

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

Comments of zRMS:	<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 classification of the formulation TOTO 75/ TYTAN 75/ HERKULES 75 is as follows:</p> <p>Eye Irrit. 2, H319 Causes serious eye irritation STOT SE3, H335: May cause respiratory irritation (for details, see. dRR, part C)</p> <p>Labelling: Warning section of the label (first page): P280: Wear eye/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P261: Avoid breathing dust/fume/gas/mist/vapours/spray P271: Use only outdoors</p> <p>Other section of the label: P270: Do not eat, drink or smoke when using this product. P264: Wash hands thoroughly after handling. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents/container to....</p> <p>and P280 as follows: <i>„Stosować rękawice ochronne, ochronę oczu/twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.”</i> “Wear protective gloves, eye/face protection and work wear (coverall) during mixing and loading and application.”</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/ attention. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P312: Call a POISON CENTER or doctor/physician if you feel unwell.</p>
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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 (default values)	25% for the concentrate 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 (default values)	25% for the concentrate 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
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Oral acute	Rat	LD50 >2000 mg/kg bw	NA
Dermal route	Rat	LD50 >2000 mg/kg bw	NA
Inhalation (4 hrs)	Rat	LC ₅₀ >5.0 mg/L (metsulfuron-methyl) LC ₅₀ >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 ₅₀ (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 (LD₅₀) 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 cm²) 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, the classification regarding the acute inhalation toxicity is not required.
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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 < Category 1 ≤ 5	0,5
	5 < Category 2 ≤ 50	5
	50 < Category 3 ≤ 300	100
	300 < Category 4 ≤ 2 000	500
Dermal (mg/kg bodyweight)	0 < Category 1 ≤ 50	5
	50 < Category 2 ≤ 200	50
	200 < Category 3 ≤ 1 000	300
	1 000 < Category 4 ≤ 2 000	1 100
Gases (ppmV)	0 < Category 1 ≤ 100	10
	100 < Category 2 ≤ 500	100
	500 < Category 3 ≤ 2 500	700
	2 500 < Category 4 ≤ 20 000	4 500
Vapours (mg/l)	0 < Category 1 ≤ 0,5	0,05
	0,5 < Category 2 ≤ 2,0	0,5
	2,0 < Category 3 ≤ 10,0	3
	10,0 < Category 4 ≤ 20,0	11
Dust/mist (mg/l)	0 < Category 1 ≤ 0,05	0,005
	0,05 < Category 2 ≤ 0,5	0,05
	0,5 < Category 3 ≤ 1,0	0,5
	1,0 < Category 4 ≤ 5,0	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)

LD₅₀ 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 cm². 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.

	substance thifensulfuron- methyl and metsulfuron-methyl)		
Thifensulfuron- methyl	0.07	0.007189133	10%
Metsulfuron-methyl	0.7	0.000716805	0.1%
		TOTAL = 0.0079059	TOTAL = 10.1%

CONCLUSION:

The sum of the fractions is ≤ 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**

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

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) ¹⁾	ST1102	0.08	I _M	<input type="checkbox"/>
Half mask with combined filter (m/l) ¹⁾	ST2102	0.02	I _M	<input type="checkbox"/>
Particle filtering half mask (appl.) ¹⁾	ST1203	0.08	I _A	<input type="checkbox"/>
		0.8	D _{A(C)}	
Half mask with combined filter (appl.) ¹⁾	ST2202	0.02	I _A	<input type="checkbox"/>
		0.8	D _{A(C)}	
Protective gloves (m/l) ²⁾	SS110	0.01	D _{M(H)}	<input type="checkbox"/>
Protective gloves (appl.) ²⁾	SS120	0.01	D _{A(H)}	<input type="checkbox"/>
Protective garment + sturdy footwear (appl.) ²⁾	SS2202	0.05	D _{A(B)}	<input type="checkbox"/>
Broad-brimmed headgear (appl.) ²⁾	SS420	0.5	D _{A(C)}	<input type="checkbox"/>
Hood and visor (appl.) ²⁾	SS520	0.05	D _{A(C)}	<input type="checkbox"/>
¹⁾ DIN EN 149 (2001), ²⁾ BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection				
Estimated inhalation exposure:	Personal protective equipment (PPE)		Factor	
I _M	no PPE		1	
I _A	no PPE		1	

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

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			
<u>Dermal exposure during mixing/loading</u>			
Hands		Hands	
SDE _{OM(H)} = (D _{M(H)} x AR x A x DA) / BW		SDE _{OM(H)} = (D _{M(H)} x AR x A x PPE ¹ x DA) / BW	
(2.4 x 0.0062 x 20 x 25%) / 70		(2.4 x 0.0062 x 20 x 1 x 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
<u>Dermal exposure during application</u>			
Hands		Hands	
SDE _{OA(H)} = (D _{A(H)} x AR x A x DA) / BW		SDE _{OA(H)} = (D _{A(H)} x AR x A x PPE ¹ x DA) / BW	
(0.38 x 0.0062 x 20 x 75%) / 70		(0.38 x 0.0062 x 20 x 1 x 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)} x AR x A x DA) / BW		SDE _{OA(B)} = (D _{A(B)} x AR x A x PPE ² x DA) / BW	
(1.6 x 0.0062 x 20 x 75%) / 70		(1.6 x 0.0062 x 20 x 1 x 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	
$SDE_{OA(C)} = (DA_{(C)} \times AR \times A \times DA) / BW$		$SDE_{OA(C)} = (DA_{(C)} \times AR \times A \times PPE^3 \times DA) / BW$	
$(0.06 \times 0.0062 \times 20 \times 75\%) / 70$		$(0.06 \times 0.0062 \times 20 \times 1 \times 75\%) / 70$	
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
Operators: Systemic inhalation exposure after application in e.g. cereals			
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 %
¹⁾ reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications), resp. ²⁾ reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden appl.), resp. ³⁾ reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional appl.) ⁴⁾ 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/ HESRKULES 75 SG /TYTAN 75 SG		
Intended use(s)	e.g. cereals		
Type of preparation	Field Crops, Tractor Mounted (FCTM)		
	Liquid		
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) ¹⁾	ST1102	0.08	I _h <input type="checkbox"/>
Half mask with combined filter (m/l) ¹⁾	ST2102	0.02	I _h <input type="checkbox"/>
Particle filtering half mask (appl.) ¹⁾	ST1203	0.08	I _a <input type="checkbox"/>
		0.8	D _{A(iC)} <input type="checkbox"/>
Half mask with combined filter (appl.) ¹⁾	ST2202	0.02	I _a <input type="checkbox"/>
		0.8	D _{A(iC)} <input type="checkbox"/>
Protective gloves (m/l) ²⁾	SS110	0.01	D _{M(H)} <input type="checkbox"/>
Protective gloves (appl.) ²⁾	SS120	0.01	D _{A(H)} <input type="checkbox"/>
Protective garment + sturdy footwear (appl.) ²⁾	SS2202	0.05	D _{A(B)} <input type="checkbox"/>
Broad-brimmed headgear (appl.) ²⁾	SS420	0.5	D _{A(iC)} <input type="checkbox"/>
Hood and visor (appl.) ²⁾	SS520	0.05	D _{A(iC)} <input type="checkbox"/>
¹⁾ DIN EN 149 (2001), ²⁾ BVL (2006) Guidelines for requirements concerning personal protective equipment in plant protection			
Estimated inhalation exposure:	Personal protective equipment (PPE)	Factor	
I _h	no PPE	1	
I _a	no PPE	1	
Estimated dermal exposure:	Personal protective equipment (PPE)	Factor	
D _{M(H)}	no PPE	1	
D _{A(H)}	no PPE	1	
D _{A(iC)}	no PPE	1	
D _{A(B)}	no PPE	1	

0

1 **Estimation of operator exposure: German model**

2

3 **Input parameters considered for the estimation of operator exposure:**

Formulation type:	Liquid	Application technique:	Field Crops, Tractor Mounted (FCTM)
Application rate (AR):	0.062 kg	Dermal hands m/l	2.4 mg/person/kg
Area treated per day	20 ha	Dermal hands appl.	0.38 mg/person/kg
Dermal absorption (DA):	25 % (concentr.)	Dermal body appl.	1.6 mg/person/kg
	75 % (dilution)	Dermal head appl.	0.06 mg/person/kg
Inhalation absorption (I _a):	100 %	Inhalation m/l (I _h):	0.0006 mg/person/kg
Body weight (BW):	70 kg/person	Inhalation appl. (I _a):	0.001 mg/person/kg
AOEL	0.07 mg/kg bw/d		

4 **Operator exposure towards Thifensulfuron methyl**

Without PPE	With PPE
Operators: Systemic dermal exposure after application in e.g. cereals	
Dermal exposure during mixing/loading	
Hands	Hands
$SDE_{DA(25)} = (D_{A(25)} \times AR \times A \times DA) / BW$ (2.4 x 0.062 x 20 x 25%) / 70	$SDE_{DA(25)} = (D_{A(25)} \times AR \times A \times PPE^{1)} \times DA) / BW$ (2.4 x 0.062 x 20 x 1 x 25%) / 70
External dermal exposure 2.976 mg/person	External dermal exposure 2.976 mg/person
External dermal exposure 0.04251 mg/kg bw/d	External dermal exposure 0.04251 mg/kg bw/d
Systemic dermal ##### mg/kg bw/d	Systemic dermal ##### mg/kg bw/d
Dermal exposure during application	
Hands	Hands
$SDE_{DA(75)} = (D_{A(75)} \times AR \times A \times DA) / BW$ (0.38 x 0.062 x 20 x 75%) / 70	$SDE_{DA(75)} = (D_{A(75)} \times AR \times A \times PPE^{1)} \times DA) / BW$ (0.38 x 0.062 x 20 x 1 x 75%) / 70
External dermal exposure 0.4712 mg/person	External dermal exposure 0.4712 mg/person
External dermal exposure 0.00673 mg/kg bw/d	External dermal exposure 0.00673 mg/kg bw/d
Systemic dermal ##### mg/kg bw/d	Systemic dermal ##### mg/kg bw/d
Body	Body
$SDE_{DA(75)} = (D_{A(75)} \times AR \times A \times DA) / BW$ (1.6 x 0.062 x 20 x 75%) / 70	$SDE_{DA(75)} = (D_{A(75)} \times AR \times A \times PPE^{1)} \times DA) / BW$ (1.6 x 0.062 x 20 x 1 x 75%) / 70
External dermal exposure 1.984 mg/person	External dermal exposure 1.984 mg/person
External dermal exposure 0.02834 mg/kg bw/d	External dermal exposure 0.02834 mg/kg bw/d
Systemic dermal ##### mg/kg bw/d	Systemic dermal ##### mg/kg bw/d
Head	Head
$SDE_{DA(iC)} = (D_{A(iC)} \times AR \times A \times DA) / BW$ (0.06 x 0.062 x 20 x 75%) / 70	$SDE_{DA(iC)} = (D_{A(iC)} \times AR \times A \times PPE^{1)} \times DA) / BW$ (0.06 x 0.062 x 20 x 1 x 75%) / 70
External dermal exposure 0.0744 mg/person	External dermal exposure 0.0744 mg/person
External dermal exposure 0.00106 mg/kg bw/d	External dermal exposure 0.00106 mg/kg bw/d
Systemic dermal ##### mg/kg bw/d	Systemic dermal ##### mg/kg bw/d
Total systemic dermal exposure: $SDE_o = SDE_{DA(25)} + SDE_{DA(75)} + SDE_{DA(iC)}$	Total systemic dermal exposure: $SDE_o = SDE_{DA(25)} + SDE_{DA(75)} + SDE_{DA(iC)}$
Total external dermal exposure 5.5056 mg/person	Total external dermal exposure 5.5056 mg/person
Total external dermal exposure 0.07865 mg/kg bw/d	Total external dermal exposure 0.07865 mg/kg bw/d
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	

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	A	B	C	D	E	F
85	Total systemic dermal exposure	0.03773	mg/kg bw/d	Total systemic dermal exposure	0.03773	mg/kg bw/d
86	Operators: Systemic inhalation exposure after application in e.g. cereals					
87	Inhalation exposure during mixing/loading					
88	$SI_{O4} = (I_{in} \times AR \times A \times IA) / BW$			$SI_{O4} = (I_{in} \times AR \times A \times PPE^{-1} \times IA) / BW$		
89	$(0.0006 \times 0.062 \times 20 \times 100\%) / 70$			$(0.0006 \times 0.062 \times 20 \times 1 \times 100\%) / 70$		
90	External inhalation	0.00074	mg/person	External inhalation	0.00074	mg/person
91	External inhalation	1.1E-05	mg/kg bw/d	External inhalation	1.1E-05	mg/kg bw/d
92	Systemic inhalation	#####	mg/kg bw/d	Systemic inhalation	#####	mg/kg bw/d
93	Inhalation exposure during application					
94	$SI_{O4} = (I_{in} \times AR \times A \times IA) / BW$			$SI_{O4} = (I_{in} \times AR \times A \times PPE^{-1} \times IA) / BW$		
95	$(0.001 \times 0.062 \times 20 \times 100\%) / 70$			$(0.001 \times 0.062 \times 20 \times 1 \times 100\%) / 70$		
96	External inhalation	0.00124	mg/person	External inhalation	0.00124	mg/person
97	External inhalation	1.8E-05	mg/kg bw/d	External inhalation	1.8E-05	mg/kg bw/d
98	Systemic inhalation	#####	mg/kg bw/d	Systemic inhalation	#####	mg/kg bw/d
99	Total systemic inhalation exposure: $SI_{O3} = SI_{O4} +$			Total systemic inhalation exposure: $SI_{O3} = SI_{O4} +$		
100	Total external inhalation exposure	#####	mg/person	Total external inhalation exposure	#####	mg/person
101	Total external inhalation exposure	#####	mg/kg bw/d	Total external inhalation exposure	#####	mg/kg bw/d
102	Total systemic inhalation exposure	#####	mg/kg bw/d	Total systemic inhalation exposure	#####	mg/kg bw/d
103	Total systemic exposure: $SE_{O3} = SDE_{O3} + SI_{O3}$			Total systemic exposure: $SE_{O3} = SDE_{O3} + SI_{O3}$		
104	Total systemic exposure	2.64318	mg/person	Total systemic exposure	2.64318	mg/person
105	Total systemic exposure	#####	mg/kg bw/d	Total systemic exposure	#####	mg/kg bw/d
106	% of AOEL	53.9	%	% of AOEL	53.9	%
107	¹⁾ reduction factor for gloves is 0.01 (professional applications) and 0.5 (home/allotment garden applications),					
108	²⁾ reduction factor for protective garment is 0.05 (prof. appl.) and 0.5 (workwear, home/allotment garden)					
109	³⁾ reduction factor for broad brimmed headgear and hood and visor is 0.5 and 0.05, respectively (professional					
110	⁴⁾ reduction factor for RPE is 0.03 (particle filter) and 0.02 (combined vapour and particle filter) (non-prof)					

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 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
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 soluti	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 soluti	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 metsulfuron- methyl)		(FFP2)- during mix/loading and gloves during application)	
Thifensulfuron- methyl	0.07	0.2346	0.0259	37%
Metsulfuron- methyl	0.25	0.023399	-	9.36%

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	L_AppRate			
Assumed area treated	50 ha/day	L_AreaTreated			
Amount of active substance applied	0,31 kg a.s./day	L_Amount			
Dermal absorption of the product	25,00%	L_AbsorpProduct			
Dermal absorption of in-use dilution	75,00%	L_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 th centile	95 th centile		
	Hands	532	2512	ACEM	
Body	542	11436	ACEM		
Head	2	28	ACEM		
Protected hands (gloves)	8	10	ACEM		
Protected body (workwear or protective garment and sturdy footwear)	7	19	ACEM		
Protected head (hood and face shield)	0	2	ACEM		
Inhalation	26	252	ACEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	No				
Clothing	Work wear - arms, body and legs covered			Incl. in ACEM model	
Head and respiratory PPE	None		1		1
Water soluble bag	No		1		

Application	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
	Hands	19	238	ACEM	
Body	4	4	ACEM		
Head	0	0	ACEM		
Protected hands (gloves)	2	47	ACEM		
Protected body (workwear or protective garment and sturdy footwear)	0	0	ACEM		
Inhalation	1	1	ACEM		
Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor	
Gloves	No				
Clothing	Work wear - arms, body and legs covered			Incl. in ACEM model	
Head and respiratory PPE	None		1		1
Closed cab	No			vehicle mounted downward spraying only	

1. Total			
	Without RPC/PPE	With RPC/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	0,0029485	
% of RIVAS	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 RIVAS	#02163 /01	#02163 /01	

Reference IIIA 7.3/04 Xxx_Operator exposure (acc. to the EFSA model)_TOTO 75 SG_thifen

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

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

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75 th centile	95 th centile		
Mixing and loading	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	
Water soluble bag			No	1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75 th centile	95 th centile		
Application	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
Closed cab			No	vehicle mounted upward spraying only	

I. 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)	0,0283805	0,0014543
% of RIVAC	405,52%	20,78%
Acute		
Total systemic exposure from mixing, loading and application (mg a. s./day)	10,6879810	0,4609324
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,1781330	0,0076820
% of RIVAC	403161,10%	46093,24%

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: Thifensulfuron-methyl:</p>
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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^{-3}Pa
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./cm ² 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^{-3}Pa
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./cm ² 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 unprotected operator to thifensulfuron-methyl and metsulfuron-methyl contained in the product TOTO 75/ TYTAN 75/ HERKULES 75 causes no unacceptable health risk 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 section of precautions for the operators:</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>
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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:	<p>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.</p> <p>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.</p> <p>The results of estimations are presented below:</p> <p>Thifensulfuron-methyl:</p> <table border="1"> <tr> <td>Resident - child</td> <td>Spray drift (75th percentile) mg/kg bw/day</td> <td>0,0042</td> <td>% of RVNAS</td> <td>5,95%</td> </tr> <tr> <td></td> <td>Vapour (75th percentile) mg/kg bw/day</td> <td>0,0011</td> <td>% of RVNAS</td> <td>1,53%</td> </tr> <tr> <td></td> <td>Surface deposits (75th percentile) mg/kg bw/day</td> <td>0,0014</td> <td>% of RVNAS</td> <td>2,01%</td> </tr> <tr> <td></td> <td>Entry into treated crops (75th percentile) mg/kg bw/day</td> <td>0,0147</td> <td>% of RVNAS</td> <td>20,95%</td> </tr> <tr> <td></td> <td>All pathways (mean) mg/kg bw/day</td> <td>0,0161</td> <td>% of RVNAS</td> <td>22,98%</td> </tr> <tr> <td>Resident - adult</td> <td>Spray drift (75th percentile) mg/kg bw/day</td> <td>0,0010</td> <td>% of RVNAS</td> <td>1,42%</td> </tr> <tr> <td></td> <td>Vapour (75th percentile) mg/kg bw/day</td> <td>0,0002</td> <td>% of RVNAS</td> <td>0,33%</td> </tr> <tr> <td></td> <td>Surface deposits (75th percentile) mg/kg bw/day</td> <td>0,0006</td> <td>% of RVNAS</td> <td>0,85%</td> </tr> <tr> <td></td> <td>Entry into treated crops (75th percentile) mg/kg bw/day</td> <td>0,0081</td> <td>% of RVNAS</td> <td>11,64%</td> </tr> <tr> <td></td> <td>All pathways (mean) mg/kg bw/day</td> <td>0,0076</td> <td>% of RVNAS</td> <td>10,90%</td> </tr> </table> <p>Metsulfuron-methyl:</p> <table border="1"> <tr> <td>Resident - child</td> <td>Spray drift (75th percentile) mg/kg bw/day</td> <td>0,0002</td> <td>% of RVNAS</td> <td>0,08%</td> </tr> <tr> <td></td> <td>Vapour (75th percentile) mg/kg bw/day</td> <td>0,0011</td> <td>% of RVNAS</td> <td>0,43%</td> </tr> <tr> <td></td> <td>Surface deposits (75th percentile) mg/kg bw/day</td> <td>0,0000</td> <td>% of RVNAS</td> <td>0,01%</td> </tr> <tr> <td></td> <td>Entry into treated crops (75th percentile) mg/kg bw/day</td> <td>0,0005</td> <td>% of RVNAS</td> <td>0,21%</td> </tr> <tr> <td></td> <td>All pathways (mean) mg/kg bw/day</td> <td>0,0016</td> <td>% of RVNAS</td> <td>0,65%</td> </tr> <tr> <td>Resident - adult</td> <td>Spray drift (75th percentile) mg/kg bw/day</td> <td>0,0000</td> <td>% of RVNAS</td> <td>0,02%</td> </tr> <tr> <td></td> <td>Vapour (75th percentile) mg/kg bw/day</td> <td>0,0002</td> <td>% of RVNAS</td> <td>0,09%</td> </tr> <tr> <td></td> <td>Surface deposits (75th percentile) mg/kg bw/day</td> <td>0,0000</td> <td>% of RVNAS</td> <td>0,00%</td> </tr> <tr> <td></td> <td>Entry into treated crops (75th percentile) mg/kg bw/day</td> <td>0,0003</td> <td>% of RVNAS</td> <td>0,12%</td> </tr> <tr> <td></td> <td>All pathways (mean) mg/kg bw/day</td> <td>0,0005</td> <td>% of RVNAS</td> <td>0,20%</td> </tr> </table> <p>Summary and conclusions:</p> <p>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.</p> <p>The incidental short-time exposure of bystander and resident (children and adult) to TOTO 75/ TYTAN 75/ HERKULES 75 causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table.</p>	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%	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%
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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 AOEL mg/kg bw/day (source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl)	Predicted systemic exposure mg/kg bw/day	Predicted exposure as % of short-term systemic AOEL
Thifensulfuron-methyl	0.07	0.0001178	0.17%
Metsulfuron-methyl	0.7	0.0000138	0.002%
		TOTAL = 0.0001316	TOTAL = 0.172%

CONCLUSION:

The sum of the fractions is ≤ 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.

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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				L_AppEquip
Formulation type	Vertebrate granules, soluble granules				L_Formul
Buffer strip	2-3 m				L_BoffStr
Application rate of the product	0,0052 kg a.s./ha				L_AppRate
Concentration of active substance (in-use dilution for liquid applications)	0,031 g a.s./l				d_ConcAct
Dermal absorption of product	25,00%				L_AbsorpProduct
Dermal absorption of in-use dilution	75,00%				L_AbsorpDilut
Oral absorption	100,00%				L_AbsorpOral
Dislodgeable foliar residue (L_AppRate*_DFFR)	0,0185 µg a.s./cm ²				d_DRF
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of 10^{-3}-3Pa				L_Water
Concentration in air	0,001 mg/m ³				d_AirConc
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person				
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person				
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person				
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person				
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person				
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person				
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person				
Exposure duration dermal	2 hours				d_ExpDur
Exposure duration inhalation	24 hours				d_ExpDurInhal
Exposure duration entry into treated crops	0,25 hours				d_ExpDurTreatCrop
Light clothing adjustment factor	18,0%				d_ClothFac
Breathing rate adult	0,23 m ³ /day/kg				d_BreatRateAd
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg				d_BreatRateCh
Drift percentage on surface (75th percentile)	5,00%				
Drift percentage on surface (mean)	4,10%				
Turf transferable residues percentage	5,00%				d_Surf
Transfer coeff. of surface deposits-adult	7300 cm ² /hour				d_KvActAd
Transfer coeff. of surface deposits-child (1-3 year old)	2500 cm ² /hour				d_KvActCh
Saliva extraction percentage	50,00%				d_SalivE
Surface area of hands mouthed	20 cm ²				d_SurfaceM
Frequency of hand to mouth activity	9,5 events/hour				d_HandMouthF
Ingestion rate for mouthing of grass per day	25 cm ³				d_IngestRate
Dislodgeable residues percentage transferability for object to mouth	20,00%				d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h				d_KvActCropAd
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h				d_KvActCropCh
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				d_KvActCropAdM
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h				d_KvActCropChM
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	0,000364	0,0007947	0,0018941
% of RfNAS	0,12%	0,42%	0,01%	0,31%	0,76%
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	0,0009505	0,0261563	0,0374800
Total systemic exposure per kg body weight (mg/kg)	0,0000747	0,0002300	0,0000158	0,0004259	0,000247
% of RfNAS	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 5G					
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%				
Dislodgeable foliar residue (L_AppRate*_DFR)	0,180 µg a. s./cm ²				
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa				
Concentration in air	0,001 mg/m ³				
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 ³ /day/kg				
Breathing rate child (1-3 year old)	1,07 m ³ /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 ² /hour				
Transfer coeff. of surface deposits-child (1-3 year old)	2000 cm ² /hour				
Saliva extraction percentage	50,00%				
Surface area of hands mouthed	20 cm ²				
Frequency of hand to mouth activity	0,5 events/hour				
Ingestion rate for mouthing of grass per day	25 cm ³				
Dislodgeable residues percentage transferability for object to mouth	20,00%				
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h				
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h				
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /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)	0,0312054	0,0107000	0,0036309	0,0784688	0,0931133
Total systemic exposure per kg body weight (mg/kg)	0,0031205	0,0010700	0,0003637	0,0078469	0,0093113
% of RfVAG	44,58%	15,29%	5,20%	112,10%	133,02%
I.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a. s./day)	0,0448183	0,0138000	0,0095046	0,2615625	0,2505998
Total systemic exposure per kg body weight (mg/kg)	0,0007470	0,0002300	0,0001584	0,0043294	0,0041767
% of RfVAG	10,67%	3,29%	2,26%	62,28%	59,67%

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

Metsulfuron-methyl	0.25	0.0189413	-	0.76%
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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 mg/kg bw/day (source: Review reports for the active substance thifensulfuron-methyl and metsulfuron-methyl)	Predicted systemic exposure mg/kg bw/day	Predicted exposure as % of short-term systemic AOEL (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:	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. 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:		
		Exposure (mg a.s./day)	% of systemic AOEL
	Cereals (TC: 0.14 m ² /h) Work duration: 2 h (inspection)		
	Work wear	0.0043	6
	Work wear and protective gloves	0.0009	1
<p><u>Conclusion:</u></p> <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 no health risk for the worker assuming the work wear (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 ² /kg a.s.	2)
Transfer coefficient (TC)	1500	cm ² /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	
<p>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)</p> <p>2) default of 1 µg a.s./cm² per kg a.s./ha acc. to Krebs et al. (2000)</p> <p>3) TC: 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000), acc. EUROPODEM 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)</p> <p>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</p> <p>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</p>			

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 ² /kg a.s.
Application rate (AR):	0.0062 kg a.s./ha	Transfer coefficient (TC):	1500	cm ² /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 ¹⁾		With PPE ²⁾	
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 %

¹⁾ acceptable without PPE: allocation of BVL code SF245-01 for spray applications

²⁾ 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 ¹⁾
Dislodgeable foliar residues (DFR)	1 µg/cm ² /kg a.s.
Transfer coefficient (TC)	1500 cm ² /person/h
Work rate per day (WR)	8 h/d
Penetration through clothing (P)	0.05 (5 %)
Systemic AOEL	0.07 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./cm² per kg a.s./ha acc. to Krebs et al. (2000)

³⁾ TC 30000 cm²/person/hour ('worst case', hand harvesting, both sides of leaves) acc. to Krebs et al. (2000), acc. EURPODEM 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 ² /kg a.s.
Application rate (AR):	0.062 kg a.s./ha	Transfer coefficient (TC):	1500 cm ² /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	0.07 mg/kg bw/d		

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

¹⁾ acceptable without PPE: allocation of BVL code SF245-01 for spray applications

²⁾ 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>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 ($i_AppRate * i_DFR$)	0,0186	$\mu\text{g a.s./cm}^2$		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm^2/hr		<i>d_DermTCUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm^2/hr		<i>d_DermTCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm^2/hr	<i>d_DermTCV2</i>
Inhalation transfer coefficient for automated applications	NA	$\text{ha/hr} * 10^{(-3)}$		<i>d_InhalTCaut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	$\text{ha/hr} * 10^{(-3)}$		<i>d_InhalTCcut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	$\text{ha/hr} * 10^{(-3)}$		<i>d_InhalTCsort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	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	$d_DermTCV1 * d_WorkHr * i_DFR * d_MAF / 1000 * i_AbsorpInuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTCV2 * d_WorkHr * i_DFR * d_MAF / 1000 * i_AbsorpInuse$	
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 ²		<i>d_DFR</i>
Working hours	2	hr		<i>d_WorkHr</i>
Dermal transfer coefficient - Total potential exposure	12500	cm ² /hr		<i>d_DermTCUCV</i>
Dermal transfer coefficient - arms, body and legs covered	1400	cm ² /hr		<i>d_DermTCV1</i>
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment		cm ² /hr	<i>d_DermTCV2</i>
Inhalation transfer coefficient for automated applications	NA	ha/hr*10 ⁴ (-3)		<i>d_InhalTCAut</i>
Inhalation transfer coefficient for cutting ornamentals	NA	ha/hr*10 ⁴ (-3)		<i>d_InhalTCcut</i>
Inhalation transfer coefficient for sorting / bundling ornamentals	NA	ha/hr*10 ⁴ (-3)		<i>d_InhalTCsort</i>
1. Total				
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves	Comments
Total systemic exposure (mg a.s./day)	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 RVNAS	830,36%	93,00%		
2. Details				
	Systemic exposure		Formula	Comments
	[mg a.s./day]	[mg a.s./kg bw/day]		
Dermal - Potential	3,4875000	0,0581250	$d_DermTCUCV * d_WorkHr * d_DFR * i_MAF / 1000 * i_AbsorpInuse$	
Dermal - Work wear - arms, body and legs covered	0,3906000	0,0065100	$d_DermTCV1 * d_WorkHr * d_DFR * i_MAF / 1000 * i_AbsorpInuse$	
Dermal - Working wear and gloves	no TC available for this assessment		$d_DermTCV2 * d_WorkHr * d_DFR * i_MAF / 1000 * i_AbsorpInuse$	
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 mg/kg bw/day (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 (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

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

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METHYL

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

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

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

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

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

7.5/04			<p>TOTO 75 SG_thifen</p> <p>GLP N/A</p> <p>Unpublished report</p> <p>Dossier Documents K-III and L-III</p> <p>⇒III A point 7.4/17</p>	
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- 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 (crop destination / purpose of crop)	G or I	pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max	(days)	e.g. g safener/synergist per ha
1													
2													
3													
4													
Field uses													
1	PL, SK	Winter wheat	F	weeds	spray medium	PL: BBCH 21-31 SK: BBCH 22-31	1	N/A	a) 0,09 b) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g b) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g	200-300	N/A	PL: plus adjuvant ASYSTENT+90 EC in dose 0,11/ha
2	PL, SK	Winter triticales	F	Weeds	spray medium	BBCH 21 -31	1	N/A	a) 0,09 b) 0,09	a) thifensulfuron methyl 61,4 g + metsulfuron methyl 6,1 g b)			PL: plus adjuvant PARTNER+ in dose 0,5 l/ha SK – extention of registration is currently pending

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													Galaper (fluroksypyrr) 250 EC in dose 0,25 l of product /ha + adiuvant Partner+ in dose 0,5 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)