          |                                    |  |
| Exposure duration dermal  | 2 hours  |                          |                                    |  |
| Exposure duration inhalation  | 24 hours   |                          |                                    |  |
| Exposure duration entry into treated crops                                  | 0,25 hours   |                          |                                    |  |
| Light clothing adjustment factor  | 18,0%  |                          |                                    |  |
| Breathing rate adult  | 0,23 m <sup>3</sup> /day/kg  |                          |                                    |  |
| Breathing rate child (1-3 year old)   | 1,07 m <sup>3</sup> /day/kg  |                          |                                    |  |
| Drift percentage on surface (75th percentile)                               | 5,60%  |                          |                                    |  |
| Drift percentage on surface (mean)  | 4,10%  |                          |                                    |  |
| Turf transferable residues percentage                                       | 5,00%  |                          |                                    |  |
| Transfer coeff. of surface deposits-adult                                   | 7300 cm <sup>2</sup> /hour   |                          |                                    |  |
| Transfer coeff. of surface deposits-child (1-3 year old)                    | 2500 cm <sup>2</sup> /hour   |                          |                                    |  |
| Saliva extraction percentage  | 50,00%   |                          |                                    |  |
| Surface area of hands mouthed   | 20 cm <sup>2</sup>   |                          |                                    |  |
| Frequency of hand to mouth activity   | 8,5 events/hour  |                          |                                    |  |
| Ingestion rate for mouthing of grass per day                                | 25 cm <sup>3</sup>   |                          |                                    |  |
| Dilutable residues percentage transferability for object to mouth           | 20,00%   |                          |                                    |  |
| Transfer coefficient for entry into treated crops (75th percentile) - adult | 7500 cm <sup>2</sup> /h  |                          |                                    |  |
| Transfer coefficient for entry into treated crops (75th percentile) - child | 2250 cm <sup>2</sup> /h  |                          |                                    |  |
| Transfer coefficient for entry into treated crops (mean) - adult            | 5980 cm <sup>2</sup> /h  |                          |                                    |  |
| Transfer coefficient for entry into treated crops (mean) - child            | 1794 cm <sup>2</sup> /h  |                          |                                    |  |
| <b>1. Total</b>   |  |                          |                                    |  |
| <b>1.1 1-3 year old child</b>   |  |                          |                                    |  |
|   | Spray drift (75th percentile)  | Vapour (75th percentile) | Surface deposits (75th percentile) | Entry into treated crops (75th percentile) |
| Total systemic exposure (mg a.s./day)                                       | 0,0312054  | 0,0107000                | 0,0036369                          | 0,0784688                                  |
| Total systemic exposure per kg body weight (mg/kg)                          | 0,0031205  | 0,0010700                | 0,0003637                          | 0,0078469                                  |
| % of RIVAS  | 44,58%   | 15,29%                   | 5,20%                              | 112,10%                                    |
| <b>1.2 Adult</b>  |  |                          |                                    |  |
|   | Spray drift  | Vapour                   | Surface deposits                   | Entry into treated crops                   |
| Total systemic exposure (mg a.s./day)                                       | 0,0448183  | 0,0138000                | 0,0095046                          | 0,2615625                                  |
| Total systemic exposure per kg body weight (mg/kg)                          | 0,0007470  | 0,0002300                | 0,0001584                          | 0,0043594                                  |
| % of RIVAS  | 10,67%   | 3,29%                    | 2,26%                              | 62,28%                                     |

**Short-term AOELs compared with exposure levels for bystander and resident following use of TOTO 75 (EFSA model)**

| Active substance      | Short-term systemic AOEL mg/kg bw/day<br><br>(source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl) | Predicted systemic exposure mg/kg bw/day | Predicted systemic exposure mg/kg bw/day<br><br>(work wear-arms, body and legs covered) | Predicted exposure as % of short-term systemic AOEL<br><br>(worst case- 1-3 year old child) |
|-----------------------|---|--|---|---|
| Thifensulfuron-methyl | 0.07  | 0.09311                                  |   | 133,02%   |



|                    |      |           |   |       |
|--------------------|------|-----------|---|-------|
| Metsulfuron-methyl | 0.25 | 0.0189413 | - | 0.76% |
|--------------------|------|-----------|---|-------|

#### CONCLUSION:

The values of predicted exposure for metsulfuron and thifensulfuron are above 100% of short-term systemic AOEL when default values of 25% for dermal absorption of product and 75% for dermal absorption of in-use dilution were used for calculations.

Based on EFSA Journal 2017;15(6):4873:

*A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed or solid-formulated. A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/ dispersed or solid-formulated.*

When default values of 10% for dermal absorption of product and 50% for dermal absorption of in-use dilution were used for calculations, the values of predicted exposure for thifensulfuron and metsulfuron are below 100% of short-term systemic AOEL and therefore exposure of the bystander and resident is acceptable.

Short-term AOELs compared with exposure levels for bystander following use of TOTO 75 (EFSA model, default values of 10% for dermal absorption of product and 50% for dermal absorption of in-use dilution).

| Active substance      | Short-term systemic AOEL<br>mg/kg bw/day<br><br>(source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl) | Predicted systemic exposure<br>mg/kg bw/day | Predicted exposure as % of short-term systemic AOEL<br><br>(worst case- 1-3 year old child) |
|-----------------------|--|---|---|
| Thifensulfuron-methyl | 0.07   | 0.0657                                      | 93.87%  |
| Metsulfuron-methyl    | 0.25   | 0.0162                                      | 0.65%   |

The results of the calculations using the recognized EFSA model, show exposure well below the AOEL value, hence TOTO 75 SG poses no undue risk to bystander and resident.

#### IIIA 7.4.2 Measurement of bystander exposure

Since the risk assessment carried out indicated that application of TOTO 75 does not pose any risk to bystanders, a study to provide a measure of bystander exposure to TOTO 75 under field conditions was not necessary and therefore was not carried out.

### III A 7.5 Worker exposure

|  |  |                        |                    |
|--|--|------------------------|--------------------|
| Comments of zRMS:  | <p>The results of worker exposure estimations to thifensulfuron-methyl and metsulfuron-methyl contained in the product TOTO 75/ TYTAN 75/ HERKULES 75 presented by the applicant are not accepted. Acc. to EFSA Journal 2017;15(6):4873, the default values of dermal absorption for solid formulation amount to 10% and 50% for concentrate and dilution, respectively. Additionally, the AOEL value used for estimation of exposure to thifensulfuron-methyl is incorrect. The results of calculations indicate that the value 0.007 mg/kg b.w. was used by the Applicant instead of 0.07 mg/kg b.w.</p> <p>According to current requirements of Polish Authorities, if a PPP is anticipated to be used only once per season, EUROPOEM II should be used to estimate worker exposure towards active substance(s) of a formulation. Therefore, the exposure data has been re-calculated based on EUROPOEM II and the results are presented below:</p> |                        |                    |
|  |  | Exposure (mg a.s./day) | % of systemic AOEL |
| Cereals (TC: 0.14 m <sup>2</sup> /h)<br>Work duration: 2 h (inspection)  |  |                        |                    |
| Work wear  | 0.0043   |                        | <b>6</b>           |
| Work wear and protective gloves  | 0.0009   |                        | <b>1</b>           |
| <u>Conclusion:</u>   |  |                        |                    |
| <p>The results of the exposure estimations indicate that the use of TOTO 75/ TYTAN 75/ HERKULES 75 containing thifensulfuron-methyl and metsulfuron-methyl according to the list of intended uses presented in GAP Table, causes <b>no health risk for the worker assuming the work wear</b> (arms, body and legs covered) is used because the calculated exposure level to thifensulfuron-methyl and metsulfuron-methyl is lower than the AOEL value for these active substances.</p> <p>Nevertheless, it is forbidden to re-enter area treated with TOTO 75/ TYTAN 75/ HERKULES 75 until spray deposit on plant surfaces has dried.</p> <p>Bearing in minds the hygienic rules the use of protective gloves and work wear is recommended when entering the treated area.</p> |  |                        |                    |

TOTO 75 SG is normally used at times, when it is not necessary to enter crops shortly after spraying. It is therefore not necessary to determine a particular re-entry time for workers. In cases where re-entry is not avoidable, personal protective equipment similar to those of the operator (gloves and standard protective garment) is regarded to provide sufficient protection.

**Reference** IIIA 7.5/01, Xxx\_worker model germam\_TOTO 75 SG\_metsulfuron

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

| Estimation of post-application exposure of workers (re-entry exposure) |                                       |                                   |    |
|--|---------------------------------------|-----------------------------------|----|
| Active substance (a.s.)  | Metsulfuron methyl                    |                                   |    |
| Product  | TOTO 75 SG/HERKULES 75 SG/TYTAN 75 SG |                                   |    |
| Intended use(s)  | e.g. cereals                          |                                   |    |
| Application rate (AR)  | 0.0062                                | kg a.s./ha                        |    |
| Number of applications (NA)  | 1                                     |                                   | 1) |
| Dislodgeable foliar residues (DFR)                                     | 1                                     | µg/cm <sup>2</sup> /kg a.s.       | 2) |
| Transfer coefficient (TC)  | 1500                                  | cm <sup>2</sup> /person/h         | 3) |
| Work rate per day (WR)   | 8                                     | h/d                               | 4) |
| Penetration through clothing (P)                                       | 0.05                                  | (5 %)                             | 5) |
| Systemic AOEL  | 0.25                                  | mg/kg bw/d                        |    |
| Dermal absorption DA)  | 75                                    | % (worst case, e.g. for dilution) |    |
| Body weight (BW)   | 60                                    | kg                                |    |

1) consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)

2) default of 1 µg a.s./cm<sup>2</sup> per kg a.s./ha acc. to Krebs et al. (2000)

3) TC 30000 cm<sup>2</sup>/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000), acc. EUROPEM II (2002): 2500 (vegetables), 3000 (strawberries), 4500 (fruits from trees), 5000 (ornamentals) acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes)

4) 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area

5) 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area

## Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

|                              |              |                                     |                            |                             |                           |
|------------------------------|--------------|-------------------------------------|----------------------------|-----------------------------|---------------------------|
| Intended use(s):             | e.g. cereals | Dislodgeable foliar residues (DFR): | 1                          | µg/cm <sup>2</sup> /kg a.s. |                           |
| Application rate (AR):       | 0.0062       | kg a.s./ha                          | Transfer coefficient (TC): | 1500                        | cm <sup>2</sup> /person/h |
| Number of applications (NA): | 1            |                                     | Work rate per day (WR):    | 8                           | h/d                       |
| Body weight (BW):            | 60           | kg/person                           | PPE                        | 5                           | %                         |
| Dermal absorption (DA):      | 75           | % ('worst case')                    |                            |                             |                           |
| AOEL                         | 0.25         | mg/kg bw/d                          |                            |                             |                           |

| Worker exposure towards Metsulfuron methyl                                    |       |            |  |       |            |
|---|-------|------------|--|-------|------------|
| Without PPE <sup>1)</sup>   |       |            | With PPE <sup>2)</sup>   |       |            |
| Worker (re-entry): Systemic dermal exposure after application in e.g. cereals |       |            |  |       |            |
| $SDE_w = (DFR \times TC \times WR \times AR \times NA \times DA) / BW$        |       |            | $SDE_w = (DFR \times TC \times WR \times AR \times NA \times PPE \times DA) /$ |       |            |
| $(1 \times 1500 \times 8 \times 0.0062 \times 1 \times 75\%) / 60$            |       |            | $(1 \times 1500 \times 8 \times 0.0062 \times 1 \times 5\% \times 75\%) / 60$  |       |            |
| External dermal exposure  | 0.07  | mg/person  | External dermal exposure   | 0.00  | mg/person  |
| External dermal exposure  | 0.00  | mg/kg bw/d | External dermal exposure   | 0.00  | mg/kg bw/d |
| Total systemic exposure   | 0.06  | mg/person  | Total systemic exposure  | 0.00  | mg/person  |
| Total systemic exposure   | ##### | mg/kg bw/d | Total systemic exposure  | ##### | mg/kg bw/d |
| % of AOEL   | 0.4   | %          | % of AOEL  | 0.0   | %          |

<sup>1)</sup> acceptable without PPE: allocation of BVL code SF245-01 for spray applications<sup>2)</sup> acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al., 2000)

The results of the calculations using the recognized Worker German Model, show exposure well below the AOEL value for metsulfuron methyl poses no undue risk to worker.

Reference IIIA 7.5/02, Xxx\_worker model germam\_TOTO 75 SG\_thifen

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

| Estimation of post-application exposure of workers (re-entry exposure)   |                                       |                                   |               |
|--|---------------------------------------|-----------------------------------|---------------|
| Active substance (a.s.)  | Thifensulfuron methyl                 |                                   |               |
| Product  | TOTO 75 SG/HERKULES 75 SG/TYTAN 75 SG |                                   |               |
| Intended use(s)  | e.g. cereals                          |                                   |               |
| Application rate (AR)  | 0.062                                 | kg a.s./ha                        |               |
| Number of applications (NA)  | 1                                     |                                   | <sup>1)</sup> |
| Dislodgeable foliar residues (DFR)   | 1                                     | µg/cm <sup>2</sup> /kg a.s.       | <sup>2)</sup> |
| Transfer coefficient (TC)  | 1500                                  | cm <sup>2</sup> /person/h         | <sup>3)</sup> |
| Work rate per day (WR)   | 8                                     | h/d                               | <sup>4)</sup> |
| Penetration through clothing (P)   | 0.05                                  | (5 %)                             | <sup>5)</sup> |
| Systemic AOEL  | 0.07                                  | mg/kg bw/d                        |               |
| Dermal absorption DA)  | 75                                    | % (worst case, e.g. for dilution) |               |
| Body weight (BW)   | 60                                    | kg                                |               |
| <sup>1)</sup> consideration of more than two applications will not be necessary if degradation on foliage of at least 50 % can be assumed between 2 applications (otherwise use multiple application factor)   |                                       |                                   |               |
| <sup>2)</sup> default of 1 µg a.s./cm <sup>2</sup> per kg a.s./ha acc. to Krebs et al. (2000)  |                                       |                                   |               |
| <sup>3)</sup> TC 30000 cm <sup>2</sup> /person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000), acc. EUROPOEM II (2002): 2500 (vegetables), 3000 (strawberries), 4500 (fruits from trees), 5000 (ornamentals) acc. US EPA Policy # 3.1 (2000): 1500 (cereals, e.g. crop inspection), 10000 (grapes) |                                       |                                   |               |
| <sup>4)</sup> 8 h/day for professional applications if re-entry tasks are intended, 2 h/day for professional applications if re-entry tasks are not intended (e.g. irrigation, maintenance) or for applications in the home and allotment garden area  |                                       |                                   |               |
| <sup>5)</sup> 5 % of dermal exposure corresponding to protective clothing incl. gloves for professionals, 50 % reduction of dermal exposure corresponding to long sleeved shirt, long trousers and gloves for applications in the home and allotment garden area   |                                       |                                   |               |

## Estimation of worker (re-entry) exposure

Input parameters considered for the estimation of worker exposure:

|                             |              |                                     |                            |                             |
|-----------------------------|--------------|-------------------------------------|----------------------------|-----------------------------|
| Intended use(s):            | e.g. cereals | Dislodgeable foliar residues (DFR): | 1                          | µg/cm <sup>2</sup> /kg a.s. |
| Application rate (AR):      | 0.062        | kg a.s./ha                          | Transfer coefficient (TC): | 1500                        |
| Number of applications (NA) | 1            |                                     | Work rate per day (WR):    | 8                           |
| Body weight (BW):           | 60           | kg/person                           | PPE                        | 5 %                         |
| Dermal absorption (DA):     | 75           | % (worst case)                      |                            |                             |
| AOEL                        | 0.07         | mg/kg bw/d                          |                            |                             |

| Worker exposure towards Thifensulfuron methyl                                 |       |   |                          |       |
|---|-------|---|--------------------------|-------|
| Without PPE <sup>1)</sup>   |       | With PPE <sup>2)</sup>                                      |                          |       |
| Worker (re-entry): Systemic dermal exposure after application in e.g. cereals |       |   |                          |       |
| SDE <sub>sys</sub> = (DFR x TC x WR x AR x NA x DA) / BW                      |       | SDE <sub>sys</sub> = (DFR x TC x WR x AR x NA x PPE x DA) / |                          |       |
| (1 x 1500 x 8 x 0.062 x 1 x 75%)  |       | (1 x 1500 x 8 x 0.062 x 1 x 5% x 75%) / 60                  |                          |       |
| External dermal exposure  | 0.74  | mg/person   | External dermal exposure | 0.04  |
| External dermal exposure  | 0.01  | mg/kg bw/d  | External dermal exposure | 0.00  |
| Total systemic exposure   | 0.56  | mg/person   | Total systemic exposure  | 0.03  |
| Total systemic exposure   | ##### | mg/kg bw/d  | Total systemic exposure  | ##### |
| % of AOEL   | 13.3  | %   | % of AOEL                | 0.7   |

<sup>1)</sup> acceptable without PPE: allocation of BVL code SF245-01 for spray applications<sup>2)</sup> acceptable only with PPE: allocation of BVL code SF1891 and SF190 for professional and home and allotment garden applications, respectively (cf. Krebs et al. 2000)

The results of the calculations using the recognized Worker German Model, show exposure well below the AOEL value for thifensulfuron methyl poses no undue risk to worker.

Reference IIIA 7.4/03 Cross Reference to 7.3/01, Xxx\_EFSA\_TOTO 75 SG\_metsul

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

| Worker exposure from residues on foliage for TOTO 75 SG            |                                     |   |   |                           |
|--|-------------------------------------|---|---|---------------------------|
| Crop type  | Cereals                             |   |   |                           |
| Indoor or outdoor  | Outdoor                             |   |   |                           |
| Application method   | Downward spraying                   |   |   |                           |
| Application equipment  | Vehicle-mounted-Drift Reduction     |   |   |                           |
| Worker's task  | Inspection, Irrigation              |   |   |                           |
| Main body parts in contact with foliage                            | Hand and body                       |   |   |                           |
| Application rate of active substance                               | 0,0062                              | kg a.s./ha                              |   | I_AppRate                 |
| Number of applications   | 1                                   |   |   | I_AppNo                   |
| Interval between multiple applications                             | 365                                 | days                                    |   | I_AppInt                  |
| Half-life of active substance                                      | 30                                  | days                                    |   | d_HalfLifeAS              |
| Multiple application factor  | 1,0                                 |   |   | d_MAF                     |
| Dermal absorption of the product                                   | 25,00%                              |   |   | I_AbsorpProduct           |
| Dermal absorption of the in-use dilution                           | 75,00%                              |   |   | I_AbsorpInuse             |
| Dislodgeable foliar residue (I_AppRate*I_DFR)                      | 0,0186                              | µg a.s./cm <sup>2</sup>                 |   | d_DFR                     |
| Working hours  | 2                                   | hr                                      |   | d_WorkHr                  |
| Dermal transfer coefficient - Total potential exposure             | 12500                               | cm <sup>2</sup> /hr                     |   | d_DermTcUCV               |
| Dermal transfer coefficient - arms, body and legs covered          | 1400                                | cm <sup>2</sup> /hr                     |   | d_DermTcCV1               |
| Dermal transfer coefficient - hands, arms, body and legs covered   | no TC available for this assessment |   | cm <sup>2</sup> /hr                                 | d_DermTcCV2               |
| Inhalation transfer coefficient for automated applications         | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |   | d_InhalTcAut              |
| Inhalation transfer coefficient for cutting ornamentals            | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |   | d_InhalTcCut              |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |   | d_InhalTcSort             |
| 1. Total   |                                     |   |   |                           |
|  | Potential exposure                  | Work wear - arms, body and legs covered | Working wear and gloves                             | Comments                  |
| Total systemic exposure (mg a.s./day)                              | 0,3487500                           | 0,0390600                               | no TC available for this assessment                 |                           |
| Total systemic exposure per kg body weight (mg/kg bw/day)          | 0,0058125                           | 0,0006510                               |   |                           |
| % of RVNAS   | 2,33%                               | 0,26%                                   |   |                           |
| 2. Details   |                                     |   |   |                           |
|  | Systemic exposure                   |   | Formula   | Comments                  |
|  | [mg a.s./day]                       | [mg a.s./kg bw/day]                     |   |                           |
| Dermal - Potential   | 0,3487500                           | 0,0058125                               | d_DermTcUCV*d_WorkHr*I_DFR*I_MAF/1000*I_AbsorpInuse |                           |
| Dermal - Work wear - arms, body and legs covered                   | 0,0390600                           | 0,0006510                               | d_DermTcCV1*d_WorkHr*I_DFR*I_MAF/1000*I_AbsorpInuse |                           |
| Dermal - Working wear and gloves                                   | no TC available for this assessment |   | d_DermTcCV2*d_WorkHr*I_DFR*I_MAF/1000*I_AbsorpInuse |                           |
| Inhalation   |                                     |   |   | Na for outdoor activities |
|  |                                     |   |   |                           |

Reference IIIA 7.4/04 Cross Reference to 7.3/01, Xxx\_EFSA\_TOTO 75 SG\_thifen

TOTO / TYTAN / HERKULES CONTAINING  
THIFENSULFURON-METHYL AND METSULFURON-  
METHYL

| Worker exposure from residues on foliage for TOTO 75 SG            |                                     |   |  |                           |
|--|-------------------------------------|---|--|---------------------------|
| Crop type  | Cereals                             |   |  |                           |
| Indoor or outdoor  | Outdoor                             |   |  |                           |
| Application method   | Downward spraying                   |   |  |                           |
| Application equipment  | Vehicle-mounted-Drift Reduction     |   |  |                           |
| Worker's task  | Inspection, irrigation              |   |  |                           |
| Main body parts in contact with foliage                            | Hand and body                       |   |  |                           |
| Application rate of active substance                               | 0,062                               | kg a.s./ha                              |  | <i>i_AppRate</i>          |
| Number of applications   | 1                                   |   |  | <i>i_AppNo</i>            |
| Interval between multiple applications                             | 365                                 | days                                    |  | <i>i_AppInt</i>           |
| Half-life of active substance                                      | 30                                  | days                                    |  | <i>d_HalfLifeAS</i>       |
| Multiple application factor  | 1,0                                 |   |  | <i>d_MAF</i>              |
| Dermal absorption of the product                                   | 25,00%                              |   |  | <i>i_AbsorpProduct</i>    |
| Dermal absorption of the in-use dilution                           | 75,00%                              |   |  | <i>i_AbsorpInuse</i>      |
| Dislodgeable foliar residue ( <i>i_AppRate</i> * <i>i_DFR</i> )    | 0,186                               | µg a.s./cm <sup>2</sup>                 |  | <i>d_DFR</i>              |
| Working hours  | 2                                   | hr                                      |  | <i>d_WorkHr</i>           |
| Dermal transfer coefficient - Total potential exposure             | 12500                               | cm <sup>2</sup> /hr                     |  | <i>d_DermTcUCV</i>        |
| Dermal transfer coefficient - arms, body and legs covered          | 1400                                | cm <sup>2</sup> /hr                     |  | <i>d_DermTcCV1</i>        |
| Dermal transfer coefficient - hands, arms, body and legs covered   | no TC available for this assessment |   |  |                           |
| Inhalation transfer coefficient for automated applications         | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |  | <i>d_InhalTcAut</i>       |
| Inhalation transfer coefficient for cutting ornamentals            | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |  | <i>d_InhalTcCut</i>       |
| Inhalation transfer coefficient for sorting / bundling ornamentals | NA                                  | ha/hr*10 <sup>4</sup> (-3)              |  | <i>d_InhalTcSort</i>      |
| <b>1. Total</b>  |                                     |   |  |                           |
|  | Potential exposure                  | Work wear - arms, body and legs covered | Working wear and gloves  | Comments                  |
| Total systemic exposure (mg a.s./day)                              | 3,4875000                           | 0,3906000                               | no TC available for this assessment                                  |                           |
| Total systemic exposure per kg body weight (mg/kg bw/day)          | 0,0581250                           | 0,0065100                               |  |                           |
| % of RIVNAS  | 830,36%                             | 93,00%                                  |  |                           |
| <b>2. Details</b>  |                                     |   |  |                           |
|  | Systemic exposure [mg a.s./day]     |   | Formula  | Comments                  |
| Dermal - Potential   | 3,4875000                           | 0,0581250                               | $d\_DermTcUCV * d\_WorkHr * i\_DFR * i\_MAF / 1000 * i\_AbsorpInuse$ |                           |
| Dermal - Work wear - arms, body and legs covered                   | 0,3906000                           | 0,0065100                               | $d\_DermTcCV1 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_AbsorpInuse$ |                           |
| Dermal - Working wear and gloves                                   | no TC available for this assessment |   | $d\_DermTcCV2 * d\_WorkHr * d\_DFR * d\_MAF / 1000 * i\_AbsorpInuse$ |                           |
| Inhalation   |                                     |   |  | Na for outdoor activities |

**Short-term AOELs compared with exposure levels for worker following use of TOTO 75 (EFSA model)**

| Active substance      | Short-term systemic AOEL<br>mg/kg bw/day<br><br>(source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl) | Predicted systemic exposure<br>mg/kg bw/day | Predicted systemic exposure<br>mg/kg bw/day<br><br>(work wear-arms, body and legs covered) | Predicted exposure as % of short-term systemic AOEL |
|-----------------------|--|---|--|---|
| Thifensulfuron-methyl | 0.07   | 0.058125                                    | 0.0581   | 93%   |
| Metsulfuron-methyl    | 0.25   | 0.00581                                     | -  | 2.33%   |

**CONCLUSION:**

The values of predicted exposure for metsulfuron and thifensulfuron are below 100% of short-term systemic AOEL and therefore exposure of the worker is acceptable (worst case assessment = no PPE for metsulfuron methyl and PPE- (work wear-arms, body and legs covered ) thifensulfuron methyl). The results of the calculations using the recognized EFSA model, show exposure well below the AOEL value, hence TOTO 75 SG poses no undue risk to worker.

## OECD IIIA 7.6 Dermal absorption

For the dermal absorption of the active substances, thifensulfuron-methyl and metsulfuron methyl from the product the notifier refers to the EU agreed data stating the value of 10%

Dermal absorption to the representative formulations was 25% for the concentrate and 75% for the in-use field dilutions based on default values. Estimated operator, worker, bystander and residential exposures were below the AOEL even when the use of personal protective equipment (PPE) is not considered for operators and workers.

## IIIA 7.7 Dislodgeable Residues

### IIIA 7.7.1 Dislodgeable Residues - foliar

This is not an EC data requirement/ not required by Directive 91/414/EEC.

### IIIA 7.7.2 Dislodgeable Residues - soil

This is not an EC data requirement/ not required by Directive 91/414/EEC.

### IIIA 7.7.3 Dislodgeable Residues - indoor surface re-volatilization

This is not an EC data requirement/ not required by Directive 91/414/EEC.

## IIIA 7.8 Epidemiology

This is not an EC data requirement/ not required by Directive 91/414/EEC.

## IIIA 7.9 Data on Formulants

CONFIDENTIAL information - data provided separately (Part C).

### IIIA 7.9.1 Material safety data sheets for each formulant

CONFIDENTIAL information - data provided separately (Part C).

### IIIA 7.9.2 Available toxicological data for each formulant

CONFIDENTIAL information - data provided separately (Part C).

## IIIA 7.10 Domestic Animal/Livestock Safety

This is not an EC data requirement/ not required by Directive 91/414/EEC.

## IIIA 7.11 Other/Special Studies

Relevant metabolites in groundwater – please see to Section 8.

## Appendix 1: List of data submitted in support of the evaluation

|                                 |      |      |   |            |
|---------------------------------|------|------|---|------------|
| <b>Annex IIIA.<br/>7.1.1/01</b> | xxx, | 2008 | Xxx, xxx, xxx, (2008) Study Code OS-11/08 Part<br>I: TOTO 75 - acute oral toxicity<br>study on rats<br><br>Report to GLP<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA 10.3.1.1 | Chemisorol |
| <b>Annex IIIA.<br/>7.1.2/01</b> | xxx  | 2008 | Xxx, xxx, xxx, (2008) Study Code OS-11/08 Part<br>II: TOTO 75 - acute dermal<br>toxicity study on rats<br><br>Report to GLP<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III                    | Chemisorol |
| <b>Annex IIIA<br/>7.1.4/01</b>  | xxx  | 2008 | Xxx, xxx, xxx, (2008) Study Code OS-11/08 Part<br>III: TOTO 75 - acute skin<br>irritation/skin corrosion study on<br>rabbits<br><br>Report to GLP<br>Unpublished report<br><br>Dossier Documents K-III and L-III  | Chemisorol |
| <b>Annex IIIA<br/>7.1.5/01</b>  | xxx  | 2008 | Xxx, xxx, xxx, (2008) Study Code OS-11/08 Part<br>IV: TOTO 75 – acute eye<br>irritation study on rabbits<br><br>Report to GLP<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III                  | Chemisorol |
| <b>Annex IIIA<br/>7.1.6/01</b>  | xxx  | 2008 | Xxx, xxx, xxx, , (2008) Study Code AI-48/08:<br>TOTO 75 – Skin sensitization<br><br>Report to GLP<br><br>Unpublished report   | Chemisorol |



|                              |       |      |   |          |
|------------------------------|-------|------|---|----------|
|                              |       |      | Dossier Documents K-III and L-III   |          |
| <b>Annex IIIA<br/>7.3/01</b> | xxxx  | 2010 | <p>Estimation of operator exposure using the German and the UK models – TOTO 75</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p> | Chemirol |
| <b>Annex IIIA<br/>7.3/02</b> | xxxx. | 2010 | <p>Estimation of operator exposure using the German and the UK models – TOTO 75</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p> | Chemirol |
| <b>Annex IIIA<br/>7.3/01</b> | Xxx   | 2016 | <p>Xxx_Operator exposure (acc. to the German model)_TOTO 75 SG_met</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p>              | Chemirol |
| <b>Annex IIIA<br/>7.3/02</b> | Xxx   | 2016 | <p>Xxx_Operator exposure (acc. to the German model)_TOTO 75 SG_thifen</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p>           | Chemirol |
| <b>Annex IIIA<br/>7.3/03</b> | Xxx   | 2016 | <p>Xxx_Operator exposure (acc. to the UK model)_TOTO 75 SG_metsulfuron</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p>                                    | Chemirol |

|                              |            |             |   |                 |
|------------------------------|------------|-------------|---|-----------------|
|                              |            |             | ⇒IIIA point 7.4/17  |                 |
| <b>Annex IIIA<br/>7.3/04</b> | <b>Xxx</b> | <b>2016</b> | <p>Xxx_Operator exposure (acc. to the UK model)<br/>_TOTO 75 SG_thifen</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p>        | <b>ChemiroI</b> |
| <b>Annex IIIA<br/>7.3/05</b> | <b>Xxx</b> | <b>2019</b> | <p>Xxx_Operator exposure (acc. to the EFSA model)<br/>_TOTO 75 SG_metsulfuron</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p> | <b>ChemiroI</b> |
| <b>Annex IIIA<br/>7.3/06</b> | <b>Xxx</b> | <b>2019</b> | <p>Xxx_Operator exposure (acc. to the EFSA model)<br/>I) _TOTO 75 SG_thifen</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.4/17</p>   | <b>ChemiroI</b> |
| <b>Annex IIIA<br/>7.4/01</b> | <b>Xxx</b> | <b>2016</b> | <p>Xxx_bystander model german_TOTO 75<br/>SG_metsulfuron</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.3/17</p>                      | <b>ChemiroI</b> |
| <b>Annex IIIA<br/>7.4/02</b> | <b>Xxx</b> | <b>2016</b> | <p>Xxx_bystander model german_TOTO 75 SG_thife</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒IIIA point 7.3/17</p>                                | <b>ChemiroI</b> |

|                                    |            |             |   |                 |
|------------------------------------|------------|-------------|---|-----------------|
| <b>Annex IIIA</b><br><b>7.4/03</b> | <b>Xxx</b> | <b>2019</b> | Xxx_Resident_exposure (acc. to the EFSA model)<br>_TOTO 75 SG_metsulfuron<br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA point 7.4/17 | <b>ChemiroI</b> |
| <b>Annex IIIA</b><br><b>7.4/04</b> | <b>Xxx</b> | <b>2019</b> | Xxx_Resident exposure (acc. to the EFSA model)<br>I)_TOTO 75 SG_thifen<br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA point 7.4/17    | <b>ChemiroI</b> |
| <b>Annex IIIA</b><br><b>7.5/01</b> | <b>Xxx</b> | <b>2016</b> | Xxx_worker model germam_TOTO 75<br>SG_metsulfuron<br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA point 7.3/17                         | <b>ChemiroI</b> |
| <b>Annex IIIA</b><br><b>7.5/02</b> | <b>Xxx</b> | <b>2016</b> | Xxx_worker model germam_TOTO 75 SG_thife<br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA point 7.3/17                                  | <b>ChemiroI</b> |
| <b>Annex IIIA</b><br><b>7.5/03</b> | <b>Xxx</b> | <b>2019</b> | Xxx_Worker_exposure (acc. to the EFSA model)<br>_TOTO 75 SG_metsulfuron<br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒IIIA point 7.4/17   | <b>ChemiroI</b> |
| <b>Annex IIIA</b>                  | <b>Xxx</b> | <b>2019</b> | Xxx_Worker exposure (acc. to the EFSA model) I)   | <b>ChemiroI</b> |

|        |  |  |   |  |
|--------|--|--|---|--|
| 7.5/04 |  |  | <u>TOTO 75 SG_thifen</u><br><br>GLP N/A<br><br>Unpublished report<br><br>Dossier Documents K-III and L-III<br><br>⇒III A point 7.4/17 |  |
|--------|--|--|---|--|

## Appendix 2: Critical Uses – justification and GAP tables

| Crop and/or situation<br><br><br><br><br>(a) | Member State or Country | Product name | F<br>G<br>or<br>I<br><br>(b) | Pests or Group of pests or controlled<br><br>(c) | Formulation |              | Application   |                       |                |                                     | Application rate per treatment |            |          | PHI<br>(days)<br><br>(l) | Remarks:<br><br>(m) |
|--|-------------------------|--------------|------------------------------|--|-------------|--------------|---------------|-----------------------|----------------|-------------------------------------|--------------------------------|------------|----------|--------------------------|---------------------|
|  |                         |              |                              |  | Type        | Conc.        | method        | growth                | number         | interval between applications (min) | kg as/hL                       | water L/ha | kg as/ha |                          |                     |
|  |                         |              |                              |  | (d-f)       | of as<br>(i) | kind<br>(f-h) | stage & season<br>(j) | min max<br>(k) |                                     | min max                        | min max    | min max  |                          |                     |

|       |    |         |   |       |    |   |             |                              |   |               |   |         |  |     |  |
|-------|----|---------|---|-------|----|---|-------------|------------------------------|---|---------------|---|---------|--|-----|--|
| TRZAW | PL | TOTO 75 | F | weeds | SG | Thifensulfuron-methyl 682 g/kg + metsulfuron-methyl 68 g/kg | Spry medium | BBCH 12-15<br><br>BBCH 22-29 | 1 | Not applicabl | thifensulfuron-methyl = 0,0205-0,0307<br>Metsulfuron-methyl = 0,00203-0,00305 | 200-300 | Thifensulfuron-methyl = 0,0614 + metsulfuron-methyl = 0,0061 | N/A |  |
|-------|----|---------|---|-------|----|---|-------------|------------------------------|---|---------------|---|---------|--|-----|--|

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

PPP (product name/code): TOTO / TYTAN / HERKULES

Active substance(s) (name and content, g/L or g/kg): Metsulfuron-methyl and Thifensulfuron-methyl

Formulation type: SG

Field of use: cereals

Zone(s): central

**Appendix B - details of all intended national GAPs within the zone** (to be sorted by crop); for existing authorisations this should be based on the existing uses in the zone

(For further information regarding filling the table see appendix D)

| 1    | 2      | 3         | 4 | 5                 | 6           | 7 | 8 | 9 | 10               | 11 | 12 | 13  | 14       |
|------|--------|-----------|---|-------------------|-------------|---|---|---|------------------|----|----|-----|----------|
| Use- | Member | Crop and/ | F | Pests or Group of | Application |   |   |   | Application rate |    |    | PHI | Remarks: |

| No.               | state(s) | or situation<br><br>(crop destination /<br>purpose of crop) | G<br>or<br>I | pests controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br><br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product / ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season   | Water<br>L/ha<br><br>min / max | (days<br>) | e.g. g safener/synergist<br>per ha   |
|-------------------|----------|---|--------------|--|------------------|--|---|--|--|--|--------------------------------|------------|--|
| 1                 |          |   |              |  |                  |  |   |  |  |  |                                |            |  |
| 2                 |          |   |              |  |                  |  |   |  |  |  |                                |            |  |
| 3                 |          |   |              |  |                  |  |   |  |  |  |                                |            |  |
| 4                 |          |   |              |  |                  |  |   |  |  |  |                                |            |  |
| <b>Field uses</b> |          |   |              |  |                  |  |   |  |  |  |                                |            |  |
| 1                 | PL, SK   | Winter wheat  | F            | weeds  | spray<br>medium  | PL: BBCH 21-31<br>SK: BBCH 22-31             | 1   | N/A  | a) 0,09<br>b) 0,09   | a) thifensulfuron methyl<br>61,4 g +<br>metsulfuron methyl 6,1 g<br><br>b) thifensulfuron methyl<br>61,4 g +<br>metsulfuron methyl 6,1 g | 200-300                        | N/A        | PL: plus adjuvant<br>ASYSTENT+90 EC in<br>dose 0,11/ha   |
| 2                 | PL, SK   | Winter triticales   | F            | Weeds  | spray<br>medium  | BBCH 21 -31                                  | 1   | N/A  | a) 0,09<br>b) 0,09   | a) thifensulfuron methyl<br>61,4 g +<br>metsulfuron methyl 6,1 g<br><br>b)   |                                |            | PL: plus adjuvant<br>PARTNER+ in dose<br>0,5 l/ha<br><br>SK – extention of<br>registration is currently<br>pending |

| 1           | 2                  | 3  | 4                 | 5   | 6                | 7  | 8   | 9  | 10   | 11   | 12                             | 13                | 14  |
|-------------|--------------------|--|-------------------|---|------------------|--|---|--|--|--|--------------------------------|-------------------|---|
| Use-<br>No. | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F<br>G<br>or<br>I | Pests or Group of<br>pests controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application      |  | Max. number<br>a) per use<br><br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | Application rate   |  |                                | PHI<br>(days<br>) | Remarks:<br><br>e.g. g safener/synergist<br>per ha  |
|             |                    |  |                   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season |   |  | kg or L<br>product / ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season   | Water<br>L/ha<br><br>min / max |                   |   |
|             |                    |  |                   |   |                  |  |   |  |  | thifensulfuro<br>n methyl<br>61,4 g +<br>metsulfuron<br>methyl 6,1 g   |                                |                   |   |
| 3           | PL, SK             | Winter rye   | F                 | Weeds   | spray<br>medium  | BBCH 21 -31                                  | 1   | N/A  | a) 0,09<br>b) 0,09   | a)<br>thifensulfuro<br>n methyl<br>61,4 g +<br>metsulfuron<br>methyl 6,1 g<br><br>b)<br>thifensulfuro<br>n methyl<br>61,4 g +<br>metsulfuron<br>methyl 6,1 g |                                |                   | PL: plus adjuvant<br>PARTNER+ in dose<br>0,5 l/ha<br><br>SK – extention of<br>registration is currently<br>pending                              |
| 4           | PL, SK             | Winter rye   | F                 | Weeds   | spray<br>medium  | BBCH 21 -31                                  | 1   | N/A  | a) 0,07<br>b) 0,07   | a)<br>thifensulfuro<br>n methyl<br>47,7 g +<br>metsulfuron<br>methyl 4,8 g<br><br>b)<br>thifensulfuro  |                                |                   | SK – extention of<br>registration is currently<br>pending: Tank Mix<br>with Galaper<br>(fluroksypyr) 250 EC<br>in dose 0,25 l of<br>product /ha |



| 1           | 2                  | 3  | 4                 | 5   | 6                | 7  | 8   | 9  | 10   | 11   | 12                             | 13            | 14   |
|-------------|--------------------|--|-------------------|---|------------------|--|---|--|--|--|--------------------------------|---------------|--|
| Use-<br>No. | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F<br>G<br>or<br>I | Pests or Group of<br>pests controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application      |  | Max. number<br>a) per use<br><br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | Application rate   |  |                                | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist<br>per ha   |
|             |                    |  |                   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season |   |  | kg or L<br>product / ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season   | Water<br>L/ha<br><br>min / max |               |  |
|             |                    |  |                   |   |                  |  |   |  |  | n methyl<br>47,7 g +<br>metsulfuron<br>methyl 4,8 g  |                                |               | PL: Tank Mix with<br><br>Galaper (fluroksypyr)<br>250 EC in dose 0,25 l<br>of product /ha<br><br>+ adjuvant<br><br>Partner+ in dose 0,5<br>l/ha                              |
| 5           | PL, SK             | Winter triticales  | F                 | Weeds   | spray<br>medium  | BBCH 21 -31                                  | 1   | N/A  | a) 0,07<br>b) 0,07   | a) thifensulfuro<br>n methyl<br>47,7 g +<br>metsulfuron<br>methyl 4,8 g<br><br>b) thifensulfuro<br>n methyl<br>47,7 g +<br>metsulfuron<br>methyl 4,8 g |                                |               | SK – extention of<br>registration is currently<br>pending: Tank Mix<br>with<br><br>Galaper (fluroksypyr)<br>250 EC in dose 0,25 l<br>of product /ha<br><br>PL: Tank Mix with |

| 1   | 2                  | 3  | 4                 | 5   | 6                | 7  | 8   | 9  | 10   | 11   | 12                             | 13                | 14   |
|---|--------------------|--|-------------------|---|------------------|--|---|--|--|--|--------------------------------|-------------------|--|
| Use-<br>No.   | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F<br>G<br>or<br>I | Pests or Group of<br>pests controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application      |  | Max. number<br>a) per use<br><br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | Application rate   |  |                                | PHI<br>(days<br>) | Remarks:<br><br>e.g. g safener/synergist<br>per ha   |
|   |                    |  |                   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season |   |  | kg or L<br>product / ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate<br>per appl.<br><br>b) max. total<br>rate per<br>crop/season | Water<br>L/ha<br><br>min / max |                   |  |
|   |                    |  |                   |   |                  |  |   |  |  |  |                                |                   | Galaper (fluroksypyr)<br>250 EC in dose 0,25 l<br>of product /ha<br><br>+ adjuvant<br><br>Partner+ in dose 0,5<br>l/ha |
| EU-wide uses (use on sowing seed, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms) |                    |  |                   |   |                  |  |   |  |  |  |                                |                   |  |
| 3   | -                  | -  | -                 | -   | -                | -  | -   | -  | -  | -  | -                              | -                 | -  |
| 4   | -                  | -  | -                 | -   | -                | -  | -   | -  | -  | -  | -                              | -                 | -  |
| Minor uses according to article 51  |                    |  |                   |   |                  |  |   |  |  |  |                                |                   |  |
| 5   | -                  | -  | -                 | -   | -                | -  | -   | -  | -  | -  | -                              | -                 | -  |
| 6   | -                  | -  | -                 | -   | -                | -  | -   | -  | -  | -  | -                              | -                 | -  |

### **Appendix 3: Additional information provided by the applicant (e.g. detailed modelling data)**

All modelling data and calculations are presented in the reports listed in Appendix 1

(see Part B, Section III, K-III)