FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: H-01-2022

Product name(s): Terbutylazyna 500 SC

Chemical active substance:

terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: ProAgri International Sp. z o.o.

Submission date: April 2024

MS Finalisation date: 11.2024; 03.2025

Version history

When	What
November 2024	ZRMs evaluated dRR submitted by Applicant
March 2025	The final Registration Report

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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 and 12-16); Application rate per treatment: 500-750 g as/ha.

Targeted range: 1.0-1.5 L/ha every 3 years

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

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

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

Applicant refers to 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 (Reg. (EU) 2021/1795).

Uses are acceptable

Magnitude of residues in livestock

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

Processing studies

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

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

Magnitude of residues in representative succeeding crops

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

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

Other / special studies

Studies are not required for maize.

Estimation of exposure through diet and other means

The proposed uses of terbuthylazine in the formulation H-01-2022 does not represent unacceptable chronic and acute risks for the consumer.

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 H-01-2022 are presented in Table 7.1-1. A list of all intended uses within the zone is given in Part B, Section 0.

Justification for the selection of the critical GAP is not relevant.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.02 mg/kg for terbuthylazine in maize 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, zRMS agrees with the authorization of the intended use.

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

Uses are restricted to once every third year on the same field at a maximum rate of 850 g/ha (Terbuthylazine, SANCO/11337/2011 rev 3, 17 June 2011, 24 March 2021; Commission Implementing Regulation (EU) 2021/824 of 21 May 2021).

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

none

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1	Maize	PL	H-01-2022	F	weeds (for details please refer to dRR B3)	SC	500 g/l	broadcast spraying	BBCH 00	1	n.a.	125-750 g sa/hL	100-400 L/ha	500-750 g sa/ha	NR	A****
2	Maize	PL	H-01-2022	F		SC	500 g/l	broadcast spraying	BBCH 12-16	1	n.a.	125-750 g sa/hL	100-400 L/ha	500-750 g sa/ha	NR	A****

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

**** Use restricted to once every third year on the same field at a maximum rate of 850 g/ha (Terbuthylazine, SANCO/11337/2011 rev 3, 17 June 2011, 24 March 2021; Commission Implementing Regulation (EU) 2021/824 of 21 May 2021).

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation H-01-2022 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 EFSA Journal 2019;17(9):5817	2011, 2019	0.004 mg/kg bw/d	dog, 1-year & rat, 2-year	100
ARfD	EFSA Journal 2011; 9(1):1969 EFSA Journal 2019;17(9):5817	2011, 2019	0.008 mg/kg bw	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	N/A**	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
** N/A - not applicable as the PHI is covered by the vegetation period of the crop

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.

The proposed uses of terbuthylazine in the formulation H-01-2022 do not represent unacceptable acute and chronic risks for the consumer.

7.1.2.2 Summary for H-01-2022

Table 7.1-4: Information on H-01-2022 (KCA 6.8)

Crop	PHI for H-01-2022 proposed by applicant	PHI sufficiently supported for	PHI for H-01-2022 proposed by zRMS	zRMS Comments (if different PHI proposed)
		terbuthylazine		
Maize	Not specified, normal growth period*	NR		

NR: not relevant
* 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 H-01-2022
Crop group	Led by terbuthylazine	
Leafy vegetables	NR	
Root vegetables	NR	

NR: not relevant

According to DAR, The United Kingdom, 2007:
No minimum waiting period is necessary when succeeding crops are sown or planted after harvest of the crop to be protected. However, it is recommended to plough the soil if sowing/planting of succeeding crops is intended in the same year as harvest of the protected crop.

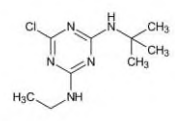
For more details, please refer to dRR Part B Section 3.

Assessment

7.2 Terbuthylazine

General data on terbuthylazine are summarized in the table below.

Table 7.2-1: General information on terbuthylazine

Active substance (ISO Common Name)	Terbuthylazine
IUPAC	N-tert-butyl-6-chloro-N'-ethyl-1,3,5-triazine-2,4-diamine
Chemical structure	
Molecular formula	$C_9H_{16}ClN_5$
Molar mass	229.71 g/mol
Chemical group	triazine
Mode of action (if available)	Broad-spectrum with strong and rapid effects. Inhibits photosynthesis (photosystem II)
Systemic	No
Company (ies)	Syngenta Crop Science
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved Date of approval: 01/01/2012 Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R0820 Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1550659094284&uri=CELEX:32019R0291 Commission Implementing Regulation (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine https://eur-lex.europa.eu/eli/reg_impl/2021/824/oj
Restriction	-

Review Report	SANCO/11337/2011 rev 3; 24 March 2021
Current MRL regulation	Reg. (EU) 2021/1795
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes. EFSA Journal 2011; 9(1):1969; EFSA Journal 2019;17(9):5817
EFSA Journal: conclusion on article 12	Yes. EFSA Journal 2020;18(1):5980
Current MRL applications on intended uses	NR

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain	High starch content	24 months	DAR, 2007 EFSA, 2011
Wheat straw	Dry commodities	24 months	DAR, 2007 EFSA, 2011
Animal products			
-	-	-	-

Conclusion on stability of residues during storage

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 (EFSA, 2011).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Not relevant.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	Maize	[triazine-U-^{14}C]-terbuthylazine	Foliar treatment, F	1.45 kg a.s./ha	1	110, 131	3-4 leaf stage	DAR, 2007 EFSA, 2011
Cereals	Maize	[triazine-U-^{14}C]-terbuthylazine	Soil spray application, F	1.50 kg a.s./ha	1	30, 111, 153	-	DAR, 2007 EFSA, 2011

Summary of plant metabolism studies reported in the EU

The metabolism of terbuthylazine (MT0) was investigated after soil and foliar treatment in cereals (United Kingdom, 2007) and assessed in the framework of the peer review. The metabolism of terbuthylazine was investigated for soil (1.5N) and foliar (1.45N) applications on maize using triazine-U-14C-labelled-terbuthylazine.
In maize, terbuthylazine is rapidly and extensively metabolised, representing less than 5% (0.003 mg eq/kg) of the total radioactive residue (TRR) in all plant parts and not being detected in mature grains at harvest following foliar application. Highest levels were seen in leaves (up to 0.3% TRR (0.009 mg eq/kg). Significant residues of metabolites MT13 (14.8% TRR (0.043 mg eq/kg) and MT14 (12.6% TRR (0.036 mg eq/kg) in leaves 30 days after soil treatment were reported. Metabolite MT14 was also significantly detected in whole plant with 23.6% TRR (0.013 mg eq/kg) 111 days after treatment (DAT) and at maturity (153 DAT) in fodder (17.5% TRR (0.049 mg eq/kg) and in grain with 20.4% TRR (0.004 mg eq/kg). It was concluded during the peer review that in maize the metabolism of terbuthylazine (MT0) in primary crop proceeds by dealkylation to desethyl metabolite (MT1) and dechlorination resulted in 2-hydroxy-terbuthylazine (MT13), which is further metabolised to the desethylhydroxy-terbuthylazine (MT14). Extractabilities were generally sufficiently high and characterisation of components in the extracted fractions was adequate.

Conclusion on metabolism in primary crops

From the available studies, it can be concluded that the metabolism of terbuthylazine is similar in the three major crop groups with the parent being extensively metabolised, however, still present at low levels and with formation of significant metabolites MT1, MT13 and MT14.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118, 364	64, 69	-	DAR, 2007 EFSA, 2011
	Spinach	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120, 329	58, 70, 120 days after treatment (30 days soil aging); 136, 156, 434 days after treatment (120 days soil aging); 405, 436 days after treatment (329 days soil aging)	-	DAR, 2007 EFSA, 2011
Root and tuber vegetables	Radish	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118, 364	64, 69	-	DAR, 2007 EFSA, 2011
	Radish	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120, 329	58, 70, 120 days after treatment (30 days soil aging); 136, 156, 434 days after treatment (120 days soil aging); 405, 436 days after treatment (329 days soil aging)	-	DAR, 2007 EFSA, 2011
Cereals	Wheat	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.5 kg a.s./ha	118, 182, 364	64 and 130 days after planting (118 days after soil treatment); 104 and 132 days (364 days after soil treatment) and of winter wheat 48, 251 and 302 days (182 days after soil treatment)	-	DAR, 2007 EFSA, 2011
	Wheat	[triazine-U-^{14}C] terbuthylazine	Soil application, F	1.0 kg a.s./ha	30, 120 329	58, 70, 120 days after treatment (30 days soil	-	DAR, 2007 EFSA,

						aging); 136, 156, 434 days after treatment (120 days soil aging); 405, 436 days after treatment (329 days soil aging)		2011

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

Summary of plant metabolism studies reported in the EU

Terbuthylazine is authorised on crops that may be grown in rotation. The field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was up to 497 days for terbuthylazine.
Two confined rotational studies were available conducted at a dose rate that achieved measured terbuthylazine soil residues covering the max PEC_{soil} (pertinent values are those for soil mixing over 20 cm) for parent terbuthylazine and should also cover the soil concentrations expected for soil metabolites MT1, MT13 and MT14.
In DAR, The United Kingdom, 2007, the two confined rotational crop studies with terbuthylazine were performed. The radiolabel was on the triazine ring. Terbuthylazine was applied onto bare soil followed by mixing over 5 cm at a rate of 1.5 kg a.s./ha (1.5N, with measured terbuthylazine in soil of 0.972 mg/kg after treatment, so representing ca. 2.4N) (study one) or at 1.0 kg a.s./ha (1N, with measured soil residues 0.364 to 0.444 mg/kg after treatment, so representing ca. 1N (study two)).
Crops were planted at nominal plant-back intervals (PBIs) of up to 364 (study one) and 329 (study two) DAT, respectively. Crops planted at each interval consisted of leafy vegetable (lettuce and spinach), roots (radish) and cereals (wheat).
Total radioactive residues in wheat grain, immature foliage and straw declined over time, while residues in lettuce and radish roots and leaves slightly increased in the study with a dose rate of 1.5 kg a.s./ha and decrease in spinach and radish root and leaves in the study with 1 kg a.s./ha dose rate.
Significant total radioactive residues were observed in the study dosed with 1.5 kg a.s./ha up to 364 DAT in lettuce (0.049 mg eq/kg), radish leaves (0.115 mg eq/kg) and roots (0.025 mg eq/kg) and wheat forage (0.365 mg eq/kg), straw (1.24 mg eq/kg), grain (0.051 mg eq/kg). In the study performed at 1 kg a.s./ha rate, 329 DAT total radioactive residues in plant samples were: spinach leaves (0.036 mg eq/kg), in radish leaves (0.058 mg eq/kg) and roots (0.025 mg eq/kg) and wheat forage (0.054 mg eq/kg), straw (0.325 mg eq/kg) and grain (0.019 mg eq/kg).
Therefore, even 1 year after treatment, significant residues from terbuthylazine were detected in edible parts of lettuce, spinach, radish and wheat and rotational field trials are considered necessary.
Levels of parent terbuthylazine were observed in the study dosed with 1.5 kg a.s./ha in lettuce (12.2% TRR; 0.0056 mg/kg); radish leaves (17.9% TRR; 0.019 mg/kg); wheat foliage (12% TRR; 0.057 mg/kg) 118 DAT and in radish leaves (10.6% TRR; 0.012 mg/kg) 364 DAT. In the study dosed with 1 kg a.s./ha, the parent was significant in wheat forage (32.3% TRR; 0.042 mg/kg), mature spinach leaves (30.8% TRR; 0.028 mg/kg), mature radish roots (25.0% TRR; 0.007 mg/kg) and wheat forage 32.4% TRR; 0.042 mg/kg) 30 DAT; in mature spinach leaves (15.4% TRR; 0.012 mg/kg) and wheat forage (13.3% TRR; 0.023 mg/kg) 120 DAT; and in wheat forage preharvest (11.1% TRR; 0.006 mg/kg) 329 DAT.
Significant residues of metabolite MT1 were observed in the study dosed with 1.5 kg a.s./ha 364 DAT in lettuce (26.7% TRR; 0.013 mg eq/kg), radish leaves (16.4% TRR; 0.019 mg eq/kg) and in wheat foliage (15.4% TRR; 0.056 mg eq/kg). In the study performed at 1 kg a.s./ha rate, 329 DAT in spinach leaves (41.7% TRR; 0.015 mg eq/kg), in wheat forage (20.4% TRR; 0.011 mg eq/kg) and straw (13.2% TRR; 0.043 mg eq/kg).
Metabolite MT13 was not reported above 10% TRR in the study dosed with 1.5 kg a.s./ha 364 DAT.
However, in the study performed at 1 kg a.s./ha rate, 329 DAT significant residues in spinach leaves (16.7% TRR; 0.006 mg eq/kg), radish leaves (10.3% TRR; 0.006 mg eq/kg), in wheat forage (18.5% TRR; 0.01 mg eq/kg), straw (24.9% TRR; 0.081 mg eq/kg), chaff (38.3% TRR; 0.079) and grain (36.8% TRR; 0.007 mg eq/kg).
Metabolite MT14 was significant in the study dosed with 1.5 kg a.s./ha 364 DAT in lettuce (10.5% TRR;

0.005 mg eq/kg), radish leaves (15.5% TRR; 0.018 mg eq/kg) and roots (17.1% TRR; 0.004 mg eq/kg). In the study performed at 1 kg a.s./ha rate, 329 DAT in spinach leaves (13.9% TRR; 0.005 mg eq/kg), radish leaves (60.3% TRR; 0.035 mg eq/kg) and roots (48.0% TRR; 0.012 mg eq/kg), in wheat forage (24.1% TRR; 0.013 mg eq/kg), straw (11.4% TRR; 0.037 mg eq/kg), chaff (12.6% TRR; 0.026 mg eq/kg) and grain (21.1% TRR; 0.004 mg eq/kg).

Summary of new plant metabolism studies

Not relevant.

Conclusion on metabolism in rotational crops

It can be concluded that the metabolism and distribution of terbuthylazine in rotational crops and the metabolic pathway observed in primary crops following soil application is similar with parent terbuthylazine, with MT1, MT13 and MT14 being the main compounds in rotational crops.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

There were no studies investigating the nature of residues of terbuthylazine in processed commodities available. The investigation of the nature of residues in processed plant commodities is not required because residues of all components of the residue definitions are below limit of quantification (LOQ) in plant commodities for human consumption.

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

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

Endpoints	
Plant groups covered	Cereals (maize)
Rotational crops covered	Leafy crops (lettuce, spinach) Root and tuber vegetables (radish) Cereals (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	No data submitted as residues in cereal grain are less than 0.01 mg/kg
Residue pattern in processed commodities similar to pattern in raw commodities?	No data submitted as residues in cereal grain are less than 0.01 mg/kg
Plant residue definition for monitoring	Terbuthylazine (MT0) (Reg. (EU) 2021/1795; EFSA Journal 2019;17(9):5817).
Plant residue definition for risk assessment	Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethyl-hydroxy-terbuthylazine (MT14) (EFSA Journal 2011; 9(1):1969)
Conversion factor from enforcement to RA	None.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[triazine-U-^{14}C]-terbuthylazine	1 control, 1 dosed animal	0.071	10	Milk	daily	DAR, 2007 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

A cow metabolism study was provided where animals were dosed with ^{14}C-terbuthylazine over 10 days at a dose rate calculated to represent a 18N and 15N dose rate for 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 mg/kg in milk, muscle and fat and <0.05 mg/kg in liver and kidney when expressed on a 1N dose basis, it was concluded that no significant residues of any metabolite are expected to be present in animal matrices (EFSA, 2011).

Summary of new animal metabolism studies

Not relevant.

Conclusion on metabolism in livestock

The setting of a residue definition and proposals for MRLs for animal products were therefore considered not necessary with regard to the representative uses (EFSA, 2011).

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

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

Endpoints	
Animals covered	Lactating cows
Time needed to reach a plateau concentration	Within 24 hours
Animal residue definition for monitoring	Not necessary for the representative uses (EFSA Journal 2011; 9(1):1969). 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
Animal residue definition for risk assessment	Not necessary for the representative uses (EFSA Journal 2011; 9(1):1969). 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
Conversion factor	-
Metabolism in rat and ruminant similar	-
Fat soluble residue	Y, Log Pow 3.4 and significant residue in fat in ruminant and poultry metabolism studies (EFSA Journal 2020;18(1):5980)

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of H-01-2022 and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize - grain	DAR, 2007, 2010 EFSA, 2011	N-EU	GAP on which MRL/EU a.s. assessment is based: 1x 0.75 kg as/ha, pre-emergence, early post emergence (12-16), PHI n.r., outdoor E: MT0: 8x<0.02 RA: MT0: 8x<0.02 MT1: 8x<0.02 MT14: 8x<0.02 (Total residues: 8x<0.06)	N/A				
	New trials	-	-					
	Overall supporting data for cGAP	N-EU	E: MT0: 8x<0.02 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	-	0.02	Yes

Maize - forage	DAR, 2007, 2010 EFSA, 2011	N-EU	GAP on which MRL/EU a.s. assessment is based: 1x 0.75 kg as/ha, pre-emergence, early post emergence (12-16), PHI n.r., outdoor 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	-	-					
	Overall supporting data for cGAP	N-EU	MT0: 8x<0.02 MT1: 8x<0.02 MT14: 7x<0.02, 0.03 (Total residues: 7x<0.06, 0.07)	MT0: 0.02 Total residues: 0.06	MT0: 0.02 Total residues: 0.07	-	-	-

* Source of EU MRL: Reg. (EU) 2021/1795
MT0: terbuthylazine
MT1: desethyl-terbuthylazine
MT14: desethyl-2- hydroxy-terbuthylazine
Total residues: Sum MT0+MT1+MT14

7.2.3.2 Conclusion on the magnitude of residues in plants

Maize
A total of 8 trials on maize in N-EU zone are available. All trials were performed according to the critical EU GAP from DAR (United Kingdom, 2007).

The residue data are valid with regard to storage stability and are sufficient to support the proposed use.

The residues arising from the proposed uses will not exceed the MRLs established for maize grain (0.02 mg/kg).

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Terbuthylazine is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens were calculated for all animal commodities, whereby cattle (all) and dairy cattle were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these groups of livestock (EFSA Journal 2020;18(1):5980)

Dietary burden calculation for purpose of maintain authorisation of H-01-2022 was performed by Excel spreadsheet Animal model 2017 and was focused only on intended uses of H-01-2022. Input values used for dietary calculation are provided below in Table 7.2-9. Results of dietary burden calculation for H-01-2022 are included in Table 7.2-10.

Table 7.2-9: Input values for the dietary burden calculation

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Corn, field (forage/silage)	0.02	STMR (EFSA, 2020)	0.02	STMR (EFSA, 2020)
Corn, field (Maize) (grain)	0.02	STMR (EFSA, 2020)	0.02	STMR (EFSA, 2020)
Corn, field (milled by-pdts)	0.02 x 1	STMR x PF* (EFSA, 2020)	0.02 x 1	STMR x PF* (EFSA, 2020)
Corn, field (hominy meal)	0.02 x 6	STMR x PF* (EFSA, 2020)	0.02 x 6	STMR x PF* (EFSA, 2020)
Corn, field (gluten feed)	0.02 x 2.5	STMR x PF* (EFSA, 2020)	0.02 x 2.5	STMR x PF* (EFSA, 2020)
Corn, field (gluten, meal)	0.02 x 1	STMR x PF* (EFSA, 2020)	0.02 x 1	STMR x PF* (EFSA, 2020)
Distiller's grain (dried)	0.02 x 3.3	STMR x PF* (EFSA, 2020)	0.02 x 3.3	STMR x PF* (EFSA, 2020)

* Default PF (Animal model 2017)

Table 7.2-10: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,003	0,003	0,07	0,07	Dairy cattle	Corn, field	gluten feed	No
Cattle (dairy only)	0,003	0,003	0,07	0,07	Dairy cattle	Corn, field	gluten feed	No
Sheep (all diets)	0,002	0,002	0,04	0,04	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0,001	0,001	0,04	0,04	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0,001	0,001	0,05	0,05	Swine (finishing)	Corn, field	gluten feed	No
Poultry (all diets)	0,003	0,003	0,05	0,05	Poultry layer	Corn, field	hominy meal	No
Poultry (layer only)	0,003	0,003	0,05	0,05	Poultry layer	Corn, field	hominy meal	No

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

The calculated dietary burdens were found to be below the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all types of livestock diets. Further investigation on the nature of residues is therefore not required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

Conclusion on metabolism in livestock

Studies are not required based on the very low level of residues of terbuthylazine in maize (DAR, The United Kingdom, 2007.

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

7.2.5.1 Available data for all crops under consideration

No new data submitted in the framework of this application.

7.2.5.2 Conclusion on processing studies

As residues of terbuthylazine exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.
Processing studies were not submitted and are not required because of the low residue levels (EFSA, 2011).

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

zRMS:

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).

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of H-01-2022. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum terbuthylazine (MT0), desethyl-terbuthylazine (MT1) and desethylhydroxy-terbuthylazine (MT14), expressed as terbuthylazine				
Intended/relevant uses				
Maize	0.06	Total residue (from supervised residue trials. See table 7.2-8)	0.06	Total residue (from supervised residue trials. See table 7.2-8)
Further uses				
Other commodities of plant and animal origin	variable	existing EU MRL*	Not relevant.	

* Source of EU MRL: Regulation (EU) 2021/1795

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

ADI	0.004 mg/kg bw/day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	55% (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.

ARfD	0.008 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Unprocessed commodities - children 5% Maize/corn (based on UK infant diet) Unprocessed commodities - adults 2% Maize/corn (based on FI men diet) Processed commodities - children 17% Maize/oil (based on NL toddler diet) 2% Maize/processed (not specified) (based on NL toddler diet) Processed commodities - adults 10% Maize/oil (based on NL general population)
NTMDI (% ADI)	Not relevant.
NEDI (% ADI)	Not relevant.
NESTI (% ARfD)	Not relevant.

Chronic exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1; calculation version 06/01/2021) provided on the internet homepage of EFSA (https://www.efsa.europa.eu/). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

The potential chronic dietary exposure was compared to the ADI of 0.004 mg/kg bw/d for terbuthylazine and TMDI values were achieved. Input values for maize were derived from existing residue trials (see Table 7.2-8). For other commodities/products of plant and animal origin input values were derived from current EU MRL (Reg. (EU) 2021/1795), representing a worst-case scenario. The highest chronic exposure was calculated for NL toddler diet, representing 55% of the ADI. For this diet the highest contributors were milk: cattle (30% of ADI), maize/corn (11% of ADI) and apples (3% of ADI). Since TMDI values are below 100%, there is no need to perform higher tier/refined chronic exposure calculation.

The potential acute dietary exposure was compared to the ARfD of 0.008 mg/kg bw/d for terbuthylazine and IESTI values were achieved. Acute exposure was performed only for intended uses. Input values for maize were derived from existing residue trials (see Table 7.2-8). Since IESTI values are below 100%, there is no need to perform higher tier/refined acute exposure calculation.

The proposed uses of terbuthylazine in the formulation H-01-2022 does not represent unacceptable chronic and acute risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

United Kingdom, 2007. Draft Assessment Report (DAR) on the active substance terbuthylazine prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC, August 2007.

United Kingdom, 2010. Additional Report to the Draft Assessment Report on the active substance terbuthylazine prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EC) No 33/2008, February 2010

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance terbuthylazine. EFSA Journal 2011;9(1):1969, 133 pp. https://doi.org/10.2903/j.efsa.2011.1969

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance terbuthylazine. EFSA Journal 2019;17(9):5817, 58 pp. doi:10.2903/j.efsa.2019.5817

EFSA (European Food Safety Authority), 2020. Review of the existing maximum residue levels for terbuthylazine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5980, doi: 10.2903/j.efsa.2020.5980

EUROPEAN COMMISSION - Final Review report for the active substance terbuthylazine finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011 and updated on 24 March 2021 in view of the approval of terbuthylazine as active substances in accordance with Regulation (EC) No 1107/2009. Terbuthylazine SANCO/11337/2011 rev 3, 17 June 2011, 24 March 2021.

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

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
KCA 6.1	Giannone, C.	1998	Stability or residues of terbuzhylazine (GS 13529) and GS 26379 (metabolite of terbuthylazine) in plant materials (analytical specimens on wheat grain and wheat straw) stored under deep freeze conditions Novartis Crop Protection AG, Basel Switzerland Report No 136/96 GLP Not Published Syngenta File N°GS13529/1557	N	Syngenta
KCA 6.1	Giannone, C.	2003	Stability of residues of GS 28260 (Metabolite of terbuthylazine) in deep freeze stored analytical specimens of wheat grain, beans and sunflowers seeds Syngenta Crop Protection AG, Basel, Switzerland	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 302/01 GLP Not Published Syngenta File N°GS13529/1854		
KCP 7.2.2	Nicollier, G.	1997	Behaviour and metabolism of GS 13529 in field grown corn after soil application of [Triazine-(U)-14C] labelled material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No CMR 07/97 GLP Not published Syngenta File N° GS13529/1486	N	Syngenta
KCP 7.2.2	Willems, H.	1998	Metabolism, distribution and expression of terbuthylazine residues in corn. Netox B.V, s-Hertegenbosch, The Netherlands Oxon Italia S.P.A., Pero, Italy Report no 197764 GLP Not published	N	Oxon
KCP 7.2.2	Salvi, M.	2002a	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France Report No 3002/00 GLP Not Published Syngenta File N° GS13529/1754	N	Syngenta
KCP 7.2.2	Salvi, M.	2002b	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France Report No 3003/00 GLP	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
			Not Published Syngenta File N° GS13529/1755		
KCP 7.2.2	Stolze, K.	1997a	Residues of CGA 77102 and Terbuthylazine (GS 13529) in maize Novartis Crop Protection AG, Basel Switzerland Novatoris Agro GmbH, Frankfurt, Germany Report No GR 15596 GLP Not Published Syngenta File N°GS13529/1500	N	Syngenta
KCP 7.2.2	Stolze, K.	1997b	Residues of CGA 77102 and Terbuthylazine (GS 13529) in maize Novartis Crop Protection AG, Basel Switzerland Novatoris Agro GmbH, Frankfurt, Germany Report No GR 14196 GLP Not Published Syngenta File N°GS13529/1501	N	Syngenta
KCP 7.2.2	Luetolf, W.	199a	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No 3004/96 GLP Not Published Syngenta File N° GS13529/1607	N	Syngenta
KCP 7.2.2	Luetolf, W.	199b	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No 3004/96 GLP Not Published Syngenta File N° GS13529/1608	N	Syngenta
KCP 7.2.2	Stolze, K.	2004a	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000	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 Syngenta Agro GmbH, Maintal, Germany Report No gr 06400 GLP Not Published Syngenta File N° SAN319/6277		
KCP 7.2.2	Stolze, K.	2004b	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany Report No gr 06300 GLP Not Published Syngenta File N° SAN319/6278	N	Syngenta
KCP 7.2.2	Stolze, K.	2004c	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany Report No gr 06200 GLP Not Published Syngenta File N° SAN319/6279	N	Syngenta
KCP 7.2.2	Stolze, K.	2004d	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany Report No gr 06100 GLP Not Published Syngenta File N° SAN319/6280	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.2	Stolze, K.	2004e	Determination of residues of CGA 77102 and GS 13529 in maize and rotational crop Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syntenta Agro GmbH, Maintal, Germany Report No gr 10200 GLP Not Published Syngenta File N° GS13529/1917	N	Syngenta
KCP 7.2.2	Stolze, K.	2004f	Determination of residues of CGA 77102 and GS 13529 in maize and rotational crop Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syntenta Agro GmbH, Maintal, Germany Report No gmz 91001 GLP Not Published Syngenta File N° GS13529/1912	N	Syngenta
KCP 7.2.2	Luetolf, W.	2003	Crop Rotation Study with S-Metholachlor (CGA 77102) and Terbuthylazine (GS 13529) in or on follow up Crop after Treatment of Maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Report No 307/00 GLP Not Published Syngenta File N° CGA77102/0662	N	Syngenta
KCP 7.2.2	Kuhne-Thu, H.	2003a	Residues Study with Terbuthylazine (GS 13529) and S-Metalochlor (CGA 77102) in or maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Report No 3037/01 GLP Not Published Syngenta File N° GS13529/1894	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 7.2.2	Kuhne-Thu, H.	2003b	Residues Study with Terbuthylazine (GS 13529) and S-Metalochlor (CGA 77102) in or maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Report No 3038/01 GLP Not Published Syngenta File N° GS13529/1895	N	Syngenta
KCP 7.2.3	Mostert, I.	1997a	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3054/95 GLP Not Published Syngenta File N° GS13529/1498	N	Syngenta
KCP 7.2.3	Mostert, I.	1997b	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3055/95 GLP Not Published Syngenta File N° GS13529/1499	N	Syngenta
KCP 7.2.3	Mostert, I.	1997c	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3052/96 GLP Not Published Syngenta File N° GS13529/1489	N	Syngenta
KCP 7.2.3	Mostert, I.	1997d	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B)	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
			Novatoris Crop Protection AG, Basel, Switzerland Report No 3085/95 GLP Not Published Syngenta File N° GS13529/1490		
KCP 7.2.3	Mostert, I.	1997e	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3053/96 GLP Not Published Syngenta File N° GS13529/1491	N	Syngenta
KCP 7.2.3	Mostert, I.	1997f	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3051/96 GLP Not Published Syngenta File N° GS13529/1492	N	Syngenta
KCP 7.2.3	Mostert, I.	1997g	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Report No 3083/95 GLP Not Published Syngenta File N° GS13529/1493	N	Syngenta
KCA 6.6.1	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	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
			GLP Not Published Syngenta File N° GS13529/1663		

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 Terbuthylazine

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

Not relevant. No new studies are submitted with this application.

A 2.1.1.1.2 Storage stability of residues in animal products

Not relevant. No new studies are submitted with this application.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

Not relevant. No new studies are submitted with this application.

A 2.1.2.1.2 Nature of residue in rotational crops

Not relevant. No new studies are submitted with this application.

A 2.1.2.1.3 Nature of residues in processed commodities

Not relevant. No new studies are submitted with this application.

A 2.1.2.2 Nature of residues in livestock

Not relevant. No new studies are submitted with this application.

A 2.1.3 Magnitude of residues in plants

Not relevant. No new studies are submitted with this application.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

Not relevant. No new studies are submitted with this application.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

Not relevant. No new studies are submitted with this application.

A 2.1.5.2 Processing studies on a core set of representative processes

Not relevant. No new studies are submitted with this application.

A 2.1.6 Magnitude of residues in representative succeeding crops

Not relevant. No new studies are submitted with this application.

A 2.1.7 Other/Special Studies

Not relevant. No other/special studies are submitted with this application.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.3.1)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Terbuthylazine (F)

LOQs (mg/kg) range from: 0,01 to: 0,05

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:	2017	Year of evaluation:	2017

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	55%	NL toddler	2,19	30%	Milk: Cattle	11%	Maize/corn	3%	Apples	44%	11%
	26%	UK infant	1,05	19%	Milk: Cattle	2%	Maize/corn	0,8%	Potatoes	25%	2%
	23%	NL child	0,92	12%	Milk: Cattle	2%	Sugar beet roots	1%	Apples	23%	0,4%
	22%	FR toddler 2 3 yr	0,86	15%	Milk: Cattle	0,8%	Apples	0,8%	Wheat	21%	0,1%
	21%	DE child	0,84	10%	Milk: Cattle	3%	Apples	1%	Wheat	21%	0,2%
	20%	FR child 3 15 yr	0,80	11%	Milk: Cattle	1%	Wheat	0,9%	Sugar beet roots	19%	0,6%
	16%	UK toddler	0,66	10%	Milk: Cattle	1,0%	Wheat	0,9%	Potatoes	16%	0,0%
	14%	RO general	0,54	6%	Milk: Cattle	1%	Maize/corn	1%	Wheat	12%	1%
	13%	DK child	0,54	6%	Milk: Cattle	1%	Rye	1%	Wheat	13%	0,0%
	13%	ES child	0,52	6%	Milk: Cattle	1%	Wheat	0,7%	Cocoa beans	12%	0,4%
	13%	DE women 14-50 yr	0,50	6%	Milk: Cattle	1%	Sugar beet roots	0,6%	Apples	12%	0,1%
	13%	GEMS/Food G11	0,50	4%	Milk: Cattle	1,0%	Potatoes	0,9%	Soyabeans	12%	0,2%
	12%	SE general	0,50	6%	Milk: Cattle	1%	Bovine: Muscle/meat	1%	Potatoes	12%	
	12%	DE general	0,49	6%	Milk: Cattle	1%	Sugar beet roots	0,6%	Apples	12%	0,1%
	12%	GEMS/Food G15	0,49	4%	Milk: Cattle	1%	Wheat	1,0%	Maize/corn	11%	1,0%
	12%	GEMS/Food G06	0,47	2%	Maize/corn	2%	Wheat	1%	Milk: Cattle	10%	2%
	12%	GEMS/Food G07	0,47	3%	Milk: Cattle	1%	Wheat	0,9%	Potatoes	11%	0,5%
	12%	FR infant	0,46	8%	Milk: Cattle	0,5%	Potatoes	0,4%	Apples	12%	0,0%
	11%	GEMS/Food G10	0,46	3%	Milk: Cattle	1,0%	Maize/corn	1,0%	Wheat	10%	1,0%
	11%	GEMS/Food G08	0,46	3%	Milk: Cattle	1%	Wheat	1,0%	Potatoes	11%	0,7%
	10%	NL general	0,39	4%	Milk: Cattle	0,7%	Sugar beet roots	0,6%	Potatoes	10%	0,1%
	10%	IE adult	0,39	2%	Milk: Cattle	0,9%	Sweet potatoes	0,6%	Wheat	9%	0,3%
	9%	FI adult	0,35	7%	Coffee beans	0,3%	Potatoes	0,2%	Rye	9%	0,0%
	7%	FR adult	0,27	2%	Milk: Cattle	0,6%	Wine grapes	0,6%	Wheat	7%	0,1%
	7%	ES adult	0,26	2%	Milk: Cattle	0,6%	Wheat	0,3%	Oranges	6%	0,1%
	6%	PT general	0,23	1%	Potatoes	1,0%	Wheat	0,7%	Maize/corn	5%	0,7%
	5%	DK adult	0,22	3%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat	5%	
	5%	LT adult	0,20	2%	Milk: Cattle	0,8%	Potatoes	0,5%	Apples	5%	0,0%
	5%	UK vegetarian	0,18	2%	Milk: Cattle	0,5%	Wheat	0,3%	Potatoes	5%	0,0%
	4%	FI 3 yr	0,18	1%	Potatoes	0,3%	Bananas	0,3%	Wheat	4%	0,0%
	4%	UK adult	0,17	1%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes	4%	0,0%
	4%	IT toddler	0,17	2%	Wheat	0,4%	Other cereals	0,4%	Tomatoes	4%	0,0%
	4%	FI 6 yr	0,14	1,0%	Potatoes	0,3%	Cocoa beans	0,2%	Wheat	4%	0,0%
	3%	IT adult	0,12	1%	Wheat	0,3%	Tomatoes	0,2%	Apples	3%	0,0%
	3%	IE child	0,12	2%	Milk: Cattle	0,3%	Wheat	0,2%	Potatoes	3%	0,0%
	2%	PL general	0,10	0,9%	Potatoes	0,5%	Apples	0,2%	Tomatoes	2%	0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Terbuthylazine (F) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

Not required. TMDI below 100%

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the Eu

The calculation is based on the large portion of the most critical consumer group.

Show results of IESTI calculation only for crops with GAPs under assessment

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)
5%	Maize/corn	0,02 / 0,06	0,40	2%	Maize/corn	0,02 / 0,06	0,13
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
17%	Maize / oil	0,02 / 1,5	1,4	10%	Maize / oil	0,02 / 1,5	0,76
2%	Maize / processed (not spe	0,02 / 0,06	0,13				
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Terbuthylazine (F) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant

Not relevant.