

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in Groundwater

Detailed summary of the risk assessment

Product code: TOTO 75 SG

Product name(s): TOTO 75 SG/ TYTAN 75 SG/ HERKULES
75 SG

Chemical active substance(s):

Thifensulfuron-methyl, 682 g/kg
Metsulfuron-methyl, 68 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

Renewal of authorization

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: January 2020

MS Finalisation date: July 2021; October 2022

Version history

When	What
July 2021	Finalisation of the assessment by zRMS
October 2022	Final Registration Report

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10 Relevance of metabolites in groundwater

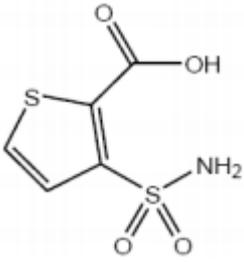
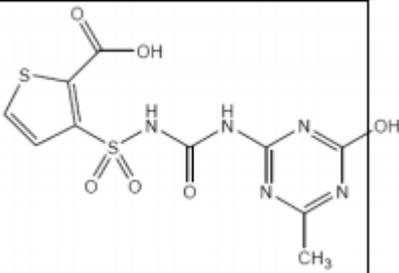
10.1 General information

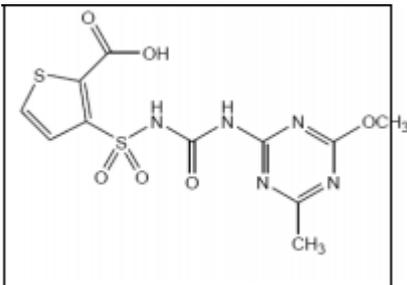
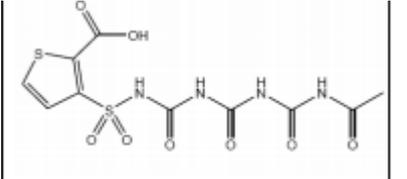
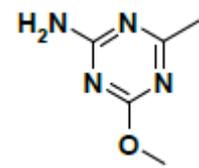
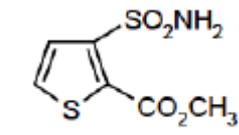
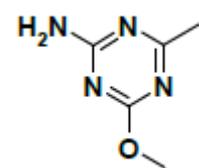
The metabolites IN-A4098, IN-L9225, 2-acid-2-triuret, IN-W8268, IN-A5546, IN-L9223 and IN-JZ789 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see PART B Section 8 of TOTO 75 SG). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

General information on the metabolites provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the GAP evaluation in chapter KCP 9.2.4 of the dRR Part B, Section 8 (Environmental fate and behaviour).

The relevance of metabolites in groundwater were evaluated during Annex I inclusion and renewal of thifensulfuron-methyl in RAR volume 1 2015 and metsulfuron-methyl in RAR volume 3 , section B6 2013. Using much more conservative PEC in gw, therefore no new risk assessment is necessary and the Jokioinen scenario was not taking into account because it is not relevant scenario in Poland and Central Zone (therefore the metabolite IN-W8268 was not included in this assessment, because it is only occur above trigger value 0.1 µg/L in Jokioinen scenario).

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Thifensulfuron-methyl	IN-L9223		Max PEC _{gw} Based on: 3.256	3.256 µg/L Focus PEARL 4.4.4 Jokioinen BBCH 21 Thiophene pathway Focus PEARL 4.4.4 4.149 µg/L Jokioinen
Thifensulfuron-methyl	IN-JZ789		Max PEC _{gw} Based on:	1.312 µg/L Focus PEARL 4.4.4 Hamburg

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Thifensulfuron-methyl	IN-L9225		Max PEC _{gw}	1.090 µg/L
			Based on:	Focus PEARL 4.4.4 Porto
Thifensulfuron-methyl	2-acid-2-triuret		Max PEC _{gw}	0.296 µg/L
			Based on:	Focus PEL-MO 5.5.3 Piacenza PEARL Thiophene pathway, Triazine pathway 0.308 µg/L Hamburg BBCH 21
Thifensulfuron-methyl	IN-A4098		Max PEC _{gw}	0.336 µg/L
			Based on:	Focus PEL-MO 5.5.3. Hamburg
Thifensulfuron-methyl	IN-A5546		Max PEC _{gw}	0.116 µg/L
			Based on:	Focus PEL-MO 5.5.3. Hamburg Triazine pathway BBCH 21 0.198 Jokioinen BBCH 21
Metsulfuron-methyl	IN-A4098		Max PEC _{gw}	0.250 µg/L
			Based on:	Focus PEARL 4.4.4 Hamburg

10.2 Relevance assessment of IN-JZ789

Comments of	- According to available toxicological data, the metabolite IN-JZ789 is con-
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ZRMs:	<p>sidered not genotoxic.</p> <ul style="list-style-type: none"> - The parent substance is not classified in regards to mammalian toxicology (RAC Opinion, 2016). Thus, it is also not necessary to consider the relevance of the metabolite. - The maximum PEC_{gw} of IN-JZ789 (acc. to the application rate presented in the GAP Table) amounts to 1.312 µg/L. - Since the predicted max. PEC_{gw} value is above the upper limit for metabolites (≥ 0.75 µg/L), the consumer risk calculation for this metabolite is required. Acc. to EFSA Journal 2015;13(7):4201, <u>the reference value of the parent substance might apply to the metabolite IN-JZ789</u>. The results of risk calculations are presented in table below: <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Exposure (µg/kg b.w./d)</th> <th>% ADI (parent substance)</th> </tr> </thead> <tbody> <tr> <td>Adults (70¹/60² kg b.w.)</td> <td>0.037/0.044</td> <td>0.37/0.44</td> </tr> <tr> <td>Toddlers (12¹/10² kg b.w.)</td> <td>0.11/0.13</td> <td>1.1/1.3</td> </tr> <tr> <td>Infants (5^{1,2} kg b.w.)</td> <td>0.2</td> <td>2</td> </tr> </tbody> </table> <p>Conclusions:</p> <p>Taking into account all toxicological data, the metabolite IN-JZ789 is considered toxicologically non-relevant. The results of consumer risk calculations indicate that the use of TOTO 75/ TYTAN 75/ HERKULES 75 according to the list of intended uses presented in GAP Table, causes no risk for health for the adults, toddlers and infants.</p> <p>¹According to EFSA Journal 2012;10(3):2579, Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.</p> <p>²WHO Guidelines for drinking-water quality: fourth edition incorporating the first addendum, 2017</p>		Exposure (µg/kg b.w./d)	% ADI (parent substance)	Adults (70 ¹ /60 ² kg b.w.)	0.037/0.044	0.37/0.44	Toddlers (12 ¹ /10 ² kg b.w.)	0.11/0.13	1.1/1.3	Infants (5 ^{1,2} kg b.w.)	0.2	2
	Exposure (µg/kg b.w./d)	% ADI (parent substance)											
Adults (70 ¹ /60 ² kg b.w.)	0.037/0.044	0.37/0.44											
Toddlers (12 ¹ /10 ² kg b.w.)	0.11/0.13	1.1/1.3											
Infants (5 ^{1,2} kg b.w.)	0.2	2											

Summary:

The relevance of the groundwater metabolite IN-JZ789 has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for IN-JZ789

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	Yes
groundwater	STEP 2	Max PEC _{gw}	1.312 µg/L

			Based on	PEC _{gw} for IN-JZ789 is 1.315. (RAR/ EFSA 2015)
Hazard assessment	STEP 3	Stage 1	No	No
		Stage 2	Non-genotoxic	Non-genotoxic
		Stage 3	Not toxic or very toxic (T or T+)	Not toxic or very toxic (T or T+)
			not currently classified as toxic or very toxic	not currently classified as toxic or very toxic
		not currently classified as toxic or very toxic	not currently classified as toxic or very toxic	
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	>0.75 µg/L
	STEP 5	Refined risk assessment		Required
		Predicted exposure (% of ADI)		No acute or repeated dose toxicity studies are available for IN-JZ789. However, given the close structural similarity between Thifensulfuron methyl and IN-JZ789, a similar hazard profile is expected. Therefore, the MAC value set for the parent (0.03 mg/L) can be used for the risk assessment of IN-JZ789. Comparison of the MAC with the maximum PEC _{gw} of 1.315 µg/L shows a ~23-fold safety margin. This margin is sufficiently large to conclude that IN-JZ789 poses no unacceptable risks to consumers through drinking water.
			ADI based on	Thifensulfuron-methyl (MAC value)

* N/A: not applicable

10.3 Relevance assessment of IN-L9223

Comments of ZRMs:	<ul style="list-style-type: none"> - According to the available toxicological data, the metabolite IN-L9223 is considered to be not genotoxic and has no pesticidal activity. The studies provided by the Applicant (Smagur and Mazur, 2015 and Antonik, 2015) have not revealed the genotoxic potential of the metabolite IN-L9223 in regards to mammalian cells under <i>in vitro</i> conditions (<i>In Vitro</i> Mammalian Cell Gene Mutation Test and <i>In Vitro</i> Mammalian Cell Micronucleus Test). - However, the toxicological profile of this metabolite is incomplete for full consumer risk assessment and <u>does not allow to establish a reference dose</u> (data gap). The results generated with OECD QSAR toolbox indicate that IN-L9223 might be more toxic than the parent substance (predicted oral LD50 value) (RAR, Thifensulfuron-methyl - Volume 3, Annex B.6 : Toxicology and Metabolism). - The parent substance is not classified in regards to mammalian toxicology (RAC Opinion, 2016). Thus, it is also not necessary to consider the relevance of the metabolite. - The maximum PEC_{gw} of IN-L9223 (acc. to the application rate presented in
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	the GAP table) amounts to 4.149 µg/L.				
	<ul style="list-style-type: none"> - Since the predicted max. PEC_{gw} value is above the upper limit for metabolites (≥ 0.75 µg/L), the consumer risk calculation for this metabolite is required. - Although <u>no reference dose has been established for this metabolite</u>, the consumer exposure with drinking water was assessed using <u>maximum allowable concentration (MAC) based on 10% of thifensulfuron - methyl of ADI value</u>. The results of risk calculations are presented in table below (noteworthy, new default body weight values¹ were employed). 				
		MAC (µg/L) (based on 10% ADI, as conservative approach)	Exposure (µg/kg b.w./d)	% of MAC	% ADI (parent substance)
	Adults (70 ¹ /60 ² kg b.w.)	35/30	0.12/0.14	11.9/13.9	1.2/1.4
	Toddlers (12 ¹ /10 ² kg b.w.)	12/10	0.35/0.41	34.6/41.5	3.5/4.1
Infants (5 ^{1,2} kg b.w.)	7	0.62	59.3	6.2	
¹ According to EFSA Journal 2012;10(3):2579, Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.					
² WHO Guidelines for drinking-water quality: fourth edition incorporating the first addendum, 2017					

Summary:

The relevance of the groundwater metabolite IN-L9223 has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.3-1 and the corresponding studies are listed in the corresponding sections..

Table 10.3-1: Summary of the relevance assessment for IN-L9223

	Assessment step		Result of assessment	
HAZ- ard ass- ess cation of ground- water contami-	STEP 1		Metabolite of no concern?	Yes
	STEP 2		Max PEC _{gw}	3.498 4.149 µg/L
			Based on	PEC _{gw} for IN-L9223 is 3.498 µg/L. (RAR/ EFSA 2015)
HAZ- ard ass- ess	STEP 3	Stage 1	Biological activity comparable to the parent?	No

		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic (T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	>0.75 µg/L
	STEP 5		Refined risk assessment	Required
		Predicted exposure (% of ADI)	Estimates from the OECD QSAR toolbox submitted from the EU TSM Task Force indicate that IN-L9223 might be more acutely toxic than the parent compound (mainly on the basis of a oral LD50). It would be prudent to assume that IN-L9223 is more toxic than the parent. Therefore, is it proposed to lower the MAC value set for the parent (0.6 mg/L) by a factor of 10. Comparison of the IN-L9223 MAC value of 0.06 mg/L with the maximum PECgw of 3.498 µg/L shows a 17-fold safety margin, which confirms that IN-L9223 poses no unacceptable risks to consumers through drinking water.	
		ADI based on	Thifensulfuron-methyl (MAC value)	

* N/A: not applicable

10.4 Relevance assessment of IN-L9225

Comments of ZRMs:	<ul style="list-style-type: none"> - According to the available toxicological data, the metabolite IN-L9225 is considered not genotoxic. It has lower or equal toxicity in comparison to the parent substance (28-d rat study) and has no pesticidal activity. - The studies provided by the Applicant (Smagur and Mazur, 2015 and Antonik, 2015) have not revealed the genotoxic potential of the metabolite IN-L9225 in regards to mammalian cells under <i>in vitro</i> conditions (In Vitro Mammalian Cell Gene Mutation Test and In Vitro Mammalian Cell Micro-nucleus Test). - The maximum PECgw of IN-L9225 (acc. to the application rate presented in the GAP table) amounts to 1.090 µg/L. - Since the predicted max. PECgw value is above the upper limit for metabolites (≥ 0.75 µg/L), the consumer risk calculation for this metabolite is required. Acc. to EFSA Journal 2015;13(7):4201, <u>the reference value of the parent substance might apply to the metabolite IN-L9225</u>. The results of risk
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calculations are presented in table below:		
	Exposure (µg/kg b.w./d)	% ADI (parent substance)
Adults (70 ¹ /60 ² kg b.w.)	0.03/0.04	0.3/0.4
Toddlers (12 ¹ /10 ² kg b.w.)	0.09/0.11	0.9/1.1
Infants (5 ^{1,2} kg b.w.)	0.16	1.6
<p>Conclusions:</p> <p>Taking into account all of the toxicological data, the metabolite IN-L9225 is considered toxicologically non-relevant. The results of consumer risk calculations indicate that the use of TOTO 75/ TYTAN 75/ HERKULES 75 according to the list of intended uses presented in GAP Table, causes no risk for health for the adults, toddlers and infants.</p> <p>¹According to EFSA Journal 2012;10(3):2579, Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.</p> <p>²WHO Guidelines for drinking-water quality: fourth edition incorporating the first addendum, 2017</p>		

Summary:

The relevance of the groundwater metabolite IN-L9225 has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.4-1 and the corresponding studies are listed in the corresponding sections..

Table 10.4-1: Summary of the relevance assessment for IN-L9225

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Hazard assessment of ground-water contamination	STEP 2		Max PEC _{gw}	1.090 µg/L
			Based on	PEC _{gw} for IN-L9223 is 1.163 µg/L. (RAR/ EFSA 2015)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No

		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic (T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	>0.75 µg/L
	STEP 5		Refined risk assessment	Required
			Predicted exposure (% of ADI)	Given the very close structural similarity between Thifensulfuron methyl and IN-L9225, a similar hazard profile is expected. Therefore, the MAC value set for the parent (0.6 mg/L) can be used for the risk assessment of IN-L9225. Comparison of the MAC with the maximum PEC _{gw} of 1.163 µg/L shows a ~500-fold safety margin. This margin is sufficiently large to conclude that IN-L9225 poses no unacceptable risks to consumers through drinking water.
			ADI based on	Thifensulfuron-methyl (MAC value)

10.5 Relevance assessment of IN-A4098

Comments of ZRMs:	<ul style="list-style-type: none"> - Acc. to EFSA Journal 2015;13(7):4201, the metabolite IN-A4098 has no pesticidal activity and has moderate acute toxicity (noteworthy, higher than the parent substance). It might be a concern for consumer exposure because the presented results exceed the limit for the relevant metabolites, i.e. 0.01 µg/L. - Acc. to report <i>Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thifensulfuron-methyl in light of confirmatory data</i>, further discussion on IN-A4098 (triazine amine, common metabolite for many active substances) is not proposed given that the EFSA PPR panel is currently assessing IN-A4098. - Due to the fact that further toxicological data is needed to perform consumer risk assessment, the Applicant provided two genotoxicity test. The results of the studies (Smagur and Mazur, 2015 and Antonik, 2015) has not revealed the genotoxic potential of the metabolite IN-A4098 in regards to mammalian cells under <i>in vitro</i> conditions (In Vitro Mammalian Cell Gene Mutation Test and In Vitro Mammalian Cell Micronucleus Test). - The predicted max. PEC_{gw} value is below the upper limit for metabolites (0.75 µg/L). Thus, the consumer risk calculation for this substance is not provided.
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Summary:

The relevance of the groundwater metabolite IN-A4098 has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.5-1 and the corresponding studies are listed in the corresponding sections..

Table 10.5-1: Summary of the relevance assessment for IN-A4098

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.586 0.336 µg/L (sum of metabolite from two active substance)
			Based on	PEC _{gw} for IN-A4098 is 0.772 µg/L. (RAR/ EFSA 2015)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic (T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	≥0.75 µg/L
	STEP 5		Refined risk assessment	Required

	Predicted exposure (% of ADI)	<p>Estimates from the OECD QSAR toolbox submitted by the EU TSM Task Force also suggest that IN-A4098 might be more actually toxic than the parent compound (mainly on the basis of the predicted oral LD50 value of 800-1200 mg/kg bw). In the absence of any further data, it would be prudent to assume that IN-A4098 of 0.06 mg/L. Comparison of the IN-14098 MAC value of 0.06 mg/L (60 µg/L) with its maximum PEC_{gw} of 0.772 µg/L shows a ~77 fold safety margin. On the basis of this margin, it is possible to conclude that IN-A4098 poses no unacceptable risks to consumers through drinking water.</p>
	ADI based on	Thifensulfuron-methyl (MAC value)

10.6 Relevance assessment of IN-A5546

Comments of ZRMs:	<ul style="list-style-type: none"> - Acc. to EFSA Journal 2015;13(7):4201, the toxicological data is not sufficient to conclude on genotoxic potential of IN-A5546 (i.e. an <i>in vitro</i> clastogenicity assay is missing and <i>in vivo</i> Micronucleus tests provides no evidence that the bone marrow was reached). It might be a concern for consumer exposure because the results exceed the limit for the relevant metabolites, i.e. 0.01 µg/L. - Due to the fact that the toxicological profile (including genotoxicity tests) of the metabolite IN-A5546 is needed to perform consumer risk assessment, the Applicant provided the results of the study (Antonik, 2016) which did not revealed the genotoxic potential of the metabolite IN-A5546 in regards to mammalian cells under <i>in vitro</i> conditions (In Vitro Mammalian Cell Gene Mutation Test). - EFSA considered (<i>Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thifensulfuron-methyl in light of confirmatory data, 2019</i>) that the available confirmatory data on IN-A5546 did not raise concerns for genotoxicity. - The predicted max. PEC_{gw} value is below the upper limit for metabolites (0.75 µg/L). Thus, the consumer risk calculation for this substance is not provided.
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Summary:

The relevance of the groundwater metabolite IN-A5546 has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of

the relevance assessment is given in Table 10.6-1 and the corresponding studies are listed in the corresponding sections..

Table 10.6-1: Summary of the relevance assessment for IN-L9223

	Assessment step		Result of assessment	
tion of groundwa- ter	STEP 1		Metabolite of no concern?	Yes
	STEP 2		Max PEC _{gw}	0.116 0.198 µg/L
			Based on	
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic (T or T+)
	Classification of parent		not currently classified as toxic or very toxic	
		Classification of metabolite	not currently classified as toxic or very toxic	
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	<0.75 µg/L
	STEP 5	Refined risk assessment		Not required
		Predicted exposure (% of ADI)		Not required
		ADI based on		Not required

10.7 Relevance assessment of 2-acid-2-triuret

Comments of ZRMs:	<ul style="list-style-type: none"> - Acc. to EFSA Journal 2015;13(7):4201, the toxicological data on the metabolite 2-acid-3-triuret is not available. - The parent substance is not classified in regards to mammalian toxicology (RAC Opinion, 2016). Thus, it is also not necessary to consider the relevance of the metabolite. - The maximum PEC_{gw} of 2-acid-3-triuret (acc. to the application rate presented in the GAP table) amounts to 0.334 µg/L and is below the upper limit for metabolites (<0.75 µg/L).
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Summary:

The relevance of the groundwater metabolite 2-acid-2-triuret has already been assessed and the assessment agreed at EU level (see reference to appropriate RAR Volume 1 2015, EFSA conclusion etc), and the relevance assessment is applicable for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). Therefore, no new risk assessment is necessary (see 10.1.4-10.1.5). Metabolite is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.7-1 and the corresponding studies are listed in the corre-

sponding sections..

Table 10.7-1: Summary of the relevance assessment for 2-acid-2-triuret

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
cation of ground-water contaminant	STEP 2		Max PEC _{gw}	0.296 µg/L
			Based on	PEC _{gw} for IN-L9223 is 0.305 µg/L. (RAR/ EFSA 2015)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic (T or T+)
	Classification of parent		not currently classified as toxic or very toxic	
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	<0.75 µg/L
	STEP 5	Refined risk assessment		Not required
		Predicted exposure (% of ADI)		Not required
		ADI based on		Not required

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information