FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **TERBUT 500 SC**

Product name(s): **TERBUT 500 SC/**

TAZOPRYM 500 SC / CORNAO 500 SC

Chemical active substance:

Terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 03/2021; 03/2022; 05/2022; **06/2022**

Version history

When	What
03/2021	Additional information about uses Terbut 500 SC with adjuvant (Point 7.2.3.2).
03/2021	ZRMS assessment
03/2022	Final Registration Report
05/2022	Review of the assessment taking into account Reg. (EU) 2021/1795
June 2022	Review of the assessment taking into account Commission Implementing Regulation (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine

Table of Contents

7 Metabolism and residue data (KCA section 6) 4

7.1 Summary and zRMS Conclusion 4
7.1.1 Critical GAP(s) and overall conclusion 6
7.1.2 Summary of the evaluation 9
7.1.2.1 Summary for terbuthylazine 9
7.1.2.2 Summary for TERBUT 500 SC 9
7.2 Terbuthylazine 11
7.2.1 Stability of Residues (KCA 6.1) 12
7.2.1.1 Stability of residues during storage of samples 12
7.2.1.2 Stability of residues in sample extracts (KCA 6.1) 12
7.2.2 Nature of residues in plants, livestock and processed commodities 12
7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) 12
7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) 13
7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) 15
7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 16
7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 16
7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 17
7.2.3 Magnitude of residues in plants (KCA 6.3) 18
7.2.3.1 Summary of European data and new data supporting the intended uses 18
7.2.3.2 Conclusion on the magnitude of residues in plants 20
7.2.4 Magnitude of residues in livestock 21
7.2.4.1 Dietary burden calculation 21
7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 23
7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 24
7.2.6 Magnitude of residues in representative succeeding crops 24
7.2.7 Other / special studies (KCA6.10, 6.10.1) 24
7.2.8 Estimation of exposure through diet and other means (KCA 6.9) 24
7.2.8.1 Input values for the consumer risk assessment 24
7.2.8.2 Conclusion on consumer risk assessment 24
7.3 Combined exposure and risk assessment 25
7.4 References 26

Appendix 1 Lists of data considered in support of the evaluation 27

Appendix 2 Detailed evaluation of the additional studies relied upon 34

Appendix 3 Pesticide Residue Intake Model (PRIMo 3) 34

A 3.1 TMDI calculations 34
A 3.2 IEDI calculations 36
A 3.3 IESTI calculations - Raw commodities 36
A 3.4 IESTI calculations - Processed commodities 37

Appendix 4 Additional information provided by the applicant 38

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Parts highlighted in grey were written by zRMS.

Commission Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.

Stability of residues

According to EFSA, 2011, residues of terbuthylazine and its metabolites in cereal samples are considered to be stable at least for 24 months at -18°C.

Metabolism

All metabolism data are active substance data and were evaluated in the EU review. The intended uses are covered by the available metabolism studies reported in the EU.

Plant residue definition for monitoring Terbuthylazine (MT0) (EFSA, 2011, 2020; ~~Regulation n°149/2008~~ Reg. (EU) 2021/1795)

Plant residue definition for risk assessment Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14) (EFSA, 2011, 2017, 2020)

Conversion factor from enforcement to RA Not necessary for maize grains (all residue data <LOQ) (EFSA 2011,2020)

Animal residue definition for monitoring and risk assessment (EFSA Journal 2020;18(1):59800):

Ruminants

Milk: Sum of terbuthylazine and MT1, expressed as terbuthylazine

Muscle, fat, liver and kidney: open

Pigs: not triggered; Poultry: not triggered

Magnitude of residues in plants

Proposed GAP: maize, 1 application, BBCH 00 and 12-16); Application rate per treatment: 0.5 kg a.s./ha. Proposed GAP is less critical than EU GAP.

Maize is a major crop in Northern Europe. Therefore, 8 NEU trials are required to support the proposed use.

GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, , pre-emergence and BBCH 12-16 PHI is not relevant, outdoor

No new data are submitted in the framework of this application.

EU unprotected trials results:
E (mg/kg): 8 X <0.02 mg/kg
RA (mg/kg):
MT0: 8x <0.02
MT1: 8x <0.02
MT14: 8x <0.02

Total residues: 8x <0.06 mg/kg
Forage (mg/kg):
MT0: 8x <0.02
MT1: 8x <0.02
MT14: 7x <0.02, 0.03
Total residues: 7x <0.06, 0.07 mg/kg
The data submitted show that no exceedance of the MRL will occur.

The presented data are sufficient to agree to uses Terbut 500 SC together with an adjuvant.

~~**Note:** MRL for terbutylazine in maize was proposed to change from 0.1 mg/kg to 0.01* mg/kg (SANTE/10444/2020)~~

~~The new Regulation has not been published yet and therefore it is not in place. New information to justify the application should be provided after the entry into force of the new Regulation.~~

05/2022 Review of the assessment taking into account Reg. (EU) 2021/1795

COMMISSION REGULATION (EU) 2021/1795 of 11 October 2021 correcting Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for terbuthylazine in or on certain products

In the afore mentioned Regulation it is stated: *Commission Regulation (EU) 2021/618 amended Regulation (EC) No 396/2005 by establishing the MRLs of terbuthylazine in sweet corn, maize/corn and sorghum erroneously at the level of 0,01 mg/kg instead of 0,02 mg/kg, which is the correct limit of quantification (LOQ). The LOQ of 0,02 mg/kg is in line with the reasoned opinion of the European Food Safety Authority on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005 .*

zRMS conclusion:

The data submitted show that no exceedance of the new MRL (0.02* mg/kg) will occur.

* - LOQ

Uses are acceptable

Magnitude of residues in livestock

The data evaluated during the Annex I inclusion of terbuthylazine are considered sufficient. No further studies are required.

Processing studies

EFSA Journal 2020;18(1):5980: *Standard hydrolysis studies are not available and were not considered necessary because residues of terbuthylazine in primary crops were below limit of quantification (LOQ).*

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No further studies have been performed

Magnitude of residues in representative succeeding crops

EFSA Journal 2020;18(1):5980: *Residues in following crops are expected to be low. However, residues of MT1 and MT14 above the LOQ occur in sunflower seeds, rape seeds, sugar beet tops and cereal straw however not at PBIs above 1 year.*

Risk mitigation measures recommended for rotational crops: one year plant-back interval or deep ploughing (more than 20 cm soil mixing) to dilute soil concentrations noting that a ploughing depth of 30 cm reduces soil residues by a factor of 1.5 and a ploughing depth of 40 cm by 50 %. (according to the EFSA Journal 2020;18(1):5980)

Estimation of exposure through diet and other means

The proposed uses of terbuthylazine in the formulation Terbut 500 SC do not represent unacceptable acute and chronic risks for the consumer.

The new MRL value (maize/corn) does not affect the assessment result.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation TERBUT 500 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for maize. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of ~~0.1~~ 0.02 mg/kg for terbuthylazine as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of terbuthylazine residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- none.

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situa-tion ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Maize (post-emergence)	PL	Terbut 500 SC	F	**Sensitive:** *Capsella bursa-pastoris* *Viola arvensis* *Chenopodium album* *Amaranthus retroflexus* *Galium aparine* *Tripleurospermum inodorum* *Veronica arvensis* *Fallopia convolvulus* *Solanum nigrum* *Matricaria Chamomilla* **Medium sensitive**: *Cyanus segetum* *Stellaria media*	SC	500 g/l	Fine spraying	BBCH 12-16	1	-	-	200	0.500 kg a.s./ha	Not relevant	A Commission Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.
					Sensitive: *Chenopodium album* *Viola arvensis* *Amaranthus retroflexus* *Galium aparine* *Tripleurospermum inodorum* *Capsella bursa-pastoris* *Veronica arvensis* *Fallopia convolvulus* *Solanum nigrum* *Matricaria Chamomilla* *Stellaria media* **Medium sensitive:** *Cyanus segetum*	SC	500 g/l	Fine spraying	BBCH 12-16	1	-	-	200-300	0.500 kg a.s./ha (with 0,2 l/ha of adiuwant)		
2	Maize (pre-	PL	Terbut 500 SC	F	**Sensitive:** *Chenopodium album*	SC	500 g/l	Fine spraying	BBCH 00	1	-	-	200-300	0.500 kg a.s./ha	Not relevant	A Commission

	emergence)				*Viola arvensis* *Amaranthus retroflexus* *Tripleurospermum inodorum* *Matricaria Chamomilla* **Medium sensitive:** *Stellaria media* *Cyanus segetum*										Implementing Regulation (EU) 2021/824 of 21 May 2021: Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.
					Sensitive: *Viola arvensis* *Amaranthus retroflexus* *Tripleurospermum inodorum* *Capsella bursa-pastoris* *Matricaria Chamomilla* **Medium sensitive:** *Fallopia convolvulus* *Geranium pusillum* *Galium aparine* *Cyanus segetum* *Stellaria media*	SC	500 g/l	Fine spraying	BBCH 00	1	-	-	200-300	0.500 kg a.s./ha (with 0,2 l/ha of adiuwant)	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation TERBUT 500 SC is composed of terbuthylazine.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of terbuthylazine

Reference value	Source	Year	Value	Study relied upon	Safety factor
Terbuthylazine					
ADI	EFSA	2011	0.004 mg/kg bw per day	1-year dog and 2-year rat studies	100
ARfD	EFSA	2011	0.008 mg/kg bw	Toxicity studies in rabbits	100

7.1.2.1 Summary for terbuthylazine

Table 7.1-3: Summary for terbuthylazine

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1.	Maize	Yes	Yes	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The proposed uses of terbuthylazine in the formulation TERBUT 500 SC do not represent unacceptable acute and chronic risks for the consumer.

As residues of terbuthylazine do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

7.1.2.2 Summary for TERBUT 500 SC

Table 7.1-4: Information on TERBUT 500 SC (KCA 6.8)

Crop	PHI for TERBUT 500 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for TERBUT 500 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Terbuthylazine		
Maize	-	NR (pre-harvest interval is covered by the growing period remaining between envisaged application and harvest)		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		**Overall waiting period proposed by zRMS for TERBUUT 500 SC**
Crop group	**Led by terbuthylazine**	
Leafy vegetables	NR	
Root vegetables	NR	

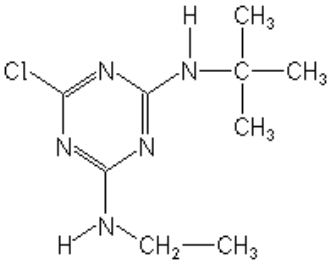
NR: not relevant

Assessment

7.2 Terbuthylazine

General data on terbuthylazine are summarized in the table below

Table 7.2-1: General information on terbuthylazine

Active substance (ISO Common Name)	Terbuthylazine
IUPAC	N-tert-butyl-6-chloro-N'-ethyl-1,3,5-triazine-2,4-diamine
Chemical structure	
Molecular formula	$C_9H_{16}ClN_5$
Molar mass	229.710 g/mol
Chemical group	Triazine
Mode of action (if available)	Inhibition of photosynthesis at photosystem II
Systemic	No
Company (ies)	Syngenta Crop Protection
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of (01/01/2012) and reference to decision (COMMISSION DIRECTIVE REGULATION (EU) No 2019/291 of 19 February 2019) https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1550659094284&uri=CELEX:32019R0291
Restriction	-
Review Report	SANCO/11337/2011– rev. 2 17/06/2011
Current MRL regulation	~~Regulation (EC) No 149/2008~~ Reg. (EU) 2021/1795
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes (EFSA, 2017 – see reference list) EFSA-Q-2017-00035
EFSA Journal: conclusion on article 12	Yes (EFSA, 2020 – see reference list) EFSA-Q-2009-00077
Current MRL applications on intended uses	~~COMMISSION REGULATION (EC) No 149/2008 of 29 January 2008 amending regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto~~

	none

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain and straw	High starch content	24 months	United Kingdom, 2010

Conclusion on stability of residues during storage

All data on the stability of residues are active substance data and were evaluated in the EU review of terbuthylazine. The data demonstrated the stability of residues of terbuthylazine/MT0, GS 26379/MT1 and GS 28620/MT14 in cereal commodities up to 24 month at ≤ - 18°C (United Kingdom, 2007).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data available.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								

Cereals	Maize	[triazine-U-^{14}C]-terbuthylazine	Foliar treatment, F	1.45-1.47 kg a.s./ha	1	131	3-4 leaf stage	United Kingdom, 2010
Cereals	Maize	[triazine-U-^{14}C]-terbuthylazine	Soil spray application, F	1.50 kg a.s./ha	1	153		United Kingdom, 2010

Summary of plant metabolism studies reported in the EU

The residues in maize as a result of application of [triazine-U-^{14}C]-terbuthylazine at 1.45 kg a.s./ha and also 1.50 kg a.s./ha can be considered sufficiently characterized and relevant fractions identified.
Once absorbed terbuthylazine is distributed over the whole plant with the highest levels seen in leaves and stem and only trace levels seen in the grain at the full ripe stage. Residues of terbuthylazine (MT0) are generally low – especially in grain indicating that terbuthylazine is metabolized rapidly. It appears that terbuthylazine is mainly metabolized into polar conjugates: in foliage the residue comprised a complex mixture of components and in the grain no single component of the residue exceeded 0.1 mg/kg. The major component of the residue is MT14/GS 28620. In grain MT14, while representing a large proportion of the TRR, accounted for a small mass of residue (<0.01 mg/kg). In no part of the maize plant did MT1 represented more than 5% TRR (0.003 mg/kg) at harvest. Extractabilities were generally sufficiently high and characterization of components in the extracted fractions was adequate.

Conclusion on metabolism in primary crops

After foliar application, it has been shown that terbuthylazine residues are distributed over the whole plant, with highest levels on the total applied radioactivity in leaves and stems and only low residue level found in ears. It appears that terbuthylazine degrades rapidly in maize plants so that only very low levels of the terbuthylazine/MT0 (up to a maximum 0.012 mg/kg in stems) remain in the plant at harvest of silage maize or grain maize. With up to 83% of the total radioactivity at harvest, terbuthylazine is mainly metabolised into polar conjugates. Furthermore, 2-hydroxy-terbuthylazine (M13), desethyl-2-hydroxy-terbuthylazine (M14), and desethyl-terbuthylazine (MT1) were found with >0.01 mg/kg fresh weight in whole plants.
Following single application of terbuthylazine to the soil at a rate of 1.5 kg/ha, residues in maize plants were: 0.055-0.287 mg/kg in the forage, 0.281 mg/kg in fodder and 0.02 mg/kg in grain.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118 DAT (variety Rexado); 364 DAT (variety	64 days after planting (variety Rexado); 69 days after	-	United Kingdom, 2010

					Sunny)	planting (variety Sunny);		
	Spinach	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120, 329 days	30 day ageing period: 58-70 DAT and 120 DAT; 120 day ageing period: 136-156 DAT and 434 DAT; 329 day ageing period: 409 and 436 DAT	-	United Kingdom, 2010
Root and tuber vege-tables	Radish	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118 DAT (variety Rex) 364 DAT (variety Selma 84)	64 days after planting (variety Rex); 69 days after planting (variety Selma 84);	Crops were separated into leaves (tops) and roots	United Kingdom, 2010
	Radish	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120, 329 days	30 day ageing period: 58-70 DAT and 120 DAT; 120 day ageing period: 136-156 DAT and 434 DAT; 329 day ageing period: 409 and 436 DAT	-	United Kingdom, 2010
Cereals	Spring and winter wheat	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118 DAT for spring wheat (variety Lona) 364 DAT for winter wheat (variety Galaxie) and spring wheat (variety Lona 2)	Spring wheat (variety Lona): 64, 130 days after sowing; Spring wheat (variety Lona 2): 104, 132 days after sowing; Winter wheat (variety Galaxie): 48, 251, 302 days after sowing	-	United Kingdom, 2010

	Summer and winter wheat	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120, 329 days	30 day ageing period: 58-70 DAT and 120 DAT; 120 day ageing period: 136-156 DAT and 434 DAT; 329 day ageing period: 409 and 436 DAT	-	United Kingdom, 2010

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

There were very low levels of non-extractible residues in leafy crops (lettuce) and roots crops (radish roots) but very high levels of non-extractible residues at harvest (up to 73.6% of TRR in grain of spring wheat (118 day plant back) harvested at full maturity. The grain non-extractables were further analysed: the glucose fraction, analysed as glucosazone, amounted to 23.5%, cellulose accounted for 4.7% and the protein fraction for a small percentage of TRR. No additional metabolite fractions were found in extracts on the grain non-extractable analysis. The results indicate that the ^{14}C-labelled break down products of the active substance have been incorporated into the plant matrix.
The simulation of different crop scenarios by ageing a sandy soil (sandy loam) treated with ^{14}C-terbuthylazine for different periods (30, 120 and 329 days) under natural conditions showed uptake of radioactivity by the plants. The study with spinach, radish and spring/winter wheat shows that most of the radioactive residues were found in the non-edible parts of plants. The residue levels in mature harvest material were lower than in immature plant parts.

Conclusion on metabolism in rotational crops

One of the studies with four rotational crops, which were planted according to procedures simulating normal agriculture practice i.e. lettuce, radish and spring wheat at 118 days and 364 days after treatment and winter wheat 182 days after soil treatment. The total radioactive residues in this study were very low at maturity (0.02 – 0.049 mg/kg) enough radioactivity was present to be able to identify and quantify the metabolites present.
The second outdoor study was with three rotational crops: spinach, radish and wheat at 30 days and 120 days after treatment and winter wheat 329 days after soil treatment. Analysis after 30 days plant back demonstrate that for human food commodities such as radish root and wheat grain that parent and metabolites are below 0.01 mg/kg.
The total radioactive residues in food items from typically rotated crops grown in soil treated at 1.5 kg a.s./ha were low, i.e. ≤ 0.05 mg/kg, except grain from spring wheat planting 118 DAT. No individual component of the residues represented >0.015 mg/kg.
Residues in radish foliage and immature wheat were higher and could be regarded as models for other crops not covered in the rotational crops study.
The nature of residues in rotational crops is the same as those identified in the primary crop (maize).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Processing studies were not submitted and are not required because of the low residue level in grain (EF-

SA, 2011).

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (maize) as foliar and soil treatment
Rotational crops covered	Leafy vegetables (Lettuce and spinach) Root and tuber vegetables (Radish) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	None
Residue pattern in processed commodities similar to pattern in raw commodities?	No statement can be made as no processing studies were submitted/evaluated
Plant residue definition for monitoring	Terbuthylazine (MT0) (~~Reg. (EC) No 149/2008~~ Reg. (EU) 2021/1795)
Plant residue definition for risk assessment	Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14) (EFSA, 2011)
Conversion factor from enforcement to RA	Not necessary for maize grains (all residue data <LOQ)

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	**Species**	**Label position**	**No of animal**	**Application details**		**Sample details**		**Reference**
				Rate (mg/kg bw/d)	**Duration (days)**	**Commodity**	**Time of sampling**	
EU data								
Lactating ruminants	Cow	[triazine-U-^{14}C]-terbuthylazine	1 control, 1 dosed animal	39 mg per day	10 days	Milk	daily	United Kingdom, 2010; EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

A cow metabolism study was provided where animals were dosed with ^{14}C-terbuthylazine over 10 days at

a dose rate calculated to represent a 18N and 15N dose rate for diary and beef cattle respectively. This study has however to be considered as not appropriate to propose a residue definition as no characterisation was performed in animal tissues, except in milk where MT1 and MT20 were identified as major metabolites (*c.a.* 50% and 12% TRR). Considering that TRRs are expected to be <0.01 mg/kg in milk, muscle and fat and <0.05 mg/kg in liver and kidney when expressed on a 1N dose basis, it was concluded that no significant residues of any metabolite are expected to be present in animal matrices. The setting of a residue definition and proposals for MRLs for animal products were therefore considered not necessary with regard to the representative uses (EFSA, 2011).

Conclusion on metabolism in livestock

The results of study appear to demonstrate that metabolism of terbuthylazine is rapid and its metabolites are eliminated from the animal quickly. Approximately 80% of the applied radioactivity was excreted in the urine with small amounts remaining in tissue and milk (0.4 and 0.1% TRR respectively).
Residues in tissues were significant (at the exaggerated dose rate of the study, 10N/13N). Residues as terbuthylazine equivalents in liver and kidney were 0.9 mg/kg and 0.6 mg/kg respectively and in other tissues between 0.02-0.5 mg/kg.
Residues in milk were lower than in tissue but were significant (at the exaggerated dose rate of the study, 10N/13N) and reached plateau after the first day. The average value for the Total Radioactive Residue (TRR) in milk was 0.082 mg/kg as terbuthylazine equivalents. Residues of metabolites in milk were also low: 0.039 mg/kg (GS 26379) and 0.005 mg/kg (GS 28273) and 0.036 mg/kg (other polar metabolites) expressed as terbuthylazine equivalents.
The study suggests that residue levels in products of animal origin are significant at the exaggerated dose rate of the study (approximately 10N in dairy cattle/13N in beef cattle). Considering the highest residues seen in tissue and milk at N rate the residues in liver and kidney could be 0.09 mg/kg (0.9 mg/kg ÷ 10) and 0.06 mg/kg (0.6 mg/kg ÷ 10) respectively (assuming 10N for dairy cattle i.e. worst case when compared with 13N for beef cattle) and in milk 0.0082 mg/kg (10N for dairy cattle: 0.082 mg/kg ÷ 10). These are the maximum possible residue levels and assume that TRR consists entirely of GS 13529/MT0 and/or GS 26379/MT1.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating cow
Time needed to reach a plateau concentration	Within 24 hours
Animal residue definition for monitoring	No data, not necessary for the representative uses (EFSA, 2011)
Animal residue definition for risk assessment	No data, not necessary for the representative uses (EFSA, 2011)
Conversion factor	n/a
Metabolism in rat and ruminant similar	n/a
Fat soluble residue	n/a

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of TERBUT 500 SC and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize	EFSA, 2011	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, pre-emergence, early post emergence (12-16), PHI n.r., outdoor E: Grain: MT0: 8x<0.02 MT1: 8x<0.02 MT14: 8x<0.02 Total residues: 8x<0.06 Forage: MT0: 8x<0.02 MT1: 8x<0.02 MT14: 8x<0.02, 0.03 Total residues: 7x<0.06, 0.07 RA: no data	N/A				
	Overall supporting data for cGAP	EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.5 kg as/ha, pre-emergence, early post emergence (12-16), PHI n.r., outdoor E: Grain: MT0: 8x<0.02 MT1: 8x<0.02	E: Grain: 0.06 Forage: 0.06 RA: -	E: Grain 0.06 Forage: 0.07 RA: -	Grain: 0.15 Forage: 0.15	~~0.1~~ 0.02*	Yes

			MT14: 8x<0.02 Total residues: 8x<0.06 Forage: MT0: 8x<0.02 MT1: 8x<0.02 MT14: 8x<0.02, 0.03 Total residues: 7x<0.06, 0.07 RA: no data					

* Source of EU MRL: ~~Reg. (EC) No 149/2008~~ Reg. (EU) 2021/1795

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize are considered acceptable, for outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

~~zRMS comment: MRL for terbutylazine in maize was proposed to change from 0.1 mg/kg to 0.01* mg/kg (SANTE/10444/2020)~~

~~The new Regulation has not been published yet and therefore it is not in place. After the entry into force of the new Regulation, new information to justify the application should be provided.~~

Proposed uses for Terbut 500 SC is also with adjuvant Hydron.
Residue studies with adjuvant have not been performed as the results of studies available at European level have been used. GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, pre-emergence, early post emergence (BBCH 12-16), PHI n.r., outdoor. The GAP presented in the residue trials at European level is more critical than the GAP proposed in the current application. The dose of the active substance in the present submission is lower and its amounts is 0.50 kg as/ha. Due to the addition of an adjuvant, the dose of active substance is reduced compared to the EU GAP. The use of an adjuvant may have an influence on the residues in the plant, while studies at the European level with an applied dose of 0.75 kg show that the residues in maize grain are below the limit of quantification (<LOQ, LOQ = 0.02) for all tasted metabolites.
No residues data are required when it is proposed that the pesticide product and adjuvant be applied before a significant part of the consumable part of the crop has developed (Health and Safety Executive 01/21). Recommended use of Terbut 500 SC in maize separately and with the adjuvant pre-emergency (BBCH 00) and post-emergence from the 2 to 6 maize leaf stage (BBCH 12-16). The risk of residues higher than LOQ after application within this period is negligible. The transport of active substances in plants from roots, stems and leaves to the grains are limited. Therefore, application of Terbut 500 SC or Terbut 500 SC with adjuvant in the BBCH 00 or BBCH 12-16 must not lead to a residue content in the grain above the LOQ.
Studies of terbuthylazine metabolism shows that terbuthylazine (MT0) and metabolites content found in the dichloromethane phase (MT13, MT14, MT1 and MT20) were below 0,0001 mg/kg in grains. The highest content of terbuthylazine and metabolites residues was obtained in leaves (68% and 52% of the activity) and stems (25% and 37% of the acticity). At the full ripe stage only 2% of TRR was found in the grain. At the full ripe stage the concentration (of metabolites in the aqueous phase) in the grains was 0.007 mg/kg. Terbuthylazine degrades rapidly in maize plants so that only low levels of MT0 remain in the plant at harvest silage maize or grain maize (Willems, 1998, DAR 2007).
Following a single application of tertuthylazine to the soil at a rate of 1.5 kg/ha in grain of maize, no single component of the residue exceeded 0,01 mg/kg. MT14 represented 20.4% TRR (total radioactive residue)/0.004 mg/kg in grain and unextracted residues represented <17.5% TRR (total radioactive residue)/0.004 mg/kg (Nicollier, 1997, DAR, 2007).
Based on data on terbutylazine metabolism in the plant:

- Terbuthylazine is distributed over the whole plant with the highest levels seens in leaves and stem and only trace lavels seen in the grain at full ripe stage.
- Residues of terbuthylazine (MT0) are generally low – especially in grain indicating that terbuthylazine is metabolized rapidly.
- It appears that terbuthylazine is mainly metabolised into polar conjugates: in grains no single component of the residue exceeded 0.1 mg/kg.
- The major component of the residue is MT14. In grain MT14, while representing a large proportion of the TRR, accounted for a small mass of residue (< 0.01 mg/kg).
- In no part of the maize plant did MT1 represent more than 5% TRR (0.003 mg/kg) at harvest.

Based on metabolism data, and taking into account that the dose of active substance was higher in the metabolism studies, it can be concluded that the risk of residue formation after use of the Terbut 500 SC

or Terbut 500 SC with adjuvant at 0.5 kg as /ha dose at the pre-emergency or post-emergency period in mazie grain will be negligible. The proposed use should not pose a risk to the consumer.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS and the uses under consideration)

Feed Commodity	Maximum dietary burden	
	Input value (mg/kg)	Comment
Sum terbuthylazine (MT0)		
Maize (grain)	0.02	Highest residue (United Kingdom, 2010)
Maize (as silage)	0.02	Highest residue (United Kingdom, 2010)
desethyl-terbuthylazine (MT1)		
Maize (grain)	0.02	Highest residue (United Kingdom, 2010
Maize (as silage)	0.02	Highest residue (United Kingdom, 2010)

Table 7.2-10: Results of the dietary burden calculation (animal model 2017)

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Terbuthylazine MT0 or metabolite GS 26379/MT1					
Dairy cattle	0.003	0.003	Corn, gluten feed	0,07	No
Dairy cattle	0.003	0.003	Corn, gluten feed	0,07	No
Lamb	0.002	0.002	Corn, gluten feed	0,04	No
Ram/Ewe	0.001	0,001	Corn, gluten feed	0,04	No
Swine (finishing)	0.001	0,001	Corn, gluten feed	0,05	No
Poultry layer	0.003	0,003	Corn, hominy meal	0,05	No
Poultry layer	0.003	0,003	Corn, hominy meal	0,05	No

All data on the dietary exposure through diet are active substance data and were evaluated in the EU review of terbuthylazine. No further review is required.

zRMS comment:
Calculation is accepted for proposed uses. According to the EFSA 2020 input values are at the limit of

quantification. CF: conversion factor between monitoring and risk assessment: 1

In the *EFSA 2020* evaluation (evaluation is still pending) calculation was done using as input values:
“

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of terbuthylazine and metabolites MT1 (desethyl-terbuthylazine) and MT14 (terbuthylazine-desethyl-2-hydroxy), expressed as terbuthylazine				
Lupin, seed	0.01*	$STMR_{Mo}$	0.01*	$STMR_{Mo}$
Lupin seed, meal	0.01*	$STMR_{Mo}$ (a)	0.01*	$STMR_{Mo}$ (a)
Sunflower, meal	0.01*	$STMR_{Mo}$ (a)	0.01*	$STMR_{Mo}$ (a)
Cotton, undelinted seed	0.01*	$STMR_{Mo}$	0.01*	$STMR_{Mo}$
Cotton, meal	0.01*	$STMR_{Mo}$ (a)	0.01*	$STMR_{Mo}$ (a)
Corn, field (Maize), grain	0.02*	$STMR_{Mo}$	0.02*	$STMR_{Mo}$
Corn, pop, grain	0.02*	$STMR_{Mo}$	0.02*	$STMR_{Mo}$
Corn, field, milled by-pdts	0.02*	$STMR_{Mo}$ (a)	0.02*	$STMR_{Mo}$ (a)
Corn, field, hominy meal	0.02*	$STMR_{Mo}$ (a)	0.02*	$STMR_{Mo}$ (a)
Corn, field, distiller's grain (dry)	0.02*	$STMR_{Mo}$ (a)	0.02*	$STMR_{Mo}$ (a)
Corn, field, gluten feed	0.02*	$STMR_{Mo}$ (a)	0.02*	$STMR_{Mo}$ (a)
Corn, field, gluten, meal	0.02*	$STMR_{Mo}$ (a)	0.02*	$STMR_{Mo}$ (a)
Sorghum, grain	0.02*	$STMR_{Mo}$	0.02*	$STMR_{Mo}$ x CF
Millet, forage	0.04	$STMR_{Mo}$ x CF(2)	0.08	HR_{Mo} x CF(2)
Corn, field, forage/silage	0.04	$STMR_{Mo}$ x CF(2)	0.08	HR_{Mo} x CF(2)
Corn, field, stover (fodder)	0.04	$STMR_{Mo}$ x CF(2)	0.04	HR_{Mo} x CF(2))
Corn, pop, stover	0.04	$STMR_{Mo}$ x CF(2)	0.04	HR_{Mo} x CF(2)
Sorghum, grain, stover	0.04	$STMR_{Mo}$ x CF(2)	0.04	HR_{Mo} x CF(2)

* Indicates that the input value is proposed at the limit of quantification. CF: conversion factor between monitoring and risk assessment which is applicable when residues according to the RD for monitoring and/or risk assessment are above LOQ.
(a): No default processing factor was applied because terbuthylazine is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.
STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

Dietary burden calculation

Relevant groups (sub-groups)	Dietary burden expressed in				Most critical subgroup (a)	Most critical commodity (b)	Trigger exceeded (Y/N)	Comments
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all)	0.0030	0.0053	0.09	0.17	Cattle (dairy)	Corn, field, forage/silage	Yes	-
Cattle (dairy only)	0.0030	0.0053	0.08	0.14	Cattle (dairy)	Corn, field, forage/silage	Yes	-
Sheep (all)	0.0014	0.0014	0.03	0.03	Sheep (lamb)	Corn, field, forage/silage	No	-
Sheep (ewe only)	0.0011	0.0011	0.03	0.03	Sheep (ram/ewe)	Corn, field, forage/silage	No	-
Swine (all)	0.0009	0.0014	0.04	0.06	Swine (breeding)	Corn, field, forage/silage	No	-
Poultry (all)	0.0021	0.0028	0.03	0.04	Poultry (layer)	Corn, field, forage/silage	No	-
Poultry (layer only)	0.0021	0.0028	0.03	0.04	Poultry (layer)	Corn, field, forage/silage	No	-
Fish	-	-	-	-	-	-	-	Not investigated.

(a): When one group of livestock includes several subgroups (e.g. poultry “all” including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as "mg/kg bw per day".
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Terbuthylazine is authorised for use on crops that might be fed to livestock. Livestock dietary burden

calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens were calculated for all animal commodities, whereby cattle (all) and dairy cattle were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock.
The metabolism of terbuthylazine residues in livestock was investigated in lactating goats and laying hens at dose rate covering the maximum dietary burdens estimated based on total radioactive residues in this review. In the ruminant metabolism study, metabolites were only characterised in milk and not in animal tissues (data gap). Based on the results of the metabolism study, in milk the following residue definitions are proposed for enforcement: sum of terbuthylazine and MT1, expressed as terbuthylazine and for risk assessment: sum of terbuthylazine and MT1, expressed as terbuthylazine. Since at the calculated dietary burden no residues are expected in this commodity, the MRL can be derived at the LOQ."

zRMS Conclusion:
The requested use on maize do not pose the risk for animal MRLs to be exceeded.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

~~The animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009.~~
The requested use on maize do not pose the risk for animal MRLs to be exceeded.

Available data

No new data were submitted in the framework of this application.

Conclusion on feeding studies

Studies are not required doe to the low level of residues of terbuthylazine in maize. The metabolites GS 13529/MT0, GS 26379/MT1 or any individual metabolite will not be found at significant levels (>0.01 mg/kg) in any edible animal tissue or milk.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. Consequently there is no requirement to address the stability of residues in processed commodities, prior to analysis.
No new data were submitted in the framework of this application.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of TERBUT 500 SC. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Terbuthylazine (MT0)				
Maize/corn	0.02*	STMR (tentative) x CF (EFSA, 2020)	0.02*	HR x CF (EFSA, 2020)
Animal origins (Bovine tissues: meat, fat, liver, kindney)	0.05	EU MRL	0.05	EU MRL

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	55 % (based on SE general)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Results for children Unprocessed commodities: Maize/corn 8% Bovine/: liver 5% Bovine: muscle/meat 5% Bovine: kidney 2% Bovine; Fat 1% Processed commodities: Maize, oil 6 % Maize, processed 0.5% Results for adults/general population Unprocessed commodities: Maize/corn 0.5% Bovine/: liver 3% Bovine: muscle/meat 4% Bovine: kidney 1% Bovine; Fat 0.6% Processed commodities: Maize, oil 3 %
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

Chronic and acute consumer exposure was calculated using revision 3 of the EFSA PRIMo 3.1.
The proposed uses of terbuthylazine in the formulation Terbut 500 SC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Not relevant. The product contains only one active substance.

7.4 References

United Kingdom, 2007. Draft Assessment Report (DAR).Initial risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance terbuthylazine. Volume 3, Annex B, part 3, B.7.

United Kingdom, 2010. Additional Report to the DAR. Risk assessment provided by the rapporteur Member State United Kingdom for the existing active substance terbuthylazine. Volume 3, Annex B, part 3, B.7.

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance terbuthylazine. Parma, Italy. EFSA Journal 2011 9(1): 1969.

EFSA (European Food Safety Authority), 2017. Peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data submitted. EFSA Journal 15(6): 4868.

EFSA (European Food Safety Authority), 2019. Updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data submitted. EFSA Journal 17(9): 5817.
EFSA (European Food Safety Authority), 2020. Review of the existing maximum residue levels for terbuthylazine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 18(1): 5980.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.1	Giannone, C.	1998	Stability or residues of terbuzhylazine (GS 13529) and GS 26379 (metabolite of terbuthylazine) in plant materials (analytical specimens on wheat grain and wheat straw) stored under deep freeze conditions Novartis Crop Protection AG, Basel Switzerland Report No 136/96 GLP, Not Published Syngenta File N°GS13529/1557	N	Syngenta
KCP 7.2.1	Giannone, C.	2003	Stability of residues of GS 28260 (Metabolite of terbuthylazine) in deep freeze stored analytical specimens of wheat grain, beans and sunflowers seeds Syngenta Crop Protection AG, Basel, Switzerland Report No 302/01 GLP, Not Published Syngenta File N°GS13529/1854	N	Syngenta
KCP 7.2.2	Nicollier, G.	1997	Behaviour and metabolism of GS 13529 in field grown corn after soil application of [Triazine-(U)-^{14}C] labelled material Novartis Crop Protection AG, Basel, Switzerland	N	Syngenta

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
			Novartis Crop Protection AG, Basel, Switzerland, Report No CMR 07/97 GLP, Not published Syngenta File N° GS13529/1486		
KCP 7.2.2.	Willems, H.	1998	Metabolism, distribution and expression of terbuthylazine residues in corn. Netox B.V, s-Hertegenbosch, The Netherlands Oxon Italia S.P.A., Pero, Italy Report no 197764 GLP: yes Published: no	N	OXN
KCP 7.2.2	Salvi, M.	2002a	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France, Report No 3002/00 GLP, Not Published Syngenta File N° GS13529/1754	N	Syngenta
KCP 7.2.2	Salvi, M.	2002b	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France, Report No 3003/00 GLP, Not Published Syngenta File N° GS13529/1755	N	Syngenta
KCP 7.2.2	Stolze, K.	1997a	Residues of CGA 77102 and Terbuthylazine (GS 13529) in maize Novartis Crop Protection AG, Basel Switzerland Novatoris Agro GmbH, Frankfurt, Germany, Report No GR 15596 GLP, Not Published Syngenta File N°GS13529/1500	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.2	Stolze, K.	1997b	Residues of CGA 77102 and Terbuthylazine (GS 13529) in maize Novartis Crop Protection AG, Basel Switzerland Novatoris Agro GmbH, Frankfurt, Germany, Report No GR 14196 GLP, Not Published Syngenta File N°GS13529/1501	N	Syngenta
KCP 7.2.2	Luetolf, W.	1999a	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP, Not Published Syngenta File N° GS13529/1607	N	Syngenta
KCP 7.2.2	Luetolf, W.	1999b	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP, Not Published Syngenta File N° GS13529/1608	N	Syngenta
KCP 7.2.2	Stolze, K.	2004a	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06400 GLP, Not Published Syngenta File N° SAN319/6277	N	Syngenta
KCP 7.2.2	Stolze, K.	2004b	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06300 GLP, Not Published Syngenta File N° SAN319/6278	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.2	Stolze, K.	2004c	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06200 GLP, Not Published Syngenta File N° SAN319/6279	N	Syngenta
KCP 7.2.2	Stolze, K.	2004d	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06100 GLP, Not Published Syngenta File N° SAN319/6280	N	Syngenta
KCP 7.2.2	Stolze, K.	2004e	Determination of residues of CGA 77102 and GS 13529 in maize and rotational crop Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syntenta Agro GmbH, Maintal, Germany, Report No gr 10200 GLP, Not Published Syngenta File N° GS13529/1917	N	Syngenta
KCP 7.2.2	Stolze, K.	2004f	Determination of residues of CGA 77102 and GS 13529 in maize and rotational crop Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syntenta Agro GmbH, Maintal, Germany, Report No gmz 91001 GLP, Not Published Syngenta File N° GS13529/1912	N	Syngenta

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 7.2.2	Luetolf, W.	2003	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on follow up Crop after Treatment of Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 307/00 GLP, Not Published Syngenta File N° CGA77102/0662	N	Syngenta
KCP 7.7.2	Kuhne-Thu, H.	2003a	Residues Study with Terbuthylazine (GS 13529) and S-Metalochlor (CGA 77102) in or maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3037/01 GLP, Not Published Syngenta File N° GS13529/1894	N	Syngenta
KCP 7.7.2	Kuhne-Thu, H.	2003b	Residues Study with Terbuthylazine (GS 13529) and S-Metalochlor (CGA 77102) in or maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3038/01 GLP, Not Published Syngenta File N° GS13529/1895	N	Syngenta
KCP 7.2.3	Mostert, I.	1997a	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3054/95 GLP, Not Published Syngenta File N° GS13529/1498	N	Syngenta
KCP 7.2.3	Mostert, I.	1997b	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3055/95 GLP, Not Published Syngenta File N° GS13529/1499	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.3	Mostert, I.	1997c	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3052/96 GLP, Not Published Syngenta File N° GS13529/1489	N	Syngenta
KCP 7.2.3	Mostert, I.	1997d	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3085/95 GLP, Not Published Syngenta File N° GS13529/1490	N	Syngenta
KCP 7.2.3	Mostert, I.	1997e	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3053/96 GLP, Not Published Syngenta File N° GS13529/1491	N	Syngenta
KCP 7.2.3	Mostert, I.	1997f	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3051/96 GLP, Not Published Syngenta File N° GS13529/1492	N	Syngenta
KCP 7.2.3	Mostert, I.	1997g	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3083/95 GLP, Not Published Syngenta File N° GS13529/1493	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.6.1	Krauss, J.	2000	Outdoor confined accumulation study on rotational crops after bareground application of [Triazine-(U)-^{14}C]GS 13529 Novartis Crop Protection AG, Basel, Switzerland, Report No 96GN32 GLP, Not Published Syngenta File N° GS13529/1663	N	Syngenta

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

Not necessary

Appendix 3 Pesticide Residue Intake Model (PRIMo 3)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Terbuthylazine

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0,0004**	ARfD (mg/kg bw):	**0,008**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	55%	SE general	0,22	55%	Bovine: Muscle/meat						
	50%	NL toddler	0,20	35%	Maize/corn	13%	Bovine: Muscle/meat	2%	Bovine: Liver		
	22%	UK infant	0,09	15%	Bovine: Muscle/meat	5%	Maize/corn	1%	Bovine: Liver		
	21%	FR child 3 15 yr	0,08	19%	Bovine: Muscle/meat	2%	Maize/corn	0,3%	Bovine: Liver		
	19%	ES child	0,08	18%	Bovine: Muscle/meat	1%	Maize/corn	0,2%	Bovine: Liver		
	18%	UK toddler	0,07	16%	Bovine: Muscle/meat	1%	Bovine: Fat tissue	0,3%	Bovine: Liver		
	17%	DK child	0,07	16%	Bovine: Muscle/meat	0,3%	Bovine: Liver	0,0%	Maize/corn		
	16%	GEMS/Food G10	0,07	11%	Bovine: Muscle/meat	3%	Maize/corn	0,9%	Bovine: Fat tissue		
	16%	FR toddler 2 3 yr	0,06	15%	Bovine: Muscle/meat	0,5%	Bovine: Liver	0,4%	Maize/corn		
	15%	GEMS/Food G07	0,06	11%	Bovine: Muscle/meat	2%	Bovine: Liver	2%	Maize/corn		
	14%	NL child	0,06	12%	Bovine: Muscle/meat	1%	Maize/corn	0,9%	Bovine: Liver		
	11%	GEMS/Food G15	0,04	6%	Bovine: Muscle/meat	3%	Maize/corn	0,7%	Bovine: Liver		
	11%	GEMS/Food G11	0,04	9%	Bovine: Muscle/meat	1%	Bovine: Fat tissue	0,6%	Maize/corn		
	10%	GEMS/Food G06	0,04	6%	Maize/corn	3%	Bovine: Muscle/meat	0,5%	Bovine: Liver		
	10%	NL general	0,04	9%	Bovine: Muscle/meat	0,5%	Maize/corn	0,3%	Bovine: Fat tissue		
	10%	ES adult	0,04	9%	Bovine: Muscle/meat	0,4%	Maize/corn	0,1%	Bovine: Liver		
	9%	UK adult	0,04	8%	Bovine: Muscle/meat	0,4%	Bovine: Fat tissue	0,2%	Bovine: Liver		
	9%	RO general	0,03	5%	Maize/corn	4%	Bovine: Muscle/meat				
	8%	FR adult	0,03	8%	Bovine: Muscle/meat	0,3%	Maize/corn	0,2%	Bovine: Liver		
	8%	GEMS/Food G08	0,03	5%	Bovine: Muscle/meat	2%	Maize/corn	0,4%	Bovine: Liver		
	8%	DK adult	0,03	7%	Bovine: Muscle/meat	0,8%	Bovine: Fat tissue	0,2%	Bovine: Liver		
	6%	IE adult	0,02	5%	Bovine: Muscle/meat	1%	Maize/corn				
	6%	DE general	0,02	5%	Bovine: Muscle/meat	0,3%	Maize/corn	0,2%	Bovine: Fat tissue		
	5%	DE women 14-50 yr	0,02	4%	Bovine: Muscle/meat	0,3%	Maize/corn	0,2%	Bovine: Fat tissue		
	5%	FR infant	0,02	4%	Bovine: Muscle/meat	0,1%	Maize/corn	0,1%	Bovine: Liver		
	5%	DE child	0,02	4%	Bovine: Muscle/meat	0,8%	Maize/corn				
	3%	LT adult	0,01	3%	Bovine: Muscle/meat	0,2%	Bovine: Liver	0,0%	Maize/corn		
	2%	PT general	0,01	2%	Maize/corn		FRUIT AND TREE NUTS				
	0,8%	IE child	0,00	0,8%	Bovine: Muscle/meat	0,0%	Maize/corn				
	0,4%	UK vegetarian	0,00	0,2%	Bovine: Fat tissue	0,1%	Bovine: Muscle/meat	0,0%	Maize/corn		
	0,1%	IT toddler	0,00	0,1%	Maize/corn		FRUIT AND TREE NUTS				
	0,1%	FI 6 yr	0,00	0,1%	Maize/corn		FRUIT AND TREE NUTS				
	0,1%	IT adult	0,00	0,1%	Maize/corn		FRUIT AND TREE NUTS				
	0,1%	FI 3 yr	0,00	0,1%	Maize/corn		FRUIT AND TREE NUTS				
	0,0%	FI adult	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				
	0,0%	PL general	0,00	0,0%	Maize/corn		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Terbuthylazine is unlikely to present a public health concern.

A 3.2 IEDI calculations

Not necessary

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Bovine: Liver	0,05 / 0,05	0,40
5%	Bovine: Muscle/meat	0,05 / 0,05	0,36
2%	Bovine: Kidney	0,05 / 0,05	0,19
2%	Maize/corn	0,1 / 0,02	0,13
1%	Bovine: Fat tissue	0,05 / 0,05	0,10

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Bovine: Muscle	0,05 / 0,05	0,28
3%	Bovine: Liver	0,05 / 0,05	0,20
1%	Bovine: Kidney	0,05 / 0,05	0,11
0,6%	Bovine: Fat tissue	0,05 / 0,05	0,05
0,5%	Maize/corn	0,1 / 0,02	0,04

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Maize/corn	0,1 / 0,1	0,67
5%	Bovine: Liver	0,05 / 0,05	0,40
5%	Bovine: Muscle/meat	0,05 / 0,05	0,36
2%	Bovine: Kidney	0,05 / 0,05	0,19
1%	Bovine: Fat tissue	0,05 / 0,05	0,10

Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Bovine: Muscle	0,05 / 0,05	0,28
3%	Maize/corn	0,1 / 0,1	0,22
3%	Bovine: Liver	0,05 / 0,05	0,20
1%	Bovine: Kidney	0,05 / 0,05	0,11
0,6%	Bovine: Fat tissue	0,05 / 0,05	0,05

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Maize / oil	0,1 / 0,5	0,47	3%	Maize / oil	0,1 / 0,5	0,25	29%	Maize / oil	0,1 / 2,5	2,3	16%	Maize / oil	0,1 / 2,5	1,3
0,5%	Maize / processed (not spe	0,1 / 0,02	0,04	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	3%	Maize / processed (not	0,1 / 0,1	0,21	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Terbuthylazine is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not necessary.