

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: TERBUT 500 SC

Product name(s): La Zina 500 SC; Tekno 500 SC

Chemical active substance(s):

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: PUH Chemirol Sp. z o.o.

Submission date: November 2019

MS Finalisation date: 11/2020; 01/2022 ; 06/2022

Version history

When	What
11/2020	Assessment
11/2021	GAP table was updated by the applicant
01/2022	Updated assessment
June 2022	Final Version after Commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

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; 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 00-05 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, BBCH 12-16 PHI is not relevant, outdoor

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 uses are considered 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 applicant completed GAP with adjuvant use (Hydravance 100 LQ).

Applicant's position is presented on page 27. The position is accepted. Uses with Hydravance 100 LQ is accepted.

According to the SANCO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.

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 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, authority, zRMS agrees with the authorization of the intended use(s).

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

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)

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)

PPP (product name/code):	TERBUT 500 SC	Formulation type:	SC ^(a, b)
Active substance 1:	terbuthylazine	Conc. of as 1:	500 g/l ^(c)
Active substance 2:	-	Conc. of as 2:	(c)
Active substance 3:	-	Conc. of as 3:	(c)
Safener:	-	Conc. of safener:	(c)
Synergist:	-	Conc. of synergist:	(c)
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		

Field of use: herbicide

[illegible]

[illegible]

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
	(c)	g/kg or g/l

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references
	2	Use official codes/nomenclatures of EU Member States
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
	4	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
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997,
Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of ap-
plication
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty
rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g,
kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be
mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Updated GAP table:

GAP rev., date: 2021-11-22

PPP (product name/code): La Zina 500 SC/Tekno 500 SC
Terbut 500 SC

Active substance 1: terbuthylazine

Active substance 2: -

Active substance 3: -

Safener: -

Synergist: -

Applicant: Innvigo Sp. z o.o.

Zone(s): Central^(d)

Verified by MS: yes

Field of use: Herbicide

Formulation type: SC^(a, b)

Conc. of as 1: 500 g/l^(c)

Conc. of as 2: ^(c)

Conc. of as 3: ^(c)

Conc. of safener: ^(c)

Conc. of synergist: ^(c)

Professional use: ☒

Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop desti- nation / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize <i>Zea mays</i> (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 00- 05	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-300	n/a		Efficacy section: this use is not ac- cepted.
2	PL	Maize <i>Zea mays</i> (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 00- 05	a)1 b)1	n/a	a) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ b) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ	a) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ b) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ	200-300	n/a		According to the SANCO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.
3	PL	Maize <i>Zea mays</i> (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 12- 16	a)1 b)1	n/a	a) 1.0 l/ha b) 1.0 l/ha	a) 0.5 kg a.s./ha b) 0.5 kg a.s./ha	200-300	n/a		According to the SANCO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.
4	PL	Maize <i>Zea mays</i> (ZEAMX)	F	Dicotyledonous weeds	Spray, medium sprayer	Spring BBCH 12- 16	a)1 b)1	n/a	a) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ b) 1.0 l/ha + 0,2 % v/v Hydra- vance 100 LQ	a) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ b) 0.5 kg a.s./ha + 0,2 % v/v Hydravance 100 LQ	200-300	n/a		According to the SANCO/11337/2011 rev 3, 24 March 2021 use should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.

Hydravance 100 LQ - Adjuvant

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9 Minimum interval (in days) between applications of the same product
	4 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	10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13 PHI - minimum pre-harvest interval
		14 Remarks may include: Extent of use/economic importance/restrictions

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 Journal 2011; 9(1):1969	2011	0.004 mg/kg bw/day	dog, 1-year & rat, 2-year	100
ARfD	EFSA Journal 2011; 9(1):1969	2011	0.008 mg/kg bw/day	Rabbit developmental study	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 (8 trials)	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

For maize, no additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: 1 application of 400 g a.s/ha at growth stage BBCH 00. Since studies presented in EU review during Annex I inclusion, were performed on two times higher rate of 844 g a.s/ha at BBCH 12-16, which is the worst case scenario.

Supervised residue trials were provided by both applicants (Sungenta and Oxon) and evaluated during EU review and presented in *EFSA Journal 2011; 9(1):1969 Peer Review of the pesticide risk assessment of the active substance terbuthylazine* . Samples were analysed for terbuthylazine but also for the metabolites MT1 and MT14 in a significant number of experiments. No residues were observed above the LOQ, except for the metabolite MT14 detected at the level of 0.03 mg/kg in maize forage in two locations. In addition, cold rotational crop trials were submitted where cereals, oilseed and tuber/root crops were rotated with maize treated as a primary crop at a dose rate of 844 to 937 g/ha. Parent residues were always below or at the LOQ of 0.02 mg/kg, MT1 was observed at the level of 0.02 to 0.06 mg/kg in cereal straw, sugar beet tops and sunflower seeds and metabolite MT14 was only detected in a single location in rapeseed grain (0.05 mg/kg). These trials confirm that parent residues are not expected to be present in rotational crops above the LOQ of 0.02 mg/kg. The residue data are supported by the storage stability studies, showing the residues of the parent, MT1 and MT14 to be stable up to 2 years when stored frozen at -18°C. Processing studies were not submitted and are not required because of the low residue levels. As a worst case, the consumer risk assessment was conducted considering the total residue levels (MT0 +MT1+MT14) observed in maize and sorghum grains (primary crop) and in oilseed and root crops (rota-

tional crops). No concern was identified, the IEDI being 10% of the ADI (WHO cluster B) and the IESTI 63% of the ARfD (carrots).

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.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No risk was identified for Acute and chronic risk assessment.

Summary of residues from supervised residue trials according to the **EFSA Journal 2011; 9(1):1969** **Peer Review of the pesticide risk assessment of the active substance terbuthylazine:**

Crop	Northern or Southern Region, field or glasshouse	Trial results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to representative uses	HR (mg/kg) (c)	STMR (mg/kg) (b)
Maize	North 1x 0.75 kg a.s./ha	<u>Grain</u> MT0: 8x <0.02 MT1: 8x <0.02 MT14: 8x <0.02 Total residues: 8x <0.06 <u>Forage</u> MT0: 8x <0.02 MT1: 8x <0.02 MT14: 7x <0.02, 0.03 Total residues: 7x <0.06, 0.07	MT0: terbuthylazine (GS 13529) MT1: desethyl-terbuthylazine (GS 26379) MT14: desethyl-2- hydroxy-terbuthylazine (GS 28620) Total residues: Sum MT0+MT1+MT14 4 additional trials on grain and forage available in Northern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14 3 additional trials on grain and forage available in Southern EU, with MT0 and MT1 <0.02 mg/kg, but not analysed for MT14	0.02*	<u>Grain</u> <0.02 (MT0) <0.06 (Total) <u>Forage</u> <0.02 (MT0) 0.07 (Total)	<u>Grain</u> <0.02 (MT0) <0.06 (Total) <u>Forage</u> <0.02 (MT0) <0.06 (Total)
	South 1x 0.844 kg a.s./ha	<u>Grain</u> MT0: 4x <0.02 MT1: 4x <0.02 MT14: 4x <0.02 Total residues: 4x <0.06 <u>Forage</u> MT0: 8x <0.02 MT1: 8x <0.02 MT14: 7x <0.02, 0.03 Total residues: 7x <0.06, 0.07	Numerous additional trials available in Northern and Southern EU where samples were analysed for terbuthylazine only. All values below the LOQ (0.02 to 0.08 mg/kg) in grain and forage.			

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	NR	NR	

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 TERBUT 500 SC
Crop group	Led by Terbutylazine	
Leafy vegetables	118 days	1 year 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)
Root vegetables	138 days	1 year 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)
Oilseeds	90 days	1 year 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)
Cereals	105 days	1 year 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)

NR: not relevant

Assessment

Terbuthylazine Assessment:

Summary for Terbuthylazine is based on studies presented during Annex I inclusion. All studies are presented in DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010) and evaluated in EFSA Journal 2011; 9(1):1969. Short description of studies for Residues in Rotational crops is presented below:

Five trials were conducted in four locations (Italy, Germany, Spain and Switzerland), over three growing seasons (2000-2002); results are shown in Table B.7.9-1 DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010), above. Each trial involved 2-3 crop types in order to investigate the potential for residues in a variety of following crops across a range of crop categories (root vegetables, cereal and oilseed/pulse rotational crops). The crops involved were: sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet.

The crops were tested in parallel and the terbuthylazine was applied as an SC using the formulation (A-9476) for which Annex I inclusion is being sought.

Samples were analysed for residues of terbuthylazine, GS 26379/MT1 and GS 28620/MT14, i.e. the major components found in the confined crop rotation study.

Succeeding crops of sunflowers, cereal, oil seed rape, sugar beet and potatoes were planted into soil treated with terbuthylazine at rates of 0.844 – 0.938kg/ha. These rates are close to the various GAPs proposed by the notifiers and in certain cases are below the rate specified in the GAP (rates are between 1N and 1.3N for Syngenta and OXON).

Winter oilseed rape was planted between 90 and 121 days after treatment (DAT) in three separate studies and the residues (for all analytes) in seed and remaining plant material were ≤ 0.02 mg/kg, except in one trial (Luetolf, 2003) where residues of GS 28620/MT14 were 0.05 mg/kg and 0.04 mg/kg in seed.

In sunflowers planted 407 DAT, residues in the seed were <0.02 mg/kg for each analyte, while in a second trial, where the seeds were sown 266 DAT seeds were taken at both BBCH 89 and 92. At BBCH 89 (fully ripe) residues of terbuthylazine and GS 26379/MT1 were 0.02 and 0.05 mg/kg in whole plant and 0.06 mg/kg in seeds mg/kg; at BBCH 92 (over ripe) residues were all <0.02 mg/kg.

Cereals were grown in 4 trials with planting intervals of between 119 and 160 DAT.

Residues in all samples of grain were <0.02 mg/kg and ≤ 0.02 mg/kg in straw.

Sugar beet was grown in 4 of the trials with planting intervals of 138 – 350 DAT, in all cases residues in roots were <0.02 mg/kg.

When planted 336 DAT sugar beet residues of GS 26379/MT1 in samples taken at BBCH 39-49 were 0.04 mg/kg in the head and in samples taken at BBCH12-14 were 0.05 mg/kg in the whole plant.

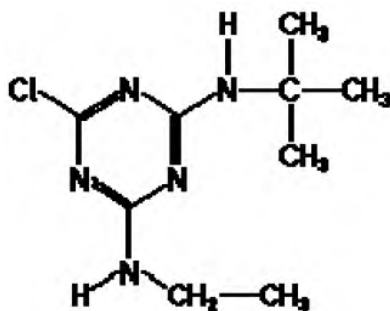
Potatoes were also planted in one trial at an interval of 401 DAT, residues were <0.02 mg/kg for all analytes.

7.2 Terbuthylazine

General data on Terbuthylazine are summarized in the table below (last updated 2016/10/29):

Table 7.2-1: General information on Terbuthylazine

Active substance (ISO Common Name)	Terbuthylazine
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IUPAC	N ² -tert-butyl-6-chloro-N ⁴ -ethyl-1,3,5-triazine- 2,4-diamine
Chemical structure	
Molecular formula	C ₉ H ₁₆ ClN ₅
Molar mass	229.7 g/mol
Chemical group	chlorotriazine
Mode of action (if available)	Inhibitor of photosystem II(PSII) – HRAC mode of action group C1, WSSA group 5
Systemic	YES
Company (ies)	Syngenta/Oxon
Rapporteur Member State (RMS)	UK
Approval status	Approved 01/01/2012 Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011.
Restriction	See Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011
Review Report	SANCO/11337/2011 rev 2 17 June 2011, SANCO/11337/2011 rev 3 24 March 2021
Current MRL regulation	Regulation (EC) No 149/2008 of 29 January 2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending EFSA Journal 2020;18(1):5980
EFSA Journal : Conclusion on the peer review	EFSA Journal 2011; 9(1):1969
EFSA Journal: conclusion on article 12	NO EFSA Journal 2020;18(1):5980
Current MRL applications on intended uses	EFSA-Q-2009-00077 (EMS) Review of all existing MRLs Status: Evaluation ongoing

* Notifier in the EU process to whom the a.s. belong(s)

** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCP 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Residues of terbuthylazine, MT1 and MT14 stable for up to 24 months in cereal commodities when stored frozen at -18°C. The stability data are sufficient to support the residues trials (RMS, 2010 DAR Terbuthylazine - Volume 3,

Annex B.7: Residues)

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereals (wheat grain, straw)	High starch content	24 months	RMS, 2010 (DAR Terbutylazine - Volume 3, Annex B.7: Residues)
Animal Products - not required			

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use TERBUT 500 SC according to the label, therefore no new studies are necessary.

7.2.1.2 Stability of residues in sample extracts (KCP 6.1)

Not relevant for this application, in supervised studies evaluated during Annex I inclusion and presented in DAR Terbutylazine - Volume 3, Annex B.7: Residues 2010, analysis time were less than 24 hours between extraction and analysis.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

The nature of residues in primary crops were evaluated during Annex I inclusion, and presented in DAR Terbutylazine - Volume 3, Annex B.7: Residues 2010.

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-14C]-	F	1.45 kg a.s./ha	1	134	Oxon study	RMS,2010 DAR Ter

		terbuthylazine						buthylazine - Volume 3, Annex B.7: Residues
Cereals	Maize	[triazine-U- ¹⁴ C]- terbuthylazine	F	1.5 kg a.s./ha	1	153	Syngenta study	RMS,2010 DAR Ter- buthylazine - Volume 3, Annex B.7: Residues

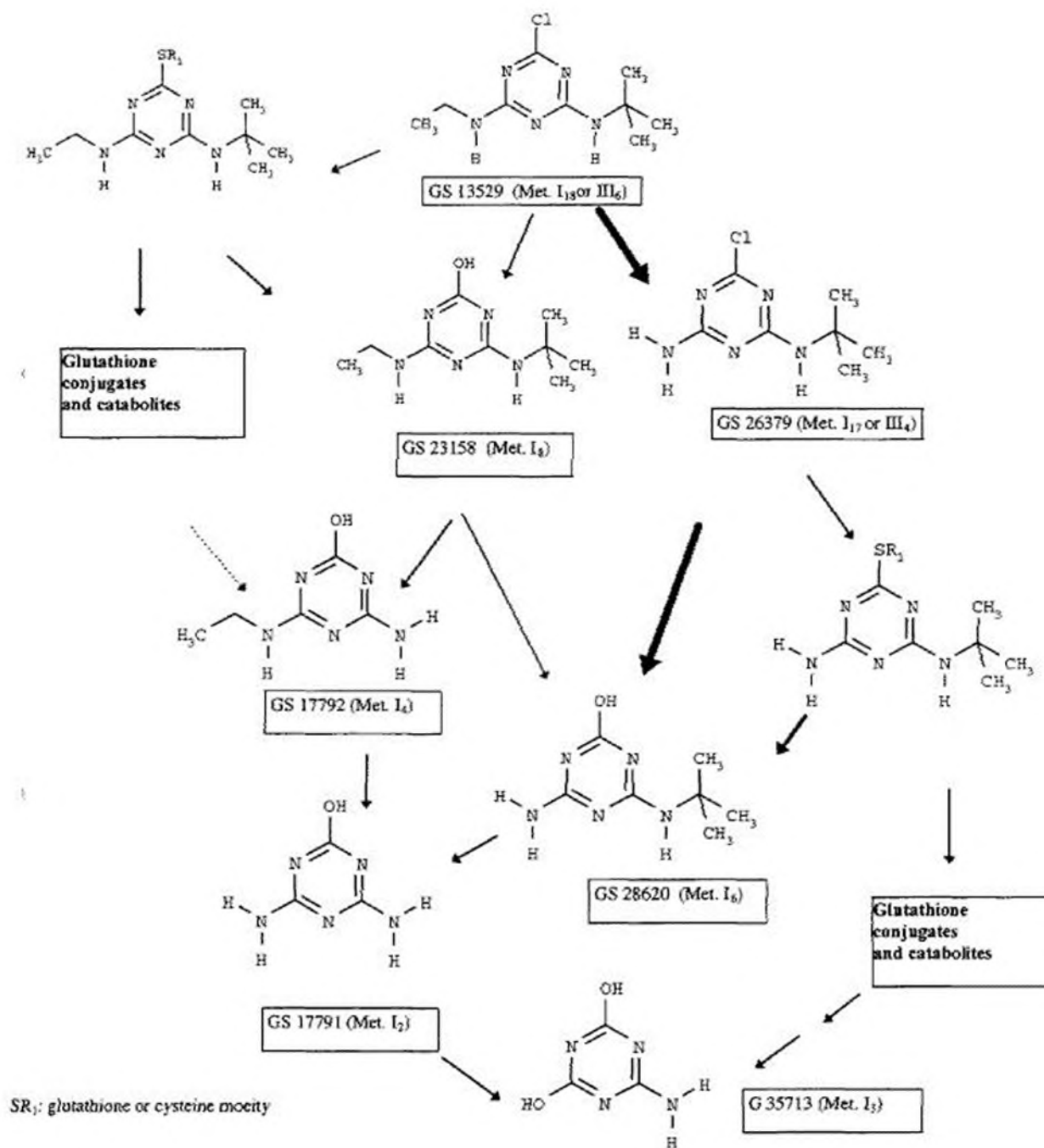
Summary of plant metabolism studies reported in the EU

Terbuthylazine is rapidly and extensively metabolised in maize, representing less than 5% of the TRR in all plant parts, and being not detected in mature grains at harvest. The metabolism in primary crop proceeds by desalkylation to the desethyl metabolite (MT1) and by dechlorination resulting in the 2- hydroxy-terbuthylazine (MT13), which are further metabolised to the desethyl-hydroxy-terbuthylazine (MT14).

The nature of the residue as a result of primary crop treatment was investigated in maize only. The Oxon notifier performed an investigation in maize (cereals) as a post-emergence study. The Syngenta notifier performed a similar investigation in maize as a pre-emergence (one day after seeding) study. Syngenta also performed a stem injection experiment. The studies were conducted at application rates relevant to the requested application rate. The findings of both notifiers' studies are in agreement with each other, these are summarized below:

- 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 (up to 16 discrete components were found in the Syngenta study) and in 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 represent 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.

Proposed metabolic pathway for terbuthylazine in corn plants:



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of TERBUT 500 SC. No new studies were necessary.

7.2.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

The nature of residues in rotational crops were evaluated during Annex I inclusion, and presented in DAR Terbutylazine - Volume 3, Annex B.7: Residues 2010.

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 Syngenta studies on Annex I								
Leafy vegetables	Lettuce	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118,364	64, 69	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues
Root and tuber vegetables	Radish	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118,364	64, 69	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues
Cereals	Wheat	[traiazine-U-14C] terbuthylazine	F	1.5 kg a.s./ha	118, 182, 364	64,130, 104,132,	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues
EU data OXON studies on Annex I								
Leafy vegetables	Spinach	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues
Root and tuber vegetables	Radish	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues
Cereals	Wheat	[traiazine-U-14C] terbuthylazine	F	1.0 kg a.s./ha	30,120, 329	58,70,120, 136,156,409, 436	none	RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues

Summary of plant metabolism studies reported in the EU

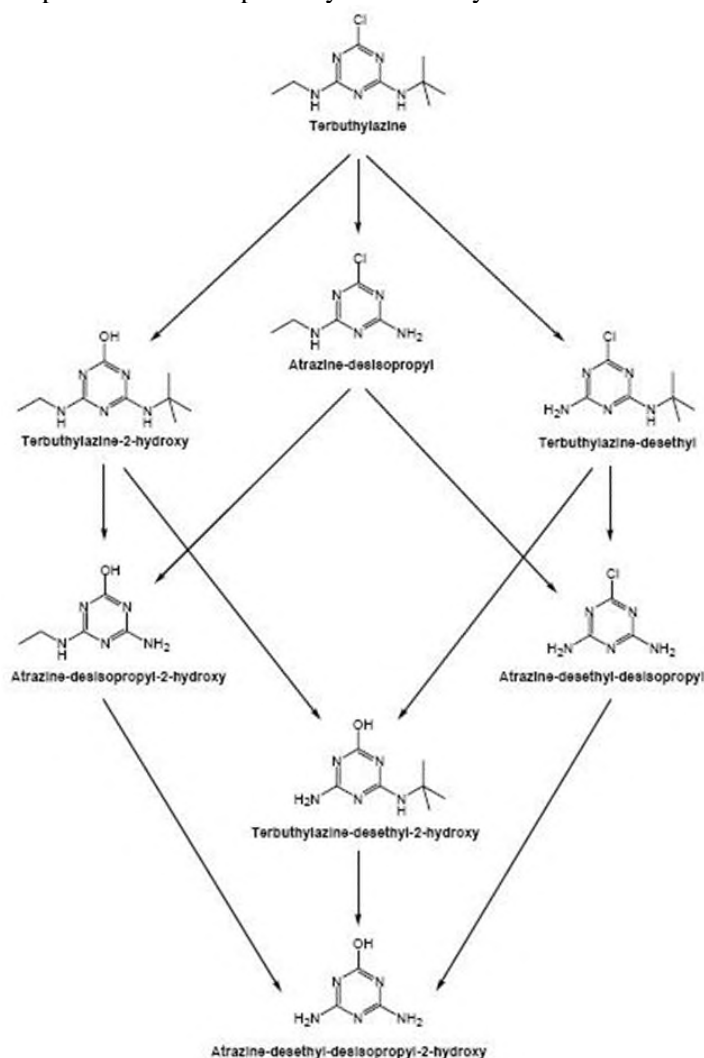
The Oxon notifier did not submit reports of field tests to investigate residues in succeeding and rotational crops. They did however provide the findings of ‘preliminary tests’ (up to Step 3, according to guideline 7524/VI/95 Rev 2) which were used to justify non-submission of field tests.

The Syngenta study (Krauss, J, 2000) indicated that the nature of the residues in rotational crops is the same as those identified in the primary crop, maize. 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. No individual component of the residues (found in food items) represented >0.015 mg/kg.

Overall residues were higher in radish foliage and wheat forage; for example immature wheat foliage from the 118 day plant back interval contained approximately 0.1 mg/kg of GS 26379/MT1 and wheat straw from the 118 day plant back interval contained 0.3 mg/kg of the same metabolite.

The additional study (Mamouni, A, 2006) which includes a 30 -day plant back interval appears to support the findings of Krauss, J., 2000. However, in order to draw a fully robust conclusion, the notifiers should be asked to address the outstanding issues associated with this study. These issues have been satisfactorily addressed in the resubmission DAR and it has been possible to draw a robust conclusion (see Section B.7.1.2.B- DAR RMS,2010 DAR Ter-buthylazine - Volume 3, Annex B.7: Residues).

Proposed metabolic pathway for terbuthylazine in rotational crops:



Conclusion on metabolism in rotational crops

A similar profile as in primary crops is observed in the rotational crops where the TRRs are mainly composed of these three metabolites: MT1 (up to 41% TRR in spinach leaves), MT13 (up to 37% TRR in cereal grain) and MT14 (up to 70% TRR in radish roots). The metabolism in rotational crops covers use of TERBUT 500 SC according to the label

7.2.2.3 Nature of residues in processed commodities (KCP 6.5.1)

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No new studies are necessary for TERBUT 500 SC, since all residues are expected to be below 0.1 mg/kg.

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

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

Endpoints	
Plant groups covered	Cereals (maize) - foliar treatment (OXON: 3-4 leaf stage) and - soil treatment (SYN: pre-emergence)
Rotational crops covered	Lettuce, radish, wheat (SYN only) and spinach, radish, summer/winter wheat (SYN & OXON)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes (terbuthylazine and metabolites MT1, MT13 and MT14 main components in rotational crops)
Processed commodities	Not provided and not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Terbuthylazine (MT0) Commission Regulation (EC) No 149/2008 of 29 January 2008 Reg. (EU) 2021/1795
Plant residue definition for risk assessment	Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14) <i>EFSA Journal 2011; 9(1):1969</i>
Conversion factor from enforcement to RA	Not necessary for maize grains (all residue data <LOQ)

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

The metabolism in livestock was evaluated during Annex I inclusion, and presented in DAR Terbutylazine - Volume 3, Annex B.7: Residues 2010 and EFSA Journal 2011; 9(1):1969

No new data submitted in the framework of this application.

Table 7.2-5: Summary of animal metabolism studies

Group	Species	Label posi- tion	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of samp- ling	
EU data								
Lactating ruminants	Cow	[triazine-U-14C]- terbuthylazine	1 control, 1 dosed animal	39 mg per day	10 days	Milk	daily	RMS,2010 DAR Ter- buthylazine - Volume 3, Annex B.7: Residues
						Urine and faeces	daily	
						Tissues	daily	

Summary of plant metabolism studies reported in the EU

The results of this study appear to demonstrate that metabolism of terbuthylazine is rapid and its metabolites are eliminated from the animal quickly. The study was carried out using an exaggerated dose rate (10N/13N) and the results must be interpreted accordingly.

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 – 0.5mg/kg.

Residues in milk were lower than in tissues 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;

0.039mg/kg (GS 26379) and 0.005mg/kg (GS 28273) and 0.036mg/kg (other polar metabolites) expressed as terbuthylazine equivalents.

It should also be noted that the study is approximately 30 years old and was not conducted according to GLP since these principles had not been established at the time. Despite this the notifiers have stated that the study complies with the current EC guidelines.

A number of inadequacies in the study have been identified and discussed in the evaluation above; they are also gathered together here for convenience:

- radiochemical purity was not reported;
- radioactivity (39% of TRR in milk, 0.029 mg/kg) in milk not characterised;
- insufficient details of the methods of analysis used to demonstrate the quality of the data and to indicate the confidence which can be attached to characterisations and identifications;
- insufficient work done to characterise or identify the metabolites present in the sampled tissues;
- no information on storage of samples and extracts was reported.

Notwithstanding these inadequacies the study provides evidence that terbuthylazine is metabolised quickly and its metabolites are eliminated (in the urine and faeces) from the animal quickly.

In summary 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 ($0.9 \text{ mg/kg} \div 10$) and 0.06 mg/kg ($0.6 \text{ mg/kg} \div 10$) 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: $0.082 \text{ mg/kg} \div 10$). These are the maximum possible residue levels and assume that the TRR consists entirely of GS 13529/MT0 and/or GS 26379/MT1; it is clear from the results for milk that this is not the case although the RMS accepts that due to the various inadequacies of the study it is not possible to be absolutely certain what proportion of the TRR will consist of any single compound.

The RMS believes it is very unlikely that at 1N residues of GS 13529/MT0, GS 26379/MT1 or any individual metabolite will be found at significant levels ($>0.01 \text{ mg/kg}$) in any edible animal tissue or milk.

Conclusion on metabolism in livestock

A cow metabolism study was provided where animals were dosed with ^{14}C -terbutylazine over 10 days at a dose rate calculated to represent a 18N and 15N dose rate for dairy 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 $<0.01 \text{ mg/kg}$ in milk, muscle and fat and $<0.05 \text{ mg/kg}$ 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.

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

Table 7.2-6: 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 Within 24 hours
Animal residue definition for monitoring	No data, not necessary for the representative uses <i>EFSA Journal 2011; 9(1):1969</i> Reg. (EU) 2021/1795
Animal residue definition for risk assessment	No data, not necessary for the representative uses <i>EFSA Journal 2011; 9(1):1969</i>
Conversion factor	Not available <i>EFSA Journal 2011; 9(1):1969</i>
Metabolism in rat and ruminant similar	Not available <i>EFSA Journal 2011; 9(1):1969</i>
Fat soluble residue	Not available <i>EFSA Journal 2011; 9(1):1969</i>

7.2.3 Magnitude of residues in plants (KCP 6.3)

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

Both Applicants provide supervised residues studies for Annex I inclusion , which covers critical GAP for Annex I inclusion and cGAP for TERBUT 500 SC containing terbuthylazine. Please refer to the RMS,2010 DAR Terbuthylazine - Volume 3, Annex B.7: Residues. Summary of available studies is presented in Table 7.2.-9.

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

Table 7.2-7: 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 calcu- lator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL com- pliance
Maize	EFSA Journal 2011; 9(1):1969	N-EU	GAP on which MRL/EU a.s. assessment is based: 1 x 0.75 kg as/ha, BBCH 12-16 PHI is not relevant, outdoor Grain: E: 8 X <0.02 mg/kg RA: 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: 7x <0.02, 0.03 Total residues: 7x <0.06, 0.07	N/A				

	New trials	N-EU	Now new trials submitted					
	Overall supporting data for cGAP	N-EU	E: 8 X <0.02 mg/kg RA: MT0: 8x <0.02 MT1: 8x <0.02 MT14: 8x <0.02 Total residues: 8x <0.06	E: 0.02 RA: 0.06	E: 0.02 RA: 0.06	-	0.1 mg/kg 0.02*	Yes

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

Applicant's position:

Presented above unprotected residues studies for which the application was carried out in the BBCH 12-16 at a dose of 1x 0.75 kg as/ha is a worse case than the currently considered application in the BBCH 00 and the maximum dose of 500 g as/ha with addition of soil adjuvant Hydravance 200. Soils can be naturally hydrophobic in nature; this is often exacerbated when the soil is left to dry for an extended time or has a high organic content. Soil hydrophobicity can lead to water pooling and surface run-off, which has a direct consequence on plant growth through restriction of water infiltration and supply to a plants' root zone in the case of turf grass and field crops. Soil quality and physiochemical properties can directly affect the penetration and percolation of water throughout the soil profile. Agrochemical treatments, in particular pre-emergent herbicides are often applied directly to soil, which is naturally a hydrophobic substrate and doesn't interact favourably with water. The hydrophobic nature of the soil can limit the penetration and infiltration of irrigation-based applications. Consequences of such unfavourable interaction can lead to surface run-off and reduced percolation and distribution of water within the soil. The application of Hydravance 200 enhances the penetration of water into hydrophobic soil, improving the wetting and percolation of water throughout the soil profile. The above mentioned properties allow the application of soil herbicides in drier conditions or with a lower water content than usual and they are not intended to change the properties of the active substance or the prepared working liquid, such as surface tension, residence time on the leaf, drop shape, etc. simply better soil wetting in dry soil conditions. Therefore, it can be predicted that application of 500 g as/ha in tank mix with adjuvant Hydravance 200 at BBCH 00 is not a worse case than application of 750 g as/ha at BBCH 12 without adjuvant.

zRMS: position is accepted.

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 both outdoor use.

Supervised residue trials were provided by both applicants. Samples were analysed for terbuthylazine but also for the metabolites MT1 and MT14 in a significant number of experiments. No residues were observed above the LOQ, except for the metabolite MT14 detected at the level of 0.03 mg/kg in maize forage in two locations.

All available data presented in EU conclusion is sufficient to support use of TERBUT 500 SC containing terbuthylazine, therefore no new studies are necessary.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary Burden calculations were performed during Annex I inclusion. New calculations were presented below with MRL-Calculator.

Table 7.2-8: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition : Terbuthylazine				
Maize (grain)	0.02	Median residue (EFSA Journal 2011; 9(1):1969)	0.02	Highest residue (EFSA Journal 2011; 9(1):1969)
Maize (as silage)	0.02	Median residue (EFSA Journal 2011; 9(1):1969)	0.02	Highest residue (EFSA Journal 2011; 9(1):1969)

Table 7.2-9: Results of the dietary burden calculation

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)
Risk assessment residue definition 1: Terbuthylazine					
Beef cattle*	0.0011	-	forage/silage	0.04	N
Dairy cattle*	0.0014	-	forage/silage	0.04	N
Ram/ewe	0.0002	-	grain	0.01	N
Lamb	0.0003	-	grain	0.01	N

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)
Breeding swine	0.001	-	forage/silage	0.03	N
Finishing swine*	0.000	-	grain	0.02	N
Broiler poultry	0.001	-	grain	0.02	N
Layer poultry*	0.001	-	grain	0.02	N
Turkey	0.001	-	grain	0.01	N

According to the DAR Terbutylazine - Volume 3, Annex B.7: Residues (2010)

Considering maize only (as maize and maize silage) the expected exposure in the diet of beef and dairy cattle is 0.2 mg/kg diet (DM) – an animal metabolism study is therefore required and has been evaluated (xxxxxxxxx 1970). Even if intakes of terbutylazine only are considered the expected exposure in the diet of beef and dairy cattle is 0.1 mg/kg diet (DM) and an animal metabolism study would therefore still be required.

Considering maize (as maize and maize silage) and potential rotational crops the expected exposure in the diet of beef and dairy cattle is 0.408 mg/kg diet and 0.288 mg/kg diet (DM) respectively.

Intakes by domestic animals from the consumption of potential rotational crops were not taken into account for the purposes of calculating the N rate of the animal metabolism study as this was considered an overly conservative approach given the residues in potential rotated crops were predominantly LOQ and the relevant crops (see Table B.7.6-1 and Section B.7.9.1) are unlikely to form the majority of the diet of domestic animals over an extended length of time.

In consideration of the animal metabolism study (xxxxxxxxxxx 1970) the RMS believes that residues of 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 (see Section B.7.2, Part vii – Conclusions) for full discussion. With regard to the consumer risk assessment no further consideration has therefore been given to residues in products of animal origin.

7.2.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According DAR Terbutylazine - Volume 3, Annex B.7: Residues (2010):

In view of the animal metabolism study submitted for the resubmission the RMS believes that residues of 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.

It was stated in the original DAR that studies are not required due to the very low level of residues of terbutylazine in maize

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

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

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

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

Due to the residues from supervised trials for representative use in maize, all residues are below LOQ, therefore no processing studies are necessary.

7.2.6 Magnitude of residues in representative succeeding crops

The Oxon and Syngenta studies indicated that the nature of the residues in rotational crops is the same as those identified in the primary crop, maize. 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. No individual component of the residues (found in food items) represented >0.015 mg/kg.

Overall residues were higher in radish foliage and wheat forage; for example immature wheat foliage from the 118 day plant back interval contained approximately 0.1 mg/kg of GS 26379/MT1 and wheat straw from the 118 day plant back interval contained 0.3 mg/kg of the same metabolite.

The SYN notifier has submitted rotational crop residues trials and these data allow a full assessment of the potential for uptake of terbuthylazine from the soil into following crops.

The Oxon notifier did not submit reports of field tests to investigate residues in succeeding and rotational crops. It was also noted that the SYN notifier submitted results of rotational crop field trials which provide evidence of significant residues in rotational crops.

Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCP 6.6.2)

Available data According to the DAR Terbuthylazine - Volume 3, Annex B.7: Residues (2010)

Field trials on sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet as succeeding crops have also been conducted. In one study, terbuthylazine was applied to the soil prior to sowing maize and in the remaining 4 trials the application was made to maize as a post emergence application, i.e. BBCH 11-14. At appropriate intervals (typical for rotational/succeeding crops) crops were sown into the soil after destruction of the maize. Crops were sampled at appropriate intervals, and samples were analysed using Analytical Method 148.06.

No new data submitted in the framework of this application.

Table 7.2-10: Summary of available studies in field rotational crops

Country, year Soil Type	Application					PHI
	Form	kg a.s./ha	kg a.s./hL (actual)	water, L/ha	no. (inc. growth stage BBCH) Application Date	Crop Commodity, (DAT Planting) Growth Stage at harvest
Italy 2000 Silt loam	A-9476 SC 500	0.938	0.234	400	1 (00 – prior to sowing) 23/03/00	Sunflowers (407) Whole Plant (BBCH 14-18) Seeds BBCH 85 Seeds BBCH 89 Potatoes (401) Tubers BBCH 43 Tubers BBCH 47 Tubers BBCH 48
Germany 2001 Silty Sand	A- 9476B SC 500	0.844		400	1 (13-14) 17/05/00	Winter oilseed rape (105) BBCH 12-14 Whole plant BBCH 87 Pods BBCH 87 Rest of plant BBCH 89-92 Grain BBCH 89-92 Straw Winter barley (132) BBCH 13 Whole plant BBCH 87 Ears BBCH 87 Rest of plant BBCH 89-92 Grain BBCH 89-92 Straw Sugar beet (336) BBCH 12-14 Whole plant BBCH 39-49 Head BBCH 39-49 Roots BBCH 49 Head BBCH 49 Roots
Germany 2002 Loamy Sand	A- 9476B SC 500	0.844		300	1 (14) 31/5/01	Winter oilseed Rape (90) BBCH 14 Whole plant BBCH 85-87 Pods BBCH 87 Rest of plant BBCH 89 Grain BBCH 89 Straw Winter barley (119) BBCH 11-21 Whole plant BBCH 85-87 Ears BBCH 85 87 Rest of plant BBCH 89 Grain BBCH 89 Straw Sugar beet (314) BBCH 12-14 Whole plant BBCH 49 Head + leaves BBCH 49 Roots BBCH 49 Head BBCH 49 Roots
Spain 2002 Sandy Loam	A- 9476B SC 500	0.937		300	1 (13-14) 31/5/00	Sunflowers (266) BBCH 15-18 Whole plant BBCH 89 Seeds

						BBCH 92 Seeds Winter wheat (160) BBCH 21-22 Whole plant BBCH 75-83 Ears BBCH 75-83 Stalks BBCH 99 Grain BBCH 99 Straw Sugar beet (138) BBCH 15-18 Whole plant BBCH 39 Head + leaves BBCH 39 Roots BBCH 49 Head + leaves BBCH 49 Roots
Switzerland 2002 Sandy Loam	A- 9476B SC 500	0.844		500	1 (11) 16/5/00	Winter oilseed rape (121) BBCH 14 Whole plant BBCH 80 Pods BBCH 89 Seeds Winter wheat (135) BBCH 21 Whole plant BBCH 83 Ears BBCH 83 Stalks BBCH 89 Grain BBCH 89 Straw Sugar beet (350) BBCH 15 Whole plant BBCH 47 Head BBCH 47 Roots BBCH 48 Head BBCH 48 Roots

Conclusion on rotational crops studies

Five trials were conducted in four locations (Italy, Germany, Spain and Switzerland), over three growing seasons (2000-2002); results are shown in Table B.7.9-1, above. Each trial involved 2-3 crop types in order to investigate the potential for residues in a variety of following crops across a range of crop categories (root vegetables, cereal and oilseed/pulse rotational crops). The crops involved were: sunflowers, potatoes, winter wheat, winter barley, winter oilseed rape, and sugar beet.

The crops were tested in parallel and the terbuthylazine was applied as an SC using the formulation (A-9476) for which Annex I inclusion is being sought. Samples were analysed for residues of terbuthylazine, GS 26379/MT1 and GS 28620/MT14, i.e. the major components found in the confined crop rotation study.

Succeeding crops of sunflowers, cereal, oil seed rape, sugar beet and potatoes were planted into soil treated with terbuthylazine at rates of 0.844 – 0.938kg/ha. These rates are close to the various GAPs proposed by the notifiers and in certain cases are below the rate specified in the GAP (rates are between 1N and 1.3N for Syngenta and OXON).

Winter oilseed rape was planted between 90 and 121 days after treatment (DAT) in three separate studies and the residues (for all analytes) in seed and remaining plant material were ≤ 0.02 mg/kg, except in one trial (Luetolf, 2003) where residues of GS 28620/MT14 were 0.05 mg/kg and 0.04 mg/kg in seed.

In sunflowers planted 407 DAT, residues in the seed were <0.02 mg/kg for each analyte, while in a second trial, where the seeds were sown 266 DAT seeds were taken at both BBCH 89 and 92. At BBCH 89 (fully ripe) residues of terbuthylazine and GS 26379/MT1 were 0.02 and 0.05 mg/kg in whole plant and 0.06 mg/kg in seeds mg/kg; at BBCH 92 (over ripe) residues were all <0.02 mg/kg.

Cereals were grown in 4 trials with planting intervals of between 119 and 160 DAT.

Residues in all samples of grain were <0.02 mg/kg and ≤0.02 mg/kg in straw.

Sugar beet was grown in 4 of the trials with planting intervals of 138 – 350 DAT, in all cases residues in roots were <0.02 mg/kg. When planted 336 DAT sugar beet residues of GS 26379/MT1 in samples taken at BBCH 39-49 were 0.04 mg/kg in the head and in samples taken at BBCH12-14 were 0.05 mg/kg in the whole plant. Potatoes were also planted in one trial at an interval of 401 DAT, residues were <0.02 mg/kg for all analytes.

7.2.7 Other / special studies (KCP6.10, 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 containing Terbutylazine. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCP 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.

The Consumer risk assessment was performed using PRIMO EFSA MODEL-TMDI Calculator using input parameters presented in Table 7.2-15.

zRMS: Chronic risk assessment was performed according to the current EU MRLs as set in the current Reg. (EU) 2021/1795. As reported in the EFSA, 2020 the CF of 1 for risk assessment were applied for all the commodities since residues in edible commodities were below the LOQ.

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
Maize	0.1 0.02	MR (worst case) according Reg. (EC) No 149/2008 Reg. (EU) 2021/1795	0.1 0.02	MR (worst case) according Reg. (EC) No 149/2008 Reg. (EU) 2021/1795
Other plant commodities	Reg. (EU) 2021/1795		-	
Animal commodities	Reg. (EU) 2021/1795		Reg. (EU) 2021/1795	

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3. Summary of results is presented below in table 7.2.-16.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev.3.1	18 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	18 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Unprocessed 31,05% Milk: Cattle Processed (children): 5,8% Maize / oil 0,5% Maize / processed (not specified) Processed (adults): 3,2% Maize / oil 29% (based on maize/oil for children) 16% (based on maize/oil for adults)

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.

The following paragraphs are to be considered as proposals, based on “standard” criteria.
Not relevant. The product contains only one active substance.

7.4 References

EFSA conclusion on the active substance terbuthylazine according to Article 20 of Commission Regulation (EC) No. 33/2008. EFSA Journal 2011;9(1):1969

RMS,2010

DAR Terbuthylazine - Volume 3, Annex B.7: Residues

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 6.1/01	Giannone, C.	1998	Stability of residues of terbuthylazine (GS13529) and GS 26379 (metabolite of terbuthylazine) in plant materials (analytical specimens of wheat grain and wheat straw) stored under deep freeze conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 136/96 GLP Not Published	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 6.1/02	Giannone, C.	2003	Stability of Residues of GS 28260 (Metabolite of Terbutylazine) in Deep Freeze Stored Analytical Specimens of Wheat Grain, Beans and Sunflower Seeds Syngenta Crop Protection AG, Basel, Switzerland, Report No 302/01 GLP Not Published	N	Syngenta
KCP 6.2.1/01	Willems H.	1998	METABOLISM, DISTRIBUTION, AND EXPRESSION OF TERBUTHYLAZINE RESIDUES IN CORN Notox B.V, 's-Hertogenbosch, The Netherlands Oxon Italia S.P.A, Pero, Italy Report-no. 197764 GLP: yes published: no	N	Oxon
KCP 6.2.2/01	xxxxxxxxxx	1970	METABOLISM STUDY OF C14 GS-13529 IN A COW – A PLATEAU STUDY D.R.C 606 GAAC 70030 6-29-70 GLP: no Published: no	Y	Syngenta/Oxon
KCP 6.3/01	Salvi, M.	2002a	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3002/00 GLP Not Published	N	Syngenta
KCP 6.3/02	Salvi, M.	2002b	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France,	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
			Report No 3003/00 GLP Not Published		
KCP 6.3/03	Stolze, K	1997a	Residues of CGA 77102 and Terbutylazine (GS 13529) in Maize Novartis Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, Report No GR 15596 GLP Not Published	N	Syngenta
KCP 6.3/04	Stolze, K.	1997b	Residues of CGA 77102 and Terbutylazine (GS 13529) in Maize Novartis Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, Report No GR 14196 GLP Not Published	N	Syngenta
KCP 6.3/05	Mostert, I.	1997a	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3054/95 GLP Not Published	N	Syngenta
KCP 6.3/06	Mostert, I.	1997b	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel,	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
			Switzerland, Report No 3055/95 GLP Not Published		
KCP 6.3/07	Luetolf, W.	1999a	Residue Study with Terbutylazine (GS 13529) in or on Maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP Not Published	N	Syngenta
KCP 6.3/08	Luetolf, W.	1999b	Residue Study with Terbutylazine (GS 13529) in or on Maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3005/96 GLP Not Published	N	Syngenta
KCP 6.3/09	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	N	Syngenta
KCP 6.3/10	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 06100 GLP Not Published	N	Syngenta
KCP 6.3/11	Stolze, K.	2004c	Determination of Residues of CGA 77102 and GS 13529 in Maize after Application of A 12310 A in	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
			Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gr 06200 GLP Not Published		a
KCP 6.3/12	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 06300 GLP Not Published	N	Syngenta
KCP 6.3/13	Kuehne-Thu,H.	2003a	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3037/01 GLP Not Published	N	Syngenta
KCP 6.3/14	Kuehne-Thu,H.	2003b	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 3038/01 GLP Not Published	N	Syngenta
KCP 6.3/15	Mostert, I	1997c	Magnitude of residues in maize and silage after application of CGA77102 and GS13529 as formulation SC 500, A-9476 B, Italy Novartis Crop Protection AG, Basel,	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
			Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3084/95 GLP Not Published		
KCP 6.3/16	Mostert, I.	1997d	Magnitude of R sidues in Maize after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3052/96 GLP Not Published	N	Syngenta
KCP 6.3/17	Mostert, I.	1997e	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3085/95 GLP Not Published	N	Syngenta
KCP 6.3/18	Mostert, I.	1997f	Magnitude of Residues in Maize and Soil after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3053/96 GLP Not Published	N	Syngenta
KCP 6.3/19	Mostert, I.	1997g	Magnitude of Residues in Maize after Application of CGA 77102 and Terbutylazine (GS 13529) as	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
			Formulation SC 500 (A-9476 B) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3051/96 GLP Not Published		a
KCP 6.3/20	Mostert, I.	1997h	Magnitude of Residues in Maize after Application of CGA 77102 and Terbutylazine (GS 13529) as Formulation SC 500 (A-9476) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3083/95 GLP Not Published	N	Syngenta a
KCP 6.3/21	Salvi, M.	2002c	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3006/00 GLP Not Published	N	Syngenta a
KCP 6.3/22	Salvi, M.	2002d	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3007/00 GLP Not Published	N	Syngenta a
KCP 6.3/23	Salvi, M.	2002e	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy	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
			Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3008/00 GLP Not Published		a
KCP 6.3/24	Salvi, M.	2002f	Residue Study with Terbutylazine (GS 13529) and S-Metolachlor (CGA 77102) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 3009/00 GLP Not Published	N	Syngenta
KCP 6.3/25	Kuehne-Thu,H.	2003c	Residue Study with S-Metolachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3054/01 GLP Not Published	N	Syngenta
KCP 6.3/26	Kuehne-Thu,H.	2003d	Residue Study with S-Metolachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3053/01 GLP Not Published	N	Syngenta
KCP 6.3/27	Kuehne-Thu,H.	2003e	Residue Study with S-Metolachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland, Report No 3052/01 GLP Not Published	N	Syngenta
KCP 6.3/28	Kuehne-Thu,H.	2003f	Residue Study with S-Metolachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Maize in Italy Syngenta Crop Protection AG, Basel,	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
			Switzerland, Report No 3051/01 GLP Not Published		
KCP 6.3/29	Pollmann B.	2001	DETERMINATION OF RESIDUES OF TERBUTHYLAZINE AFTER APPLICATION OF TERBUTHYLAZINE 500 G/L SC AND TERBUTHYLAZINE 75% WG IN MAIZE – 1 SITE IN FRANCE AND 3 SITES IN GERMANY, 2000 ArGe GAB Biotech/IFU, D-75223 Niefern-Öschelbronn Oxon Italia S.P.A, Pero, Italy Report-no. 20001117/E1-FPMA GLP: yes published: no	N	Oxon
KCP 6.3/30	Freschi G.	2001a	GENERATION OF MAIZE SAMPLES, SUITABLE FOR RESIDUES ANALYSIS FOLLOWING APPLICATION IN POST- EMERGENCE OT TERBUTHYLAZINE 75% WG AND 500 G7L SC Sipcam Experimental Service, Salerano Sul Lambro Lo, Italy Oxon Italia S.P.A, Pero, Italy Report-no. TZ1 GLP: yes published: no	N	Oxon
KCP 6.3/31	Freschi G.	2000a	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (PLANT) Sipcam Residue Analysis Unit, Salerano sul Lambro (Lo),Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1245 GLP: yes published: no	N	Oxon
KCP 6.3/32	Freschi G.	2000c	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (GRAIN) Sipcam Residue Analysis Unit, Salerano sul	N	Oxon

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
			Lambro (Lo),Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1247 GLP: yes published: no		
KCP 6.3/32	Domenichini P.	2002	GENERATION OF MAIZE GRAIN OR GREEN SILAGE MAIZE SAMPLES, SUITABLE FOR RESIDUE ANALYSIS FOLLOWING APPLICATION ON POST- EMERGENCE OF TERBUTHYLAZINE 75% WG AND TERBUTHYLAZINE 500 G/L SC (FIELD TRIALS CARRIED OUT IN ITALY IN THE YEAR 2001) Sipcam Experimental Service, Salerano Sul Lambro Lo, Italy Oxon Italia S.P.A, Pero, Italy Report-no. TZ/2 GLP: yes published: no	N	Oxon
KCP 6.3/33	Freschi G.	2002a	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (GRAIN) Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1308 GLP: yes published: no	N	Oxon
KCP 6.3/34	Freschi G.	2002b	RESIDUE ANALYSIS OF TERBUTHYLAZINE IN MAIZE SAMPLES (WHOLE PLANT) Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1309 GLP: yes published: no	N	Oxon
KCP 6.3/35	Schulz J	1996	FINAL REPORT ABOUT TESTING THE RESIDUAL BEHAVIOUR OF OXN 924 SC 500 IN MAIZE	N	Oxon

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
			UNDER FIELD CONDITIONS (FIELD REPORT) Agroplan, Berliner Straße 75, D-47574 Goch-Nierswalde Oxon Italia S.P.A, Pero, Italy Report-no. AGR/RP-H 95/OXN 924 SC 500 GLP: yes published: no		
KCP 6.3/36	Domenichini P.	2004	DETERMINATION OF THE MAGNITUDE OF THE RESIDUES OF TERBUTHYLAZINE 500G/L SC IN SILAGE MAIZE TREATED IN POST-EMERGENCE Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1336 GLP: yes published: no	N	Oxon
KCP 6.6.1/01	Krauss, J.	2000	Outdoor Confined Accumulation Study on Rotational Crops after Bareground Application of [Triazine-(U)-14C]GS 13529 Novartis Crop Protection AG, Basel, Switzerland, Report No 96GN32 GLP Not Published	N	Syngenta
KCP 6.6.1/02	Salvi, M.	2002 g	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Follow-up Crop after Treatment of Maize in Italy Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 310/00 GLP Not Published	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 6.6.1/03	Stolze, K.	2004e	Determination of Residues of CGA 77102 and GS 13529 in Maize and Rotational Crops 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 Syngenta Agro GmbH, Maintal, Germany, Report No gr 10200 GLP Not Published	N	Syngenta
KCP 6.6.1/04	Stolze, K.	2004f	Determination of Residues of CGA 77102 and GS 13529 in Maize and Rotational Crops Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2001 and 2002 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, Report No gmz91001 GLP Not Published	N	Syngenta
KCP 6.6.1/05	Sole, C.	2003	Crop Rotation Study with S-Metolachlor (CGA 77102) and Terbutylazine (GS 13529) in or on Follow-up Crop After Treatment of Maize in Spain Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No 311/00 GLP Not Published	N	Syngenta
KCP 6.6.1/06	Luetolf, W.	2003	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbutylazine (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	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 6.6.1/07	Mamouni A.	2006	Terbuthylazine: Confined accumulation of 14c-terbuthylazine in rotational crops. RCC AG., Itingen, Switzerland Oxon Italia S.p.A, Pero, Italy Report-no. A05940 GLP: Yes Published: No	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

A 2.1 Terbutylazine

No new data provided.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.004	ARfD (mg/kg bw):	0.008
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Details - chronic risk assessment

Details - acute risk assessment/children

Supplementary results - chronic risk assessment

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IED/TMDI)

		No of diets exceeding the ADI : ---						Exposure resulting from			
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI (NED/IED) calculation (based on average food consumption)	18%	NL toddler	0.70	18%	Maize/corn		Grapefruits				
	3%	GEMS/Food G06	0.13	3%	Maize/corn		Grapefruits				
	3%	UK infant	0.10	3%	Maize/corn		Grapefruits				
	2%	RO general	0.10	2%	Maize/corn		Grapefruits				
	2%	GEMS/Food G10	0.07	2%	Maize/corn		Grapefruits				
	2%	GEMS/Food G15	0.06	2%	Maize/corn		Grapefruits				
	1%	PT general	0.05	1%	Maize/corn		Grapefruits				
	1%	GEMS/Food G08	0.04	1%	Maize/corn		Grapefruits				
	1%	FR child 3 15 yr	0.04	1%	Maize/corn		Grapefruits				
	0.8%	GEMS/Food G07	0.03	0.8%	Maize/corn		Grapefruits				
	0.7%	ES child	0.03	0.7%	Maize/corn		Grapefruits				
	0.7%	NL child	0.03	0.7%	Maize/corn		Grapefruits				
	0.5%	IE adult	0.02	0.5%	Maize/corn		Grapefruits				
	0.4%	DE child	0.02	0.4%	Maize/corn		Grapefruits				
	TMDI (NED/IED) calculation (based on average food consumption)	0.3%	GEMS/Food G11	0.01	0.3%	Maize/corn		Grapefruits			
0.2%		NL general	0.01	0.2%	Maize/corn		Grapefruits				
0.2%		FR toddler 2 3 yr	0.01	0.2%	Maize/corn		Grapefruits				
0.2%		ES adult	0.01	0.2%	Maize/corn		Grapefruits				
0.2%		DE women 14-50 yr	0.01	0.2%	Maize/corn		Grapefruits				
0.2%		FR adult	0.01	0.2%	Maize/corn		Grapefruits				
0.1%		DE general	0.01	0.1%	Maize/corn		Grapefruits				
0.1%		IT toddler	0.00	0.1%	Maize/corn		Grapefruits				
0.1%		FI 6 yr	0.00	0.1%	Maize/corn		Grapefruits				
0.1%		FR infant	0.00	0.1%	Maize/corn		Grapefruits				
0.0%		IT adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		FI 3 yr	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		UK toddler	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		UK vegetarian	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		LT adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		FI adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		UK adult	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		PL general	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		IE child	0.00	0.0%	Maize/corn		Grapefruits				
0.0%		DK child	0.00	0.0%	Maize/corn		Grapefruits				
0.0%	DK adult	0.00	0.0%	Grapefruits		Grapefruits					
0.0%	DK adult	0.00	0.0%	Grapefruits		Grapefruits					

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

A 3.2 IEDI calculations



LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0.004	ARID (mg/kg bw):	0.008
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

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 (IED/TMDI)

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

MRLs set at the LOQ (in % of ADI)

Exposure resulting from commodities under assessment (in % of ADI)

TMDI/NEDI calculation (based on average food consumption)

18%

NL toddler

0.70

18%

Maize/com

3%

GEMS/Food G06

0.13

3%

Maize/com

Grapefruits

3%

UK infant

0.10

3%

Maize/com

Grapefruits

2%

RO general

0.10

2%

Maize/com

Grapefruits

2%

GEMS/Food G10

0.07

2%

Maize/com

Grapefruits

2%

GEMS/Food G15

0.06

2%

Maize/com

Grapefruits

1%

PT general

0.05

1%

Maize/com

Grapefruits

1%

GEMS/Food G08

0.04

1%

Maize/com

Grapefruits

1%

FR child 3-15 yr

0.04

1%

Maize/com

Grapefruits

0.8%

GEMS/Food G07

0.03

0.8%

Maize/com

Grapefruits

0.7%

ES child

0.03

0.7%

Maize/com

Grapefruits

0.7%

NL child

0.03

0.7%

Maize/com

Grapefruits

0.5%

IE adult

0.02

0.5%

Maize/com

Grapefruits

0.4%

DE child

0.02

0.4%

Maize/com

Grapefruits

0.3%

GEMS/Food G11

0.01

0.3%

Maize/com

Grapefruits

0.2%

NL general

0.01

0.2%

Maize/com

Grapefruits

0.2%

FR toddler 2-3 yr

0.01

0.2%

Maize/com

Grapefruits

TMDI/NEDI calculation (based on average food consumption)

0.2%

ES adult

0.01

0.2%

Maize/com

Grapefruits

0.2%

DE women 14-50 yr

0.01

0.2%

Maize/com

Grapefruits

0.2%

FR adult

0.01

0.2%

Maize/com

Grapefruits

0.1%

DE general

0.01

0.1%

Maize/com

Grapefruits

0.1%

IT toddler

0.00

0.1%

Maize/com

Grapefruits

0.1%

FI 6 yr

0.00

0.1%

Maize/com

Grapefruits

0.1%

FR infant

0.00

0.1%

Maize/com

Grapefruits

0.0%

IT adult

0.00

0.0%

Maize/com

Grapefruits

0.0%

FI 3 yr

0.00

0.0%

Maize/com

Grapefruits

0.0%

UK toddler

0.00

0.0%

Maize/com

Grapefruits

0.0%

UK vegetarian

0.00

0.0%

Maize/com

Grapefruits

0.0%

LT adult

0.00

0.0%

Maize/com

Grapefruits

0.0%

FI adult

0.00

0.0%

Maize/com

Grapefruits

0.0%

UK adult

0.00

0.0%

Maize/com

Grapefruits

0.0%

PL general

0.00

0.0%

Maize/com

Grapefruits

0.0%

IE child

0.00

0.0%

Maize/com

Grapefruits

0.0%

DK child

0.00

0.0%

Maize/com

Grapefruits

DK adult

Grapefruits

DK adult

Grapefruits

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Terbutylazine is unlikely to present a public health concern.

A 3.3 TMDI calculations (input values: Reg. (EU) 2021/1795)



Terbuthylazine			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):		0,004	ARID (mg/kg bw): 0,008
Source of ADI:		Source of ARID:	
Year of evaluation:		Year of evaluation:	

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 :			---					Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)	
TMD/UNED/IEDI calculation (based on average food consumption)	48%	NL toddler	1,91	30%	Milk: Cattle	4%	Maize/corn	3%	Apples			
	25%	UK infant	1,01	19%	Milk: Cattle	0,8%	Potatoes	0,7%	Wheat			
	23%	NL child	0,91	12%	Milk: Cattle	2%	Sugar beet roots	1%	Apples			
	21%	FR toddler 2-3 yr	0,86	15%	Milk: Cattle	0,8%	Apples	0,8%	Wheat			
	21%	DE child	0,84	10%	Milk: Cattle	3%	Apples	1%	Wheat			
	20%	FR child 3-15 yr	0,79	11%	Milk: Cattle	1%	Wheat	0,9%	Sugar beet roots			
	16%	UK toddler	0,66	10%	Milk: Cattle	1,0%	Wheat	0,9%	Potatoes			
	13%	DK child	0,54	6%	Milk: Cattle	1%	Rye	1%	Wheat			
	13%	ES child	0,50	6%	Milk: Cattle	1%	Wheat	0,7%	Cocoa beans			
	13%	RO general	0,50	6%	Milk: Cattle	1%	Wheat	0,9%	Potatoes			
	12%	SE general	0,50	6%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Potatoes			
	12%	DE women 14-50 yr	0,50	6%	Milk: Cattle	1%	Sugar beet roots	0,6%	Apples			
	12%	GEMS/Food G11	0,50	4%	Milk: Cattle	1,0%	Potatoes	0,9%	Soyabeans			
	12%	DE general	0,49	6%	Milk: Cattle	1%	Sugar beet roots	0,6%	Apples			
	12%	GEMS/Food G15	0,46	4%	Milk: Cattle	1%	Wheat	0,9%	Potatoes			
	12%	FR infant	0,46	8%	Milk: Cattle	0,5%	Potatoes	0,4%	Apples			
	11%	GEMS/Food G07	0,45	3%	Milk: Cattle	1%	Wheat	0,9%	Potatoes			
	11%	GEMS/Food G08	0,44	3%	Milk: Cattle	1%	Wheat	1,0%	Potatoes			
	11%	GEMS/Food G10	0,43	3%	Milk: Cattle	1,0%	Wheat	0,8%	Soyabeans			
	11%	GEMS/Food G06	0,42	2%	Wheat	1%	Milk: Cattle	0,9%	Tomatoes			
	10%	NL general	0,39	4%	Milk: Cattle	0,7%	Sugar beet roots	0,6%	Potatoes			
	9%	IE adult	0,38	2%	Milk: Cattle	0,9%	Sweet potatoes	0,6%	Wheat			
	9%	FI adult	0,35	7%	Coffee beans	0,3%	Potatoes	0,2%	Rye			
	7%	FR adult	0,27	2%	Milk: Cattle	0,6%	Wine grapes	0,6%	Wheat			
	6%	ES adult	0,26	2%	Milk: Cattle	0,6%	Wheat	0,3%	Oranges			
	5%	DK adult	0,22	3%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat			
	5%	PT general	0,21	1%	Potatoes	1,0%	Wheat	0,6%	Wine grapes			
	5%	LT adult	0,20	2%	Milk: Cattle	0,8%	Potatoes	0,5%	Apples			
	5%	UK vegetarian	0,18	2%	Milk: Cattle	0,5%	Wheat	0,3%	Potatoes			
	4%	FI 3 yr	0,18	1%	Potatoes	0,3%	Bananas	0,3%	Wheat			
4%	UK adult	0,17	1%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes				
4%	IT toddler	0,16	2%	Wheat	0,4%	Other cereals	0,4%	Tomatoes				
4%	FI 6 yr	0,14	1,0%	Potatoes	0,3%	Cocoa beans	0,2%	Wheat				
3%	IT adult	0,12	1%	Wheat	0,3%	Tomatoes	0,2%	Apples				
3%	IE child	0,12	2%	Milk: Cattle	0,3%	Wheat	0,2%	Potatoes				
2%	PL general	0,10	0,9%	Potatoes	0,5%	Apples	0,2%	Tomatoes				

Conclusion:

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

A 3.4 IESTI calculations - Raw commodities

Show results for all crops								
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	8%	Maize/corn	0.1 / 0.1	0.67	3%	Maize/corn	0.1 / 0.1	0.22
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

A 3.5 IESTI calculations - Processed commodities

[illegible]

IESTI calculations (maize and animal commodities, Reg. (EU) 2021/1795)

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			
<p>The acute risk assessment is based on the ARID. The calculation is based on the large portion of the most critical consumer group.</p>								<p>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.</p>							
Show results for all crops															
<p>Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):</p>				<p>Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):</p>				<p>IESTI new Results for children No. of commodities for which ARID/ADI is exceeded (IESTI new):</p>				<p>IESTI new Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI new):</p>			
---				---				---				---			
IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
31%	Milk: Cattle	0,02 / 0,02	2,5	10%	Milk: Cattle	0,02 / 0,02	0,77	31%	Milk: Cattle	0,02 / 0,02	2,5	10%	Milk: Cattle	0,02 / 0,02	0,77
6%	Milk: Goat	0,02 / 0,02	0,48	5%	Milk: Goat	0,02 / 0,02	0,37	6%	Milk: Goat	0,02 / 0,02	0,48	5%	Milk: Goat	0,02 / 0,02	0,37
2%	Honey and other	0,05 / 0,05	0,18	4%	Milk: Sheep	0,02 / 0,02	0,30	2%	Honey and other	0,05 / 0,05	0,18	4%	Milk: Sheep	0,02 / 0,02	0,30
2%	Poultry: Muscle/meat	0,01 / 0,01	0,17	1%	Poultry: Muscle	0,01 / 0,01	0,12	2%	Poultry: Muscle/meat	0,01 / 0,01	0,17	1%	Poultry: Muscle	0,01 / 0,01	0,12
2%	Maize/corn	0,02 / 0,02	0,13	0,9%	Honey and other	0,05 / 0,05	0,07	2%	Maize/corn	0,02 / 0,02	0,13	0,9%	Honey and other apiculture	0,05 / 0,05	0,07
2%	Eggs: Chicken	0,01 / 0,01	0,12	0,7%	Bovine: Muscle	0,01 / 0,01	0,06	2%	Eggs: Chicken	0,01 / 0,01	0,12	0,7%	Bovine: Muscle	0,01 / 0,01	0,06
2%	Swine: Muscle/meat	0,01 / 0,01	0,12	0,7%	Other farmed animals:	0,01 / 0,01	0,06	2%	Swine: Muscle/meat	0,01 / 0,01	0,12	0,7%	Other farmed animals:	0,01 / 0,01	0,06
1%	Bovine: Liver	0,01 / 0,01	0,08	0,6%	Swine: Muscle/meat	0,01 / 0,01	0,05	1%	Bovine: Liver	0,01 / 0,01	0,08	0,6%	Swine: Muscle/meat	0,01 / 0,01	0,05
0,9%	Bovine: Edible offals	0,01 / 0,01	0,07	0,6%	Equine: Muscle/meat	0,01 / 0,01	0,05	0,9%	Bovine: Edible offals	0,01 / 0,01	0,07	0,6%	Equine: Muscle/meat	0,01 / 0,01	0,05
0,9%	Bovine: Muscle/meat	0,01 / 0,01	0,07	0,6%	Sheep: Muscle/meat	0,01 / 0,01	0,05	0,9%	Bovine: Muscle/meat	0,01 / 0,01	0,07	0,6%	Sheep: Muscle/meat	0,01 / 0,01	0,05
0,9%	Milk: Sheep	0,02 / 0,02	0,07	0,6%	Poultry: Liver	0,01 / 0,01	0,05	0,9%	Milk: Sheep	0,02 / 0,02	0,07	0,6%	Poultry: Liver	0,01 / 0,01	0,05
0,9%	Other farmed animals:	0,01 / 0,01	0,07	0,5%	Maize/corn	0,02 / 0,02	0,04	0,9%	Other farmed animals:	0,01 / 0,01	0,07	0,5%	Maize/corn	0,02 / 0,02	0,04
0,8%	Equine: Muscle/meat	0,01 / 0,01	0,06	0,5%	Eggs: Chicken	0,01 / 0,01	0,04	0,8%	Equine: Muscle/meat	0,01 / 0,01	0,06	0,5%	Eggs: Chicken	0,01 / 0,01	0,04
0,7%	Sheep: Muscle/meat	0,01 / 0,01	0,05	0,5%	Bovine: Liver	0,01 / 0,01	0,04	0,7%	Sheep: Muscle/meat	0,01 / 0,01	0,05	0,5%	Bovine: Liver	0,01 / 0,01	0,04
0,5%	Bovine: Kidney	0,01 / 0,01	0,04	0,4%	Bovine: Edible offals (other	0,01 / 0,01	0,03	0,5%	Bovine: Kidney	0,01 / 0,01	0,04	0,4%	Bovine: Edible offals (other than	0,01 / 0,01	0,03
Expand/collapse list															
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								Total number of commodities found exceeding the ARID/ADI in children and adult diets (IESTI new calculation)							
---				---				---				---			
Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI new):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI new):			
---				---				---				---			
IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Maize / oil	0,02 / 0,5	0,47	3%	Maize / oil	0,02 / 0,5	0,25	6%	Maize / oil	0,02 / 0,5	0,47	3%	Maize / oil	0,02 / 0,5	0,25
0,5%	Maize / processed (not spe	0,02 / 0,02	0,04					0,5%	Maize / processed (not	0,02 / 0,02	0,04				
Expand/collapse list															
<p>Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Terbutydazone is unlikely to present a public health risk. For processed commodities, no exceedance of the ARID/ADI was identified.</p>															

Appendix 4 Additional information provided by the applicant

No new data provided.