FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: TERBUT 500 SC

Product names: **TERBUT 500 SC/**

TAZOPRYM 500 SC / CORNAO 500 SC

Chemical active substance:

Terbuthylazine, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

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

Submission date**:** 08/2020

MS Finalisation date: 10/2021; 03/2022; 05/2022; 05/2022

06/2022; 08/2022

Version history

When	What
10/2021	ZRMS evaluated the updated dRR by Applicant.
March 2022	Final Registration Report
05/2022	Review of the assessment taking into account Reg. (EU) 2021/1795
May 2022	Supplemented by expert- toxicology section and efficacy section
June 2022	Review of the assessment taking into account Commission Implementing Regulation (EU) 2021/824 of 21 May 2021 amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine
August 2022	Some confidential data were masked

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PART A
RISK MANAGEMENT

1 Details of the application

This application was submitted by company Synthos Agro Sp. z o.o., ul Chemików 1, 32-600 Oświecim, Poland.
The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to **TERBUT 500 SC**/TAZOPRYM 500 SC/CORNAO 500 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of **TERBUT 500 SC**/TAZOPRYM 500 SC/CORNAO 500 SC have been made using endpoints agreed in the EU review of terbuthylazine.

1.1 Application background

The application is submitted for registration of plant protection product **TERBUT 500 SC**/TAZOPRYM 500 SC/CORNAO 500 SC in Poland according to art. 33 of Regulation 1107/2009. The product has not been previously evaluated in any country from Central Zone of Europe according to Uniform Principles. The zRMS is Poland.

The application is for the approval of **TERBUT 500 SC**/TAZOPRYM 500 SC/CORNAO 500 SC a suspension - flowable concentrate (SC) containing 500 g/L of terbuthylazine for use as a post emergence herbicide in maize crop.

1.2 Letters of Access

The Applicant has conducted and submitted own studies on TERBUT 500 SC which are sufficient to evaluate of the product.
Only the access to the equivalency of the active substance is submitted.
Accesses to the protected data are not necessary due to their termination on 1 January 2017.

1.3 Justification for submission of tests and studies

The Applicant has conducted and submitted own studies on TERBUT 500 SC which are sufficient to evaluate of the product. Data protection claims and a list of submitted test reports and study are included in each section of dRR for TERBUT 500 SC and in Part C.

1.4 Data protection claims

All data submitted in Part C are confidential. Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4, on all references specified in Sections 1-10 of Part B in the form of " List of data submitted in support of the evaluation".

2 Details of the authorization decision

2.1 Product identity

Product code	TERBUT 500 SC
Product name in MS	TERBUT 500 SC, TAZOPRYM 500 SC, CORNAO 500 SC
Authorization number	First autorization
Function	Herbicide
Applicant	Synthos Agro Sp. z o.o.
Active substance(s) (incl. content)	Terbuthylazine 500 g/L
Formulation type	suspension - flowable concentrate [Code: SC]
Packaging	packagings for professional users 1L HDPE bottles 5L, 10L, 20L HDPE canisters
Coformulants of concern for national authorizations	No coformulants of concern
Restrictions related to identiy	No
Mandatory tank mixtures	No
Recommended tank mixtures	Hydron

2.2 Conclusion

The evaluation of the application for product name resulted in the decision to grant the authorization.

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

Fate: The evaluation of the application for product Terbut 500 SC resulted in the decision to grant the authorization. The restricted to use Terbut 500 SC: once every third year on the same field (the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011).

Ecotoxicology: The evaluation of the application for Terbut 500 SC resulted in the decision to grant the authorization only for pre-emergence use.

Efficacy section: not accepted solo pre-emergence use. Post-emergence use (solo and in the mixture tank with adiuvant) and pre-emergence use with adiuvant is accepted.

2.3 Substances of concern for national monitoring

National monitoring data is not available/known to the Applicant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4, H302 Skin Sens. 1, H317 STOT RE 2, H373 Aquatic Acute, 1 H400 Aquatic Chronic, 1 H410

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	**GHS07, GHS08, GHS09**
Signal word:	**Warning**
Hazard statement(s):	**H302 – Harmful if swallowed** **H317 – May cause an allergic skin reaction.** **H373 – May cause damage to organs thorough prolonged or repeated exposure.** **H410 – Very toxic to aquatic life with long lasting effects.**
Precautionary statement(s):	**P260 – Do not breathe dust/fume/gas/mist/vapours/spray.** **P264 - Wash hand thoroughly after handling.** **P270 - Do not eat, drink or smoke when using this product.** **P272 - Contaminated work clothing should not be allowed out of the workplace**. **P280 -Wear protective gloves/protective clothing/eye protection/face protection** **P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.** **P330 - Rinse mouth**. **P314 - Get medical advice/attention if you feel unwell.** **P302+P352- IF ON SKIN: Wash with plenty of water.** **P333+P313- If skin irritation or rash occurs: Get medical advice/ attention.** P363- Wash contaminated clothing before reuse. **P501 - Dispose of contents/ container to an approved waste disposal plant.**
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]**

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008: -	

TERBUT 500 SC contains the active substance – terbuthylazine, which is classified as STOT RE 2 with hazard statement H373. Its concentration in the product is equal to 50 %. This concentration is above concentration limit (10%) stated in Table 3.9.4 of Regulation (EC) 1272/2008, therefore the product is classified as **STOT RE 2** with hazard statement **H373**.

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	**To protect aquatic organisms for pre - and post-emergence** uses respect a: -5m buffer non-spray zone with 5 meter vegetated filter strip to surface water bodies **To protect non-target terrestrial plants respect a:** - 3 m buffer zone or -1 m and use of 75% drift reducing nozzles

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Work wear (arms, body and legs covered) and Gloves during mixing/loading and application process should be applied.
Worker protection:	
respective code if available	Gloves during mixing/loading and application process should be applied.
Integrated pest management (IPM)/sustainable use:	
respective code if available	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
SPe3	**To protect aquatic organisms for pre - and post-emergence** uses respect a: -5m buffer non-spray zone with 5 meter vegetated filter strip to surface water bodies **To protect non-target terrestrial plants respect a:** - 3 m buffer zone or -1 m and use of 75% drift reducing nozzles
Other specific restrictions	
respective code if available	No other requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Environmental protection:		Relevant for use no.
	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters must be adopted	1-2

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Terbut 500 SC, Tezoprym 500 SC, Cornao 500 SC/ Terbut 500 SC		GAP rev. 1, date: 04.2020
Active substance 1:	terbuthylazine	Formulation type:	suspension concentrate (SC)
Applicant:	Synthos Agro sp. Z o.o.	Conc. of as 1:	500 g/L
Zone(s):	central	Professional use:	☒
Verified by MS:	no	Non professional use:	☐
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					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 (post-emergence)~~	~~F~~	~~**Sensitive:**~~ ~~*Capsella bursa-pastoris*~~ ~~*Viola arvensis*~~ ~~*Chenopodium album*~~ ~~*Amaranthus retroflexus*~~ ~~*Galium aparine*~~ ~~*Tripleurospermum inodorum*~~ ~~*Veronica arvensis*~~ ~~*Fallopia convolvulus*~~ ~~*Solanum nigrum*~~ ~~*Matricaria Chamomilla*~~ ~~**Medium sensitive:**~~ ~~*Cyanus segetum*~~ ~~*Stellaria media*~~	~~Fine spraying~~	~~BBCH 12-16~~	~~1~~	~~-~~	~~1 l/ha~~	~~500 g as/ha~~	~~200-300 l/ha~~		Ecotoxicology section not accepted post-emergence use,
				~~**Sensitive:**~~ ~~*Chenopodium album*~~ ~~*Viola arvensis*~~ ~~*Amaranthus retroflexus*~~ ~~*Galium aparine*~~	~~Fine spraying~~	~~BBCH 12-16~~	~~1~~	~~-~~	~~1 l/ha + 0,2 (adiuwant)~~	~~500 g as/ha~~	~~200-300 l/ha~~		Ecotoxicology section not accepted post-emergence use,

				~~*Tripleurospermum inodorum*~~ ~~*Capsella bursa-pastoris*~~ ~~*Veronica arvensis*~~ ~~*Fallopia convolvulus*~~ ~~*Solanum nigrum*~~ ~~*Matricaria Chamomilla*~~ ~~*Stellaria media*~~ ~~**Medium sensitive:**~~ ~~*Cyanus segetum*~~									
2	PL	Maize (pre-emergence)	F	~~**Sensitive:**~~ ~~*Chenopodium album*~~ ~~*Viola arvensis*~~ ~~*Amaranthus retroflexus*~~ ~~*Tripleurospermum inodorum*~~ ~~*Matricaria Chamomilla*~~ ~~**Medium sensitive:**~~ ~~*Stellaria media*~~ ~~*Cyanus segetum*~~	~~Fine spraying~~	~~BBCH 00~~	~~1~~	~~-~~	~~1 l/ha~~	~~500 g as/ha~~	~~200-300 l/ha~~		Efficacy section not accepted solo use. Use shall be limited to one application every three years on the same field at a maximum dose of 850 g ter-buthylazine per hectare
				Sensitive: *Viola arvensis* *Amaranthus retroflexus* *Tripleurospermum inodorum* *Capsella bursa-pastoris* ~~*Matricaria Chamomilla*~~ **Medium sensitive:** *Fallopia convolvulus* *Geranium pusillum* *Galium aparine* *Cyanus segetum* *Stellaria media* *Chenopodium album*	Fine spraying	BBCH 00	1	-	1 l/ha + 0,2 l/ha (adiuwant)	500 g as/ha	200-300 l/ha		Use shall be limited to one application every three years on the same field at a maximum dose of 850 g ter-buthylazine per hectare

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 application
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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous white liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point up to the boiling point. It has a self ignition temperature above 650 °C. In aqueous solution, it has a pH value around 7.76 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging.

Its technical characteristics are acceptable for a Suspension Concentrate formulation.
The intended concentration of use is 0.33% to 0.50%.
Physical-Chemistry data cover concentration from 0.27% to 0.75%. All results are within the scope of acceptance. Due to the fact that those concentration uses represents worse case than intended they should be deemed as accepted.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

Terbut 500 SC is a suspension concentrate (SC) containing 500 g/L terbuthylazine. The primary mode of action of Terbuthylazine is the inhibition of photosynthesis in the photosystem II (Hill reaction). Terbuthylazine is a triazine selective systemic herbicide absorbed principally through the roots, but also through the foliage, with translocation acropetally in the xylem and accumulation in the apical meristems and leaves. Terbuthylazine binds to the plastoquinone-binding protein in photosystem II, inhibiting electron transport. During visual observation no effects of the measure on non-target organisms were found.
Weeds controlled by the plant protection product Terbut 500 SC are: CAPBP, VIOAR, CHEAL, AMARE, GALAP, MATIN, VERAR, POLCO, SOLNI, MATCH, CENCY, STEME and GERPU.

3.3 Efficacy data

Preliminary studies have not been conducted because the active substance (terbuthylazine) is known and has long been used in the protection of plants. The effect of the active substances is well known and sufficient large scale efficacy trials are available to evaluate the effectiveness of TERBUT 500 SC. Therefore, preliminary tests are not described and not required.
The efficacy of reduced rates of TERBUT 500 SC for weed control (CAPBP, VIOAR, CHEAL, AMARE, GALAP, MATIN, VERAR, POLCO, SOLNI, MATCH, CENCY, STEME and GERPU) in

maize (pre-emergence and post-emergence) was investigated in field tests carried out in 2017 and 2019. In the appropriate researches of efficacy were tested several doses and to register was chosen the lowest effective. All researches were conducted according to EPPO standard PP 1/225 *'Minimum effective dose'.*

The applicant has proposed doses of Terbut 500 SC / Tazoprym 500 SC / Cornao 500 SC (product code: Terbut 500 SC) that reflect those of currently-authorised terbuthylazine products across the EU. In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

During field tests Applicant used different doses of herbicide Terbut 500 SC / Tazoprym 500 SC / Cornao 500 SC (product code: Terbut 500 SC) containing terbuthylazine (500 g/l). So, in the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).

Terbut 500 SC was studied at following doses:

- pre-emergence use (BBCH 00-00): solo – 1,0 l/ha Terbut 500 SC (N dose) and with adjuvant: 0,8 l/ha Terbut 500 SC+0,2 l/ha adjuvant (0,8N); 1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant (N); 1,2 l/ha Terbut 500 SC +0,2 l/ha adjuvant (1,2N) and 1,5 l/ha Terbut 500 SC + 0,2 l/ha adjuvant (1,5N).
- post-emergence use (BBCH 12-16): solo at three different doses: 0,8 l/ha (0,8N); 1,0 l/ha (N); 1,2 l/ha (1,2N) and with adjuvant at one dose: 1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant (N).

Based on results achieved on studied weeds in the 26 maize trials, it can be concluded that to consistently control frequently occurring weeds in maize, Terbut 500 SC / Tazoprym 500 SC / Cornao 500 SC should be applied:

- early post-emergence (BBCH 12-16) solo at dose 1,0 l/ha and with adjuvant at dose 1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant.
- pre-emergence (BBCH 00-00) – solo at dose 1,0 l/ha and with adjuvant at dose 1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant.

EFFICACY EVALUATION:

EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

Applicant submitted in total 26 efficacy trials carried out in two different growing seasons (2017 and 2019) for pre-emergence use and post-emergence use. It is in line with appropriate EPPO standards.

For pre-emergence used Applicant submitted in total 14 field studies and for post-emergence used – 26 field trials. All trials were carried out in accordance to EPPO standards: EPPO PP 1/135 (4), EPPO PP 1/181 (4), EPPO PP 1/152 (4) and EPPO PP 1/50 (3).

During trials different doses were studied:

- for pre-emergence use – 1,0 l/ha for support solo use and for mixture tank use with adjuvant: 0,8 l/ha Terbut 500 SC+0,2 l/ha adjuvant; 1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant; 1,2 l/ha Terbut 500 SC+0,2 l/ha adjuvant and 1,5l/ha Terbut 500 SC +0,2 l/ha adjuvant.
- for post -emergence use: 0,8 l/ha; 1,0 l/ha; 1,2 l/ha for solo use and 1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant for use in the mixture tank with adjuvant.

Only trials with greater than 5 weeds/m^2 or over 2% ground cover have been included. In the opinion of ZRMs weed species which occurred only in 1 trial, should be excluded from label and GAP table.

Applicant submitted classification of weed sensitivity in accordance to Polish rules. According to EPPO

PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. According to Polish rules – at least 4 valid trials should be presented for major weeds and at least 2 valid trials for minor weeds. Therefore, based on knowledge of major/minor status of weeds in Poland, weeds with insufficient results should be excluded.

Below, we presented the list of studied weeds with classification of its sensitivity observed at recommended dose at solo use (1,0 l/ha) and in the mixture tank with adjuvant (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) weed at pre- and post-emergence use in maize:

- **post emergence use at BBCH 12-16:**

CHEAL –major weed in maize – S in solo use at 1,0 l/ha (12 trials) and S in use in the mixture tank – 24 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

VIOAR –minor weed in maize – S in solo use at 1,0 l/ha (12 trials) and S in use in the mixture tank – 18 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

AMARE –major weed in maize – S in solo use at 1,0 l/ha (10 trials) and S in use in the mixture tank – 13 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

GALAP –major weed in maize – S in solo use at 1,0 l/ha (7 trials) and S in use in the mixture tank – 11 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

MATIN –major weed in maize – S in solo use at 1,0 l/ha (9 trials) and S in use in the mixture tank – 12 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

CAPBP –minor weed in maize – S in solo use at 1,0 l/ha (7 trials) and S in use in the mixture tank – 11 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

VERAR –minor weed in maize – S in solo use at 1,0 l/ha (6 trials) and S in use in the mixture tank – 6 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

POLCO –major weed in maize – S in solo use at 1,0 l/ha (6 trials) and S in use in the mixture tank – 13 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

SOLNI –major weed in maize – S in solo use at 1,0 l/ha (6 trials) and S in use in the mixture tank – 7 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

MATCH –major weed in maize – due to not enough trials, this weed should be excluded from GAP table and label project for use in solo use (1,0 l/ha – 3 trials, at least 4 valid trials are required). MATCH is S weed at use in the mixture tank with adjuvant (5 trials).

STEME –minor weed in maize – MS in solo use at 1,0 l/ha (2 trials) and S in use in the mixture tank – 5 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

CENCY –minor weed in maize – MS in solo use at 1,0 l/ha (2 trials) and MS in use in the mixture tank – 5 trials (1,0 l/ha Terbut 500 SC+0,2 l/ha adjuvant).

- **pre-emergence use at BBCH 00-00**

CHEAL – major weed in maize – 13 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 1 trial for solo use (1,0 l/ha). CHEAL at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 4 are required) and in the mixture tank can be concluded as MS weed.

VIOAR – minor weed in maize – 6 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 1 trial for solo use (1,0 l/ha). VIOAR at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 2 are required) and in the mixture tank can be concluded as S weed.

AMARE – major weed in maize – 5 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 2 trials for solo use (1,0 l/ha). AMARE at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 4 are required) and in the mixture tank can be concluded as S weed.

GALAP – major weed in maize – 4 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and lack of trials for solo use (1,0 l/ha). GALAP at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 4 are required) and in the mixture tank can be concluded as MS weed.

MATIN – major weed in maize – 5 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 2 trials for solo use (1,0 l/ha). MATIN at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 4 are required) and in the mixture tank can be concluded as S weed.

CAPBP – minor weed in maize – 3 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and lack of trials for solo use (1,0 l/ha). CAPBP at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 2 are required) and in the mixture tank can be concluded as S weed.

POLCO – major weed in maize – 5 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and lack of trials for solo use (1,0 l/ha). POLCO at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 4 are required) and in the mixture tank can be concluded as MS weed.

MATCH – major weed in maize – 2 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 1 trial for solo use (1,0 l/ha). MATCH at solo and in the mixture tank use should be excluded from GAP table and label project due to not enough number of trials (at least 4 valid trials for each use are required).

STEME – minor weed in maize – 4 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 1 trial for solo use (1,0 l/ha). STEME at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 2 are required) and in the mixture tank can be concluded as MS weed.

CENCY – minor weed in maize – 4 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and only 1 trial for solo use (1,0 l/ha). CENCY at solo use should be excluded from GAP table and label project due to not enough number of trials (at least 2 are required) and in the mixture tank can be concluded as MS weed.

GERPU – major weed in maize – 3 trials for use in the mixture tank (1,0 l/ha Terbut 500 SC + 0,2 l/ha adjuvant) and lack of trials for solo use (1,0 l/ha). GERPU at solo and in the mixture tank use should be excluded from GAP table and label project due to not enough number of trials (at least 4 valid trials for each use are required).

SUMMARY: Terbut 500 SC / Tazoprym 500 SC / Cornao 500 SC (product code: Terbut 500 SC) is a pre-emergence (BBCH 00-00) and an early post-emergence (BBCH 12-16) herbicide in maize to control weeds.

Accepted weed in Polish label:

- **pre-emergence use:**

✓ **solo use at 1,0 l/ha:** lack of accepted weed species. All should be excluded from GAP table and label project.

✓ **mixture tank use (1,0 l/ha Terbut 500 SC + 0,2 l/ha Hydron adjuvant):** *susceptible weeds:* VIOAR, AMARE, MATIN, CAPBP and *moderately susceptible weeds:* CHEAL, GALAP, POLCO, STEME, CENCY, GERPU.

- **post-emergence use:**

✓ **solo use at 1,0 l/ha:** *susceptible weeds*: CHEAL, VIOAR, AMARE, GALAP, MATIN, CAPBP, VERAR, POLCO, SOLNI and *moderately susceptible weeds:* STEME, CENCY.

✓ **mixture tank use (1,0 l/ha Terbut 500 SC + 0,2 l/ha Hydron adjuvant):** *susceptible weeds*: CHEAL, VIOAR, AMARE, GALAP, MATIN, MATCH, CAPBP, VERAR, POLCO, SOLNI, STEME and *moderately susceptible weeds:* CENCY.

Accepted volume of water: 200-300 l/ha

Accepted BBCH of maize: for pre-emergence BBCH 00-00 and for post-emergence BBCH 12-16.

Adjuvant: The name HYDRON is the trade name of the adjuvant codenamed xxx used in the study. The formulation xxx and HYDRON are identical products, with identical composition and physicochemical, toxicological and ecotoxicological properties (the Applicant has included a relevant explanation - at the time of research in 2017, the trade name of the formulation did not yet function in official documents). In the Polish label Terbut in the mixture tank with Hydron as adiuvant is accepted.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Terbut 500 SC contains one active ingredient: terbuthylazine. According to HRAC (Herbicide Resistance Action Committee) classification terbuthylazine belongs to group C1, photosystem II inhibitors. Evidence of resistance to terbuthylazine has been limited to 5 weed species globally. The first documented cases of weed resistance to terbuthylazine were found in Czech Republic. Also in the areas of Czech Republic, New Zealand and Italy it was reported that *Polygonum lapathifolium, Chenopodium album, Senecio vulgaris, Solanum nigrum* and *Amaranthus retroflexus* may be resistant to C1 group herbicides.

Terbuthylazine belongs to the chemical group of Triazines. Terbuthylazine is rapidly translocated to the chloroplasts of the plant cell. Terbuthylazine is primarily interrupting the electron transport in photosystem II (Hill-reaction) and consequently an inhibitor of photosynthesis. The herbicidal activity of Terbuthylazine was first reported in 1966. It is applied world-wide in a wide range of crops like maize, sorghum, vines, orchards, forest and potatoes as a broad-spectrum herbicide against broad-leaved weeds.
The Herbicide Resistance Action Committee (HRAC) grouped the mode of action of terbuthylazine in the international HRAC group C1. Following herbicides are included in HRAC group C1/5:

Mechanism of resistance: Resistance occurs generally when naturally existing unsusceptible biotypes are selected by repeated applications of the same "selecting factor" – e.g. one herbicide. The further development and spread of the resistance particularly depend on the seed production of the weed species and on the fitness of the resistant biotypes. However, herbicides mostly effect a specific target site, which are controlled by one or a few genes, so that one mutation of few genes already can cause a resistance. Use of herbicides with the same mode of action in one population can produce a considerable selection pressure, which may result in fast reproduction of the resistant biotypes. These biotypes can generate increased population sizes and may infest more arable land without limitation, because the sensitive species and varieties are controlled by the herbicide or the same MOS group of herbicides.
Triazine group are applied in crops like sugar beet, potatoes and cereals for a selective and targeted weed control as an important mean of modern crop management. Although the development of resistance or even reduced susceptibility is a long-term process as weeds usually produce only one generation per year and new, resistant individuals spread quite slowly within the population, it is evident that a repeated application of herbicides with the same mode of action over 20-30 years results in selection pressure and induces selection of resistant eco-types.

Evidence of resistance: Terbuthylazine, belonging to the chemical group of Triazine, is classified with HRAC code C1 and with the biochemical mode of action "Inhibition of photosynthesis at photosystem".

#	Year	Species	Country	MOAs	Actives	Situations
1	1982	*Polygonum lapathifolium*	Czech Republic	Photosystem II inhibitors (C1/5)	atrazine, terbuthylazine, terbutryn, prometryn, cyanazine, lenacil	Railways
2	1986	*Chenopodium album*	Czech Republic	Photosystem II inhibitors (C1/5)	atrazine, simazine, terbuthylazine, terbutryn, prometon, cyanazine, lenacil	Corn (maize), Sugar beets
3	1988	*Senecio vulgaris*	Czech Republic	Photosystem II inhibitors (C1/5)	atrazine, simazine, terbuthylazine, terbutryn, prometryn, cyanazine, lenacil	Orchards, Railways
4	1999	*Amaranthus retroflexus*	Italy	Photosystem II inhibitors (C1/5)	chloridazon = pyrazon, terbuthylazine, metamitron	Corn (maize), Soybean, Sugar beets
5	1999	*Solanum nigrum*	New Zealand	Photosystem II in-	atrazine, terbuthylazine, prometryn,	Corn (maize)

#	Year	Species	Country	MOAs	Actives	Situations
				hibitors (C1/5)	cyanazine	

(***Source:*** *http://weedscience.org/Summary/ResistByActive.aspx).*

Photosystem II inhibitors (C1/5) group comprises of very large number of herbicidal active ingredients and terbuthylazine is just one active substance out of 25. In spite of significant resistance of weeds to herbicides representing photosystem II inhibitors group only 5 weed species were found to develop resistance directly to terbuthylazine. **There is no report documenting weeds species resistant to terbuthylazine from Poland.**

Cross resistance: According to HRAC org. cross resistance is defined as the expression of a genetically-endowed mechanism conferring the ability to withstand herbicides from different chemical classes. It relates to herbicides from different chemical groups but of the same mode of action. If there is a resistance to at least two or more a.s. from the same chemical group or even from different chemical groups but of the same mode of action – cross resistance is a case.
Triazine herbicides have been persistently used for weed control in maize production in many parts of the world and this practice has led to widespread resistance in target weeds. The first report of herbicide resistance involved a triazine herbicide (Ryan, 1970), and since then triazine resistance has become the most prevalent and well characterized example of herbicide resistance world-wide. It is noteworthy that biotypes highly resistant to triazine herbicides as a result of a modified D1 protein are not resistant to the chemically distinct substituted urea herbicides, despite the fact that the substituted urea herbicides are also potent PS2 inhibitors (reviewed by Gronwald, 1994). The substituted urea and triazine herbicides bind to overlapping, but not identical, sites in PS2 (reviewed by Trebst, 1991). As a result, the mutation Ser 264 Gly providing resistance to triazine herbicides does not affect binding of substituted urea herbicides (Arntzen et al., 1982; Trebst, 1991). Plants containing triazine-resistant PS2 are resistant to other PS2-inhibiting herbicide chemistries including the triazinones, uracils, and pyridazinones (Fuerst et al., 1986; Ducruet and De Prado, 1982; Oettmeier et al., 1982; De Prado et al., 1989).

Multiple resistance: Cross resistance and multiple resistance is a very dynamic ongoing process, and the major prevention strategy is this - included in Good Agricultural Practice and Integrated Pest Management strategies with avoidance of sequential use of herbicides belonging to the same SOAs and cross resistant groups (B/2 and C2/7) – in a first place. There are 2 cases of multiple weeds resistance to photosystem II inhibitors (C1/5) herbicides. It is important to notify that there are no cases of multiple resistance relative to Photosystem II inhibitors C1/5 group found in Poland up to date.

Sensitivity data: For the active substances: terbuthylazine – no baseline sensitivity studies were available to the applicant. The overview of the Herbicide Resistance Action Committee (HRAC) about the evidence of resistance can replace baseline sensitivity studies. The International Survey of Herbicide Resistant Weeds (http://www.weedscience.org/in.asp) cites cases of resistance to HRAC herbicide group C1/5 in the Central Zone: in Germany, Poland and Czech Republic. Sensitivity data should be generated and available in the future to measure sensitivity shift and resistance development.

There were no special studies organized by the applicant concerning weed resistance risk. System of monitoring, testing and informing about resistance which is in place thanks to plant protection industry and the network of dedicated scientists as well as resulting communication with users, seems to be sufficient for the informed market introduction of Terbut 500 SC.

Generally, evidences of resistance to HRAC Group C1/5 (Photosystem II inhibitors) and specifically to terbuthylazine are well documented by Weed Science organization and Herbicide Resistance Action Committee. 5 weeds species are reported worldwide being resistant to terbuthylazine, out of which 4 were reported in Europe, and none in Poland so far**.**
The resistance risk is regarded acceptable if Terbut 500 SC is used under adherence to the management strategy and label recommendations.

To prevent further development of resistance or cross-resistance and to maintain effective control of target weeds:

- apply Terbut 500 SC at the recommended dose rate,
- apply a maximum of 1 application per season in the optimum development phase of weeds,

- use herbicides with different modes of action and overlapping weed spectrum,
- prevent weeds reproduction by seed or by vegetative proliferation,
- control efficacy of the applications. If applications show decreasing efficacy and other reasons (e.g. weather, application timing) can be excluded, consult local advisors,
- use a reasonable crop rotation and mix of different herbicides programs,
- integrate Terbut 500 SC into an overall pest management program,
- clean equipment between sites and avoid movement of plant material between sites,
- implement cultural practices known to reduce weed development,
- monitor publicly available information regarding weed resistance
- often consult local advisors.

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broad-leaved weeds.

3.3.2 Adverse effects on treated crops

In the evaluation process the fact that the active ingredient – terbuthylazine is used in many plant protection products and has been commonly used in crop protection for many years were taken into consideration.

The Applicant submitted in total 10 selectivity studies conducted in one growing season (2019) on herbicide (Terbut 500 SC) containing this active substance.

The selectivity evaluation of the herbicide was performed according to appropriate EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction.

Phytotoxicity assessment was carried out with the use of different cultivars of maize (commercially grown varieties: ex. Kwins, PR39H32, Farmgiant, P8400, Farmfire, Pyroxenia 130, Pioneer, San, P8400). Dosages N (recommended: for solo use – 1,0 l/ha and in the mixture tank with adiuvant: 1,0 l/ha Terbut 500 SC+ adiuvant 0,2 l/ha) and 2N (doubled recommended: for solo use 2,0 l/ha and for use in mixture tank: 2,0 l/ha Terbut 500 SC + 0,4 l/ha adiuvant) were studied in all trials. Experimental details and assessments methods were in accordance to EPPO standards.

In all trials standard reference products were used (in pre-emergence use: Lumex 537,5 SE at dose 3,5 l/ha and 7,0 l/ha and for post-emergence use – Tezosar 500 SC at dose 1,0 l/ha and 2,0 l/ha.

No phytotoxicity symptoms were observed for any tested dosage for all tested maize varieties. The crop developed normally and did not involve a loss in yield at harvest.

3.3.3 Observations on other undesirable or unintended side-effects

The strict adherence to all the rules during the herbicide techniques treatments as well as observance of GEP rules, it can protect the neighboring plants from potential adverse effects relating to the protection of the crop. It is crucial to take care when carrying the liquid spray drift during spraying as well as to keep the appropriate buffer-zone.
No effects observed on non-target organisms.

3.4 Methods of analysis (Part B, Section 5)

It was confirmed that presented validated methods of analysis of the active compound Terbuthylazine and relevant impurities as Atrazine, Simazine and Propazine in the product TERBUT 500 SC are specific and capable of determinating amount of each of mentioned components.

The validation parameters are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.4.

Methodology validated in March 2018 according to SANCO /3030 /99 rev.4 ,test is accepted .

According to the results methodology fulfil the requirements according to SANCO /3030 /99 rev.5. too and it is accepted.

3.4.1 Analytical method for the formulation

With respect to toxicological, eco-toxicological or environmental aspects TERBUT 500 SC does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are:

- none

Commodity/crop	Supported/ Not supported
Maize	Supported

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

Formulation does not contain any substances classified as:

- acute dermal toxicity,
- skin irritant,
- respiratory sensitizer,
- germ cell mutagenic,
- cancerogenic,
- toxic on reproduction,
- toxic on specific target organs (single exposure),
- aspiration hazard.

Terbut is classified: Acute Tox.4/H302, Skin Sens.1/H317, STOT RE 2/ H373

3.5.2 Operator exposure

~~Operator exposure to TERBUT 500 SC was not evaluated as part of the EU reviews of terbuthylazine. Therefore all relevant data and risk assessments have been provided and are considered to be adequate. Operator exposure was assessed using the AOEL agreed in the EU reviews for terbuthylazine equal to 0.0032 mg/kg b.w./day.~~
~~It can be concluded that according to the EFSA GD Exposure Calculator calculations and comparing the estimated exposure to the AOEL for terbuthylazine the risk for the operator using TERBUT 500 SC with vehicle mounted (downward spraying) on professional uses is acceptable when personal protective equipment is used (gloves during mixing/loading and application process; work wear (arms, body and~~

~~legs covered) during application process~~.

According to the EFSA AOEM Model, it can be concluded that the risk for the operator is acceptable with use of gloves, protective garment + sturdy footwear: M/L and A.
It can be concluded that according to the EFSA calculations and comparing the estimated exposure to the AOEL for terbuthylazine the risk for the operator using TERBUT 500 SC with vehicle-mounted (downward spraying - tractor mounted boom spray with drift reductio) on professional uses is acceptable when personal protective equipment is used (gloves during mixing/loading and application process; work wear (arms, body and legs covered) during application process
Implication for labelling: P280: Wear protective gloves, protective clothing

~~Use of plant protection product TERBUT 500 SC is safe for operator, taking into account proposed dose of product, type of usage, type of personal protective equipment (gloves, protective garment and sturdy footwear). Using tractor mounted boom sprayer and maintain general rules of safety and hygiene of working with plant protection n products and comply with requirements enclosed in label, risk during employ TERBUT 500 SC is acceptable, absorbed dose of terbuthylazine has safe value, below AOEL for these active ingredients.~~

3.5.3 Worker exposure

~~Worker exposure to TERBUT 500 SC has not been evaluated as part of an EU review for proposed critical use rate/crop. Estimation of exposure for worker performing work on treated field (maize) was made based on EFSA GD Exposure Calculator. The main pathway of exposure to workers is dermal route.~~

In the case of application to maize: the calculated worst case exposure to terbuthylazine is lower than AOEL value, i.e. exposure is equal to 54.7% of the AOEL for terbuthylazine, assuming that PPE is used as additional personal protective equipment (Gloves and work wear when handling treated crops).
The worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE.
P280: Wear protective gloves, protective clothing

3.5.4 Bystander and resident exposure

Estimations of bystander exposure (adults and children) for terbuthylazine, using the critical uses, have shown that this exposure is below of the AOEL for terbuthylazine, therefore the product does not pose a an unacceptable health risk to the public according to Martin S. model. Bufor zone 5 m
Calculated exposure of people living (adults and children) near the fields where TERBUT 500 SC is used is below of the AOEL for terbuthylazine, therefore the product does not pose an unacceptable health risk to the public.

According to the AOEM calculator results of the exposure estimations suggest that the use of TERBUT 500 SC according to the intended uses presented in GAP, causes unacceptable health risk for resident (adult and child).

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

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

Stability of residues

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

Metabolism

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

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

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

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

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

Ruminants

Milk: Sum of terbuthylazine and MT1, expressed as terbuthylazine

Muscle, fat, liver and kidney: open

Pigs: not triggered; Poultry: not triggered

Magnitude of residues in plants

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

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

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

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

EU unprotected trials results:
E (mg/kg): 8 X <0.02 mg/kg
RA (mg/kg):
MT0: 8x <0.02
MT1: 8x <0.02
MT14: 8x <0.02
Total residues: 8x <0.06 mg/kg
Forage (mg/kg):

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

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

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

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

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

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

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

zRMS conclusion:

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

* - LOQ

Uses are acceptable

Magnitude of residues in livestock

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

Processing studies

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

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

Magnitude of residues in representative succeeding crops

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

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

3.6.2 Consumer exposure

TMDI (% ADI) according to EFSA PRIMo 3.1	55 % (based on SE general)
IESTI (% ARfD) according to EFSA PRIMo 3.1	Results for children Unprocessed commodities: Maize/corn 8% Bovine/: liver 5% Bovine: muscle/meat 5% Bovine: kidney 2% Bovine; Fat 1% Processed commodities: Maize, oil 6 % Maize, processed 0.5% Results for adults/general population Unprocessed commodities: Maize/corn 0.5% Bovine/: liver 3% Bovine: muscle/meat 4% Bovine: kidney 1% Bovine; Fat 0.6% Processed commodities: Maize, oil 3 %

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

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

3.7 Environmental fate and behaviour (Part B, Section 8)

The predicted environmental concentrations (PEC values) in soil, surface water, sediment and groundwater are provided in Part B, Section 8. The long-term concentrations are based on results obtained for the active substance contained in the formulation. Calculated PEC values demonstrates that the TERBUT 500 SC is safe for the environment.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PECs of terbuthylazine and its metabolites in soil, has been assessed assuming that active substance is evenly distributed in the top 5 cm soil horizon with a soil bulk density 1.5 g/cm^3 and DT_{50} value established in the EFSA peer review. Calculations were performed for the bare soil and for maize BBCH 12-16 with max. dose (1.2 L/ha). The calculated values of PECs for each scenario were accepted.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PECs of terbuthylazine and its metabolites in groundwater were calculated with FOCUS PEARL and FOCUS PELMO on the basis of EU agreed endpoints that were summarized in EFSA peer review. The PECgw were calculated for the highest application rate recommended for use for bare soil and maize, applied for 500 g a.s./ha. Obtained PECgw of terbuthylazine in each scenario and for the recommended use of TERBUT 500 SC are significant below the trigger value of 0.1 µg/L. Concentrations of metabolites MT1, MT13, MT14, LM3, LM5 and LM6 are over 0.1 µg/L. However in dRR part B10, low risk of those

metabolites was proved and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.
The PECgw calculations for metabolites were assessed and presented in the report *Updated peer review of the pesticide risk assessment for the active substance terbuthylazine in light of confirmatory data* EFSA Journal 2019;17(9):5817
According the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011 **the active substance terbuthylazine should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.**

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PECs of terbuthylazine and its metabolites in surface water were calculated using values established in the EFSA peer review. Results obtained from FOCUS STEP 1, 2, 3 and 4 showed no risk for aquatic life after application when appropriate risk mitigation are used (described in section 3.8.2).

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance terbuthylazine is between 10^{-5} and 10^{-4} Pa. Hence the active substance terbuthylazine is regarded as volatile (volatilisation from soil and plant surfaces). However due to rapid photochemical degradation, exposure of adjacent surface waters and terrestrial ecosystems by the terbuthylazine due to volatilization with subsequent deposition is not considered.

3.8 Ecotoxicology (Part B, Section 9)

An estimation of risk indicate acceptable risk for each organisms of each range of assessed issues, taking into consideration adequate mitigation measures.
According the Regulation (EU) 2021/824 amending Regulations (EU) No 540/2011 and (EU) No 820/2011 **the active substance terbuthylazine should be restricted to once every third year on the same field at a maximum rate of 850 g/ha.**

3.8.1 Effects on terrestrial vertebrates

An estimation of risk indicate low risk for birds of each range of assessed issues. Calculations con-ducted due to the influence of TERBUT 500 SC due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for mammals. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.
An estimation of risk indicate low risk for terrestrial vertebrates of each range of assessed issues.
Calculations conducted due to the influence of TERBUT 500 SC due to the acute toxicity did not indicate any hazardous properties and danger for mammals.
However ,the long-term risk assessment needs further refinement for focal species wood mouse.
For pre- emergence application the safe use was demonstrated. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

3.8.2 Effects on aquatic species

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance

with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
Taking into consideration risk mitigation calculations for TERBUT 500 SC – pre-emergence use, following risk mitigation measures should be applied:
PRE-EMERGENCE and POST –EMERGENCE USES:
-5m buffer non-spray zone with 5 meter vegetated filter strip to surface water bodies
Using the above-mentioned precautions, formulation TERBUT 500 SC can be used and will not have a negative impact on aquatic species

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The risk assessment for bees was carried out regarding oral and dermal toxicity endpoints and individual application rates.

Calculations conducted due to the influence TERBUT 500 SC due to the acute oral and contact toxicity did not indicate any hazardous properties and danger. According to Reg. 284 the chronic tests for adult bees and larvae should be provided by the applicant.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.
The HQ values based on a result of extended laboratory test is higher than the trigger value, indicating risk to non-target arthropods from terbuthylazine following application of TERBUT 500 SC.
Therefore a higher-tier aged-residue study was performed. According to study, low risk to non-target arthropods is expected from the application of TERBUT 500 SC following application according to the proposed GAP.

3.8.5 Effects on soil organisms

The evaluation of the risk for soil macro- and microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
For earthworms, the calculated TER_{lt} for terbuthylazine are below the trigger value of 5. However the field study performed in southern Germany and Denmark show that, there is no risk for earthworm after 1 year after application of SC formulation in rate of 844 g a.s./ha, which value is much higher than proposed 500 g a.s./ha. Therefore the risk for earthworm is considered as a low.
The calculated TER_{lt} for terbuthylazine are above the trigger value of 5, indicating acceptable chronic risk to other macro-organisms from the proposed uses of TERBUT 500 SC.
The risk to soil micro-organisms is considered to be low for all representative uses.

3.8.6 Effects on non-target terrestrial plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Taking into consideration risk mitigation calculations for TERBUT 500 SC – use in maize, following risk mitigation measures should be applied to non-target plants:
- **3 m buffer zone or**
- **1 m and use of 75% drift reducing nozzles**

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant

3.9 Relevance of metabolites (Part B, Section 10)

The groundwater metabolites MT1, MT13, MT14, LM3, LM5 and LM6 are considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment for metabolites is given in is given in Table. 10.2-1. Studies supporting PEC_{gw} data are based on result summarized in peer review (EFSA Journal 2011; 9(1):1969) and updated peer review of the pesticide (EFSA Journal 2019;17(9):5817) terbuthylazine.
In Part B10 of dRR for terbuthylazine appropriate justifications show low risk for contamination of groundwater and low risk for human.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Rozporządzenie wykonawcze Komisji (UE) 2021/824 z dnia 21 maja 2021 r.

Środek należy stosować raz na trzy lata na tym samym polu w maksymalnej dawce 850 g terbutyloazyny na hektar.

Sekcja pozostałości:

Zalecane środki ograniczające ryzyko dla upraw następczych (jedna z dwóch opcji do rozważenia przez aplikanta): roczna przerwa między sadzeniem roślin lub głęboka orka (mieszanie gleby po-wyżej 20 cm) w celu rozcieńczenia stężeń gleby, przy czym należy zauważyć, że głębokość orki wynosząca 30 cm zmniejsza pozostałości gleby o współczynnik 1,5, a głębokość orki wynosząca 40 cm na 50%. (według EFSA Journal 2020; 18 (1): 5980).

Sekcja ekotoksykologii:

Środek nie może być stosowany powschodowo.

Sekcja skuteczności:

Zastosowanie solo przed wschodowo nie jest akceptowane. Zastosowanie powschodowo (solo i z adiuwantem) oraz przed wschodowo z adiuwantem jest akceptowalne przez skuteczność. Z uwagi na ocenę ekotoksu w etykiecie zaakceptowano tylko zastosowanie przedwschodowo z adiuwantem. Lista uwzględnionych chwastów i ich wrażliwość jest zgodna z przedstawioną dokumentacją i wykonaną oceną.

Sekcja toksykologii:
W części ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK dodać:
- Po wykonaniu zabiegu umieść w widocznych miejscach wokół pola tablice ostrzegawcze z napisem „Zakaz wstępu osób niepowołanych do obszaru poddanego działaniu środków ochrony roślin

- Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon oraz odpowiednie obuwie (np. Kalosze

- W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.
W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne

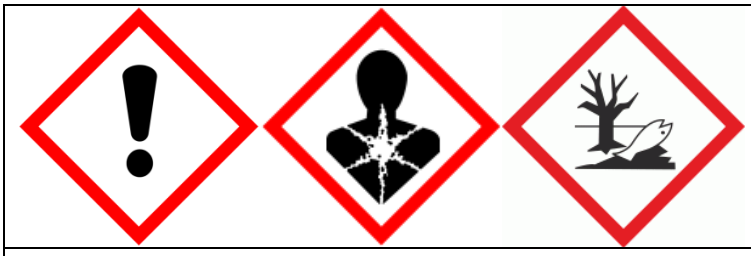
Posiadacz zezwolenia:
Synthos Agro Sp. z o. o., ul. Chemików 1, 32 – 600 Oświęcim, tel. + 48 (33) 847 47 77, fax.+48 (33) 847 47 78, e – mail: rejestracja@synthosgroup.com

TERBUT 500 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
terbutylazyna (związek z grupy triazyn) **– 500 g/L**

Zezwolenie MRiRW nr R- ……..



Uwaga	
H302	Działa szkodliwie po połknięciu.
H317	Może powodować reakcję alergiczną skóry.
H373	Może spowodować uszkodzenie narządów w następstwie długotrwałego lub powtarzalnego narażenia.
H410	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P260	Nie wdychać mgły, par, rozpylonej cieczy.
~~P273~~	~~Unikać uwalniania do środowiska.~~
P280	Stosować rękawice ochronne, odzież ochronną, ochronę oczu, ochronę twarzy.
P301 + P312	W PRZYPADKU POŁKNIĘCIA: w przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem.
P302 + P352	W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody z mydłem.
P330	Wypłukać usta.
P333 + P313	W przypadku podrażnienia skóry lub wysypki: Zgłosić się pod opiekę lekarza.
P501	Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie, koncentrat w postaci stężonej zawiesiny do rozcieńczania wodą (SC). Stosowany w przedwschodowej ~~i powschodowej~~ ochronie kukurydzy. Zgodnie z klasyfikacją HRAC substancja czynna terbutylazyna zaliczana jest do grupy C1.

DZIAŁANIE NA CHWASTY

Środek pobierany jest głównie poprzez korzenie chwastów i w niewielkim stopniu poprzez ich liście, powoduje zakłócenia w procesie fotosyntezy, wywołując w pierwszej kolejności chlorozy liści widoczne w szczególności w przestrzeniach międzynerwowych, a także na brzegach i wierzchołkach. Niszczy chwasty od fazy kiełkowania do fazy 4 liści. Środek ogranicza wschody chwastów przez 6-8 tygodni po wykonaniu zabiegu.
Umiarkowane opady i ciepła pogoda sprzyjają działaniu środka.

Stosowanie przedwschodowe:

Dawka :

~~1,0 l/ha~~	~~Chwasty wrażliwe:~~	~~Komosa biała, fiołek polny, szarłat szorstki, maruna nadmorska, rumianek pospolity,~~
	~~Chwasty średniowrażliwe:~~	~~Gwiazdnica pospolita, chaber bławatek~~
Terbut 500 SC 1,0 l/ha + HYDRON 0,2 l/ha	Chwasty wrażliwe:	Fiołek polny, szarłat szorstki, maruna nadmorska, tasznik pospolity, ~~rumianek pospolity~~
	Chwasty średniowrażliwe:	Przytulia czepna, rdestówka powojowata, gwiazdnica pospolita, chaber bławatek, bodziszek drobny,

		komosa biała

~~**Stosowanie powschodowe:**~~

~~Dawka:~~

~~1,0 l/ha~~	~~Chwasty wrażliwe:~~	~~Tasznik pospolity, fiołek polny, komosa biała, szarłat szorstki, przytulia czepna, maruna nadmorska, przetacznik polny, rdestówka powojowata, psianka czarna, rumianek pospolity,~~
	~~Chwasty średniowrażliwe:~~	~~Gwiazdnica pospolita, chaber bławatek~~
~~Terbut 500 SC 1,0 l/ha + HYDRON 0,2 l/ha~~	~~Chwasty wrażliwe:~~	~~Komosa biała, fiołek polny, szarłat szorstki, przytulia czepna, maruna nadmorska, tasznik pospolity, przetacznik polny, rdestówka powojowata, psianka czarna, rumianek polny, gwiazdnica pospolita,~~
	~~Chwasty średniowrażliwe:~~	~~Chaber bławatek~~

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Środek stosować w odpowiedniej fazie rozwojowej chwastów uwzględniając zalecane fazy rozwojowe rośliny uprawnej.

Kukurydza

Środek należy stosować raz na trzy lata na tym samym polu w maksymalnej dawce 850 g terbutyloazyny na hektar.

Zalecana/maksymalna dawka dla jednorazowego zastosowania:

~~1) Terbut 500 SC 1,0 l/ha lub~~

2) Terbut 500 SC 1,0 l/ha + HYDRON 0,2 l/ha

Termin stosowania:

- środek stosować przedwschodowo (BBCH 00) ~~lub~~
- ~~środek stosować powschodowo od fazy 2 do 6 liści kukurydzy (BBCH 12-16).~~

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Zalecana ilość wody: 200-300 l/ha
Zalecane opryskiwanie: średniokropliste

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Nie dotyczy

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,

- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Środka nie należy stosować na stanowiskach gdzie występują biotypy chwastów o potwierdzonej odporności na substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy C1.

3. W celu uzyskania najwyższej skuteczności działania środka, dokładnie pokryć cieczą użytkową zwalczane chwasty.

4. Nie zaleca się stosowania środka w liniach wsobnych kukurydzy i na plantacjach nasiennych bez uprzedniego wykonania próbnego zabiegu w celu sprawdzenia, czy nie występują objawy uszkodzenia roślin lub bez skontaktowania się z doradcą albo przedstawicielem posiadacza zezwolenia.

5. W niesprzyjających warunkach pogodowych (np. susza, przymrozki, duże wahania temperatur pomiędzy nocą i dniem), środek może spowodować na niektórych odmianach kukurydzy, przemijające uszkodzenia liści, które nie maja negatywnego wpływu na jakość i wielkość plonu.

6. Środka nie stosować:
- w kukurydzy cukrowej,
- na rośliny słabe lub uszkodzone przez przymrozki, choroby lub szkodniki, mokre,
- w czasie opadu deszczu lub przed spodziewanym deszczem,
- w temperaturze (mierzonej przy gruncie) poniżej 12°C i powyżej 25°C,
- w czasie południowych upałów i silnego nasłonecznienia,
- po długotrwałej suszy,
- na glebach bardzo przepuszczalnych.

7. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

NASTĘPSTWO ROŚLIN

~~Środek rozkłada się w glebie w ciągu okresu wegetacji do poziomu niestwarzającego zagrożenia dla roślin uprawianych następczo.~~

~~W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) po wykonaniu orki przedsiewnej można jedynie uprawiać kukurydzę.~~

Zalecana jest roczna przerwa między sadzeniem roślin lub głęboka orka (mieszanie gleby powyżej 20 cm) w celu rozcieńczenia stężeń gleby, przy czym należy zauważyć, że głębokość orki wynosząca 30 cm zmniejsza pozostałości gleby o współczynnik 1,5, a głębokość orki wynosząca 40 cm na 50%.

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki)-roczna przerwa miedzy sadzeniem roślin.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Środek przed użyciem dokładnie wymieszać. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą, dokładnie wymieszać, a następnie uzupełnić wodą do potrzebnej objętości i ponownie dokładnie wymieszać.
Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać.
Opróżnione opakowanie przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.
Warunkiem optymalnego działania środka jest równomierne pokrycie chwastów cieczą użytkową.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.
Niewystarczające wymycie aparatury po zabiegu i pozostawienie resztek środka w opryskiwaczu może być przyczyną silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

By uniknąć szkód dla upraw innych niż kukurydza, całe urządzenie opryskiwacza musi być zupełnie wyczyszczone od wewnątrz i na zewnątrz. Dlatego natychmiast po oprysku opróżnić zbiornik z cieczy. Opłukać wnętrze zbiornika i przemyć czystą wodą wraz z wężami i dyszami. Każde zanieczyszczenie na zewnątrz opryskiwacza powinno być usunięte przez mycie czystą wodą.
Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.
Po wykonaniu zabiegu umieść w widocznych miejscach wokół pola tablice ostrzegawcze z napisem „Zakaz wstępu osób niepowołanych do obszaru poddanego działaniu środków ochrony roślin

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
Dokładnie umyć ręce po użyciu.
Unikać zanieczyszczenia skóry.
Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.
W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.
W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
W celu ochrony wód podziemnych konieczne jest stosowanie środka raz na trzy lata na tej samej powierzchni.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 5 m od zbiorników i cieków wodnych ~~lub 2 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, dla zastosowania przedwschodowego,~~
- ~~4 m od zbiorników i cieków wodnych lub 2 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, dla zastosowania powschodowego.~~

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie od terenów nieużytkowanych rolniczo strefy ochronnej o szerokości:

- 3 m lub 1 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% zarówno dla zastosowania przed- i powschodowego.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze od 0°C - 30°C.

Chronić przed mrozem.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruć lub z lekarzem.
W przypadku połknięcia natychmiast skontaktować się z ośrodkiem zatruć lub z lekarzem.
W przypadku dostania się na skórę. Umyć dużą ilością wody z mydłem.
W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku dostania się do dróg oddechowych. Wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

Okres ważności 2 lata
Data produkcji -
Zawartość netto
Numer partii

Appendix 3 Letter of Access

Only the access to the equivalency of the active substance is submitted.
Accesses to the protected data are not necessary due to their termination on 1 January 2017.

Appendix 4 Lists of data considered for national authorization

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.2.1	Paweł Śliwa, M. Sc.	2018	Terbut 500 SC Determination of explosive properties. Institute of Industrial Organic Chemistry; BF-14/18; Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 2.3.1	Paulina Flasińska, MSc.	2018	Terbut 500 SC Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry BC-31/18; Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.3.3	Paulina Flasińska, MSc.	2018	Terbut 500 SC Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry BC-31/18; Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.4.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.5.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 2.5.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.6.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.7.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.7.3	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 2.7.4	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.7.5	Enzo Arévalo, Ph.D.;	2019	Terbut 500 SC Part II: Determination of physicochemical properties after the first year storage. Research Network Łukasiewicz Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2019 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.7.5	Enzo Arévalo, Ph.D.;	2020	Terbut 500 SC Part III: Determination of physicochemical properties after the second year storage. Research Network Łukasiewicz Institute of Industrial Organic Chemistry Study code: BF-07/18 Warsaw; April 2020 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.8.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 2.8.3.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.8.3.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.8.5.1.1	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.8.5.1.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 2.8.7.2	Idris Al Amin, Ph.D.	2018	Terbut 500 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage. Institute of Industrial Organic Chemistry Study code: 07/18 Warsaw; March 2018 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 2.11	Piotr Paleń, M. Sc.	2018	Terbut 500 SC Effectiveness of the equipment cleaning procedure Piotr Paleń Synthos Agro Sp. z o.o.; AGRO/17/18; Oświęcim; March 2018 Non GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL01 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL02 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL03 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL04 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL05 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Poland, 2017. SGS Polska Sp. z o.o. SGS/2017/145/PL06 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Czech Republic, 2017. SGS Polska Sp. z o.o. SGS2017H001CZ01 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Germany, 2017. SGS Polska Sp. z o.o. SGS2OI7HOO1GERO1 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Germany, 2017. SGS Polska Sp. z o.o. SGS2OI7HOO1GERO2 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Germany, 2017. SGS Polska Sp. z o.o. SGS2OI7HOO1GERO3 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Germany, 2017. SGS Polska Sp. z o.o. SGS2OI7HOO1GERO4 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Emilia Walczak	2017	Efficacy evaluation of Terbut 500 SC when applied pre and post emergence into maize, to control of wide range of broad leaves weeds, Germany, 2017. SGS Polska Sp. z o.o. SGS2OI7HOO1GERO5 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Ce/04 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Dziem/03 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Gr/01 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Nw/01 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Nw/05 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Łukasz Sobiech	2019	Efficacy of Terbut 500 SC in control of weeds in maize cultivation. Poznań University of Life Sciences AH/19/K/14/Ra/02 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 3.2.3	Zdzisław Jaskólski	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL06 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 3.2.3	Mateusz Ćwiek	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL07 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Mateusz Świtkowski	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL08 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Grzegorz Dąbrowski	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL09 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Maciej Kasperek	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL10 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Łukasz Nasalski	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL11 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Michał Springer	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL12 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP 3.2.3	Mateusz Ćwiek	2019	EVALUATION EFFICACY OF TERBUT 500 SC APPLIED IN MAIZE SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL13 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Beata Szymańska	2019	Evaluation of the phytotoxicity of the product Terbut 500 SC in the cultivation of corn. Poznań University of Life Sciences AH/19/K/14/BR/2 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Beata Szymańska	2019	Evaluation of the phytotoxicity of the product Terbut 500 SC in the cultivation of corn. Poznań University of Life Sciences AH/19/K/14/GR/5 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Beata Szymańska	2019	Evaluation of the phytotoxicity of the product Terbut 500 SC in the cultivation of corn. Poznań University of Life Sciences AH/19/K/14/NW/1 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Beata Szymańska	2019	Evaluation of the phytotoxicity of the product Terbut 500 SC in the cultivation of corn. Poznań University of Life Sciences AH/19/K/14/RA/4 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Beata Szymańska	2019	Evaluation of the phytotoxicity of the product Terbut 500 SC in the cultivation of corn. Poznań University of Life Sciences AH/19/K/14/ZŁ/3 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP 3.2.3	Grzegorz Dąbrowski	2019	Evaluation of the selectivity of the product Terbut 500 S.C. in maize. SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL01 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Maciej Kasperek	2019	Evaluation of the selectivity of the product Terbut 500 S.C. in maize. SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL02 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Mateusz Ćwiek	2019	Evaluation of the selectivity of the product Terbut 500 S.C. in maize. SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL03 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Łukasz Nasalski	2019	Evaluation of the selectivity of the product Terbut 500 S.C. SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL04 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 3.2.3	Mateusz Świtkowski	2019	Evaluation of the selectivity of the product Terbut 500 S.C. in maize. SynTech Research Poland Sp. z o.o. Terbut 500 S.C.-PL05 GEP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.1	Małgorzata Wołoszynowska MSc.	2018	Terbut 500 SC Method development and validation for the determination of active substance and relevant impurities content in the formulation. Institute of Industrial Organic Chemistry Study code: BA-07-18 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 5.1.2	Weronika Dec, PhD	2018	Validation included in the study. Terbut 500 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G/286/17 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Aneta Gierbuszewska, MSc	2018a	Validation included in the study. Terbut 500 SC Terrestrial Plant Test: Vegetative Vigour Test. Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G/287/17 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Aneta Gierbuszewska, MSc	2018b	Validation included in the study. Validation included in the report: Terbut 500 SC Earthworm Reproduction Test (*Eisenia andrei*). Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G/284/17 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Magdalena Wołany, MSc	2020	Validation included in the study. Terbut 500 SC Collembolan (Folsomia candida) Reproduction Test. Research Network Łukasiewicz Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G/60/19 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Patrycja Holewik MSc Eng.	2020	Validation included in the study. Terbut 500 SC Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil. Research Network Łukasiewicz Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G/61/19 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

KCP 5.1.2	Elżbieta Kulec-Płoszczyca, MSc.	2018a	Validation included in the study. Terbut 500 SC Daphnia magna, acute immobilisation test. Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W/10/18 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Elżbieta Kulec-Płoszczyca, MSc.	2018b	Validation included in the study. Terbut 500 SC Pseudokirchneriella subcapitata SAG 61.81 Growth inhibition test. Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W/11/18 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Elżbieta Kulec-Płoszczyca, MSc.	2018c	Validation included in the study. Terbut 500 SC Lemna gibba CPCC 310, Growth inhibition test. Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W/12/18 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	xxx.	2018	Validation included in the study. Terbut 500 SC Rainbow Trout, Acute Toxicity Test, Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W/13/18 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 5.1.2	Dennis Janota, Msc.	2019	Validation included in the study. Terbut 500 SC Navicula pelliculosa SAG 1050-3, Growth inhibition test. Research Network Łukasiewicz Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W/53/19 GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP 7.1.4	Gruszka K.	2017	Terbyt 500 SC: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER) Study code: OES-17/17 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP	N	Y	study report never submitted before	Synthos Agro Sp z.o.o Oświęcim

			Unpublished				
KCP 7.1.4	Krakowian D.	2017	TERBUT 500 SC: *In vitro* Skin Irritation: Reconstructed Human Epidermis Test Method. Krakowian D., 2019. Study code: SIT-3/17. Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp z.o.o Oświęcim
KCP 7.1.5	xxx	2017	Terbyt 500 SC: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage. Study code: ICE-12/17. Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	study report never submitted before	Synthos Agro Sp z.o.o Oświęcim
KCP 10.2	Janota, D.	2019	Terbut 500 SC, Navicula pelliculosa SAG 1050-3, Growth inhibition test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/53/19 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 10.2	Kulec-Płoszczyca E.	2018	Terbut 500 SC, Daphnia magna, Acute immobilisation test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/10/18 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 10.2	Kulec-Płoszczyca E.	2018	Terbut 500 SC, Pseudokirchneriella subcapitata SAG 61.81, Growth inhibition test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/11/18 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 10.2	Kulec-Płoszczyca E.	2018	Terbut 500 SC, Lemna gibba CPCC 310, Growth inhibition test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/12/18 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP 10.2	xxx	2018	Terbut 500 SC, Rainbow Trout, Acute Toxicity Test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/13/18 GLP; Unpublished	Y	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP.10.3.1	Parma P.	2017	Terbut 500 SC, Honeybees (*Apis mellifera* L.), Acute Oral	N	Y	study report never submitted before	Synthos

			Toxicity Test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/87/17 GLP; Unpublished				Agro Sp. z o.o Oświę-cim
KCP.10.3.1	Parma P.	2017	Terbut 500 SC, Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test, Institute of Industrial Organic Chemistry (Pszczyna) Study code: W/88/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP.10.3.2	Vaughan, R	2020	TERBUT 500 SC – A rate-response extended laboratory study to determine effects on the ladybird beetle, Coccinella septempunctata (Coleoptera: Coccinellidae) Mambo-Tox UK, Study code CHR-19-17 GLP, Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.3.2	Vaughan, R	2020	TERBUT 500 SC – A rate-response extended laboratory study to determine effects on the green lacewing, Chrysoperla carnea (Neuroptera, Chrysopidae) Mambo-Tox UK, Study code CHR-19-17 GLP, Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.3.2	Fallowfield, L.	2020	TERBUT 500 SC – An aged-residue extended laboratory study to determine effects on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae), Mambo-Tox UK, Study code CHR-19-17, GLP, Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.3.2	Parma P.	2018	An extended laboratory test for evaluating the effects of TERBUT 500 SC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez) Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/89/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim
KCP.10.3.2	Parma P.	2018	An extended laboratory test for evaluating the effects of TERBUT 500 SC on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry (Pszczyna) Study code: B/90/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświę-cim

KCP.10.4	Gierbuszewka A.	2018	TERBUT 500 SC, Earthworm Reproduction Test (*Eisenia andrei*) Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/284/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.4	Holewik, P.	2019	TERBUT 500 SC, Predatory mite (*Hypoaspis* (Geolaelaps) *aculeifer*) reproduction test in soil Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/61/19 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.4	Wołany, M.	2019	TERBUT 500 SC, Collembolan *(Folsomia candida)* Reproduction Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/60/19 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.5	Gierbuszewka A.	2018	TERBUT 500 SC, Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/285/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.6	Dec W.	2018	TERBUT 500 SC, Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/286/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim
KCP.10.6	Gierbuszewska A.	2018	TERBUT 500 SC, Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry (Pszczyna) Study code: G/287/17 GLP; Unpublished	N	Y	study report never submitted before	Synthos Agro Sp. z o.o Oświęcim

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner

KCP 5.1.2	Dieterle, R.	1993	GS 13529, Applicability of Multiresidue Method DFG S 19 for Determination of GS 13529 in Maize (Grain and Whole Plant) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 121-92 GLP Not Published Syngenta File N° GS13529/1080	N	N	-	Syngenta
KCP 5.1.2	Ferguson L.	2009	Terbuthylazine – Independent Laboratory Validation of Analytical Method No. REM 201.01 for the Determination of Terbuthylazine (GS13529) and its Metabolites GS26379 and GS28620 in Whole Maize Plants and Rape Seed Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.A, Pero, Italy Charles River Laboratories, Edinburgh, United Kingdom, 30377 GLP Not published Syngenta File No GS13529_10121	N	N	-	Oxon/ Syngenta
KCP 5.1.2	Anon.	1987	S7 multi-method for Triazine Herbicides, DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. Published Syngenta File N° N/0862	N	N	-	-
KCP 5.1.2	Freschi G.	2002c	Validation of The Method For Residues Analysis of Terbuthylazine In Maize Samples (Grain) Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1288 GLP Not published	N	N	-	Oxon

KCP 5.1.2	Freschi G.	2004	Validation Of The Multiresidue Analytical Method For Quantification Of Terbuthylazine In Maize Specimens: Grain And Silage Research Centre "E. Gagliardini", Salerano sul Lambro, Italy Oxon Italia S.P.A, Pero, Italy Report-no. SIP1431 GLP Not published	N	N	-	Oxon
KCP 5.2	Anon.	1987	S7 multi-method for Triazine Herbicides, DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. DFG Deutsche Forschungsgemeinschaft, Manual of Pesticide Residue Analysis Volume 1. Pesticides Commission. Published Syngenta File N° N/0862	N	N	-	-
KCP 5.2	Ferguson L.	2009	Terbuthylazine – Independent Laboratory Validation of Analytical Method No. REM 201.01 for the Determination of Terbuthylazine (GS13529) and its Metabolites GS26379 and GS28620 in Whole Maize Plants and Rape Seed Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.A, Pero, Italy Charles River Laboratories, Edinburgh, United Kingdom, 30377 GLP Not published Syngenta File No GS13529_10121	N	N	-	Oxon/ Syngenta

KCP 5.2	Dieterle, R.	1993	GS 13529, Applicability of Multiresidue Method DFG S 19 for Determination of GS 13529 in Maize (Grain and Whole Plant) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No 121-92 GLP Not Published Syngenta File N° GS13529/1080	N	N	-	Syngenta
KCP 5.2	Luetolf, W.	1995a	Determination of residues of parent compound by gas chromatography (GC), Soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM 148.05 GLP Not Published Syngenta File N° GS13529/1276	N	N	-	Syngenta
KCP 5.2	Figueiredo, J.	2003	Determination of GS13529 (Terbuthylazine) and its metabolites GS26379, GS28620, and GS23158 in Soil by LC-MS/MS. REM 148.11. Syngenta Crop Protection AG, Basel, Switzerland, Report No REM 148.11 Not GLP Not Published Syngenta File N° GS13529/1835	N	N	-	Syngenta
KCP 5.2	Todd M.	2002a	Validation Of Methodology For The Post-Registration Monitoring Of Residues Of Terbuthylazine And Its Two Major Metabolites Desethyl Terbuthylazine And 2-Hydroxy Terbuthylazine In Soil Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 228/024125 GLP Not Published	N	N	-	Oxon

KCP 5.2	Robinson, N.	2004	Residue Analytical Method for the Determination of Residues of Terbuthylazine (GS13529), GS23158, GS26379 and GS28620 in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, Report No RAM 426/01 GLP Not Published Syngenta File N° GS13529/1916	N	N	-	Syngenta
KCP 5.2	Todd M.	2002b	Terbuthylazine: Validation Of Methodology For The Determination Of Residues Of Terbuthylazine And Its Two Major Metabolites Desethyl Terbuthylazine And 2-Hydroxy Terbuthylazine In Drinking And Surface Water Huntingdon Life Sciences Limited, Cambridgeshire, UK Oxon Italia S.P.A, Pero, Italy Report-no. OXN 229/024126 GLP Not Published	N	N	-	Oxon
KCP 5.2	Zietz E.	2009	Terbuthylazine - Validation of an Analytical Method (Draft GRM015.02A) for the Determination of Residues of the Terbuthylazine Metabolites CSCD648241 and GS16984 in Groundwater, Surface Water, and Drinking Water Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.A, Pero, Italy SGS Institut Fresenius GmbH, D-65232 Taunusstein, Germany IF 08/01259634, T000964-09 GLP Not Published Syngenta File No GS13529_10092	N	N	-	Oxon/ Syngenta

KCP 5.2	Zietz E.	2009b	Terbuthylazine: Analysis of CSCD692760 (LM3) in groundwater samples from wells with documented uses of terbuthylazine on upstream fields in Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom; Oxon Italia, S.p.A, Pero, Italy SGS Institut Fresenius GmbH, D-65232 Taunusstein, Germany IF-09/01393295, T0001794-09 Not GLP Not Published Syngenta File No GS13529_10097	N	N	-	Oxon/ Syngenta
KCP 5.2	Tribolet, R.	1992	Sampling of air and determination of residues of parent compound by gas chromatography Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, Report No REM-148-03 GLP Not Published Syngenta File N° GS13529/1057	N	N	-	Syngenta
KCP 5.2	Schulz M., Ullrich-Mitzel A.	1995	Analytical Method For The Determination Of Terbuthylazine In Air RCC AG., Itingen, Switzerland Oxon Italia S.P.A, Pero, Italy Report-no. 385615 GLP Not Published	N	N	-	Oxon
KIIA 5.8.1	xxxx	2003	GS26379: Acute Oral Toxicity Study in the Rat – Up and Down Procedure Syngenta Crop Protection AG, Basell Report No CTL/AR7315 GLP Not published Syngenta File N GS26379/0020	Y		-	SYNGENTA
KIIA 5.8.1	xxxx.	2004	Assesment of acute oral toxicity with terbuthylazine-desethyl in the rat (acute class method) Oxon Italia S. p. A.	Y		-	OXON

KIIA 5.8.1	xxxx	2003	GS26379: Bacterial Mutation Assay in *S. typhimurium* and *E. coli* Syngenta Crop Protection AG, Basell Report No CTL/YV6393 GLP Not published Syngenta File N GS26379/0021	Y		-	SYNGENTA
KIIA 5.8.1	xxxx.	2004	Evaluationof the mutagenic activity of terbuthylazine-desethyl in the Salmonella typhimurium reverse mutation assay and the Escherichia coli reverse mutation assay (with independent repeat) Oxon Italia S. p. A. GLP Not published File GS13529_10044	Y		-	OXON
KIIA 5.8.1	xxxx	2003	GS26379: *In vitro* Cytogeenetic assay in human lymphocytes Syngenta Crop Protection AG, Basell Report No CTL/SV1196 GLP Not published Syngenta File N GS26379/0022	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2004	GS26379:L5178Y TK+/- Mouse lymphoma mutation assay Syngenta Crop Protection AG, Basell Report No VV0297-REG GLP Not published File No GS26379/0024	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2006	GS26379: rat bone marrow micronucleus test Syngenta Crop Protection AG, Basell GLP Not published File No GS26379/0026	Y		-	SYNGENTA

KIIA 5.8.1	xxxx	2006	GS26379: in vivo rat liver unscheduled DNAsynthesis assay Syngenta Crop Protection AG, Basell GLP Not published File No GS26379/0025	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	1971	90-day subacute oral toxicity study with GS 26379 technical in albino rats Novartis Crop Protection AG, Basell Not GLP Not published File No GS26379/0001	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2001	GS23158 tech. (metabolite of GS13529): Acute Oral Toxicity in the Rat (limit test) Syngenta Crop Protection AG, Basell Report No 20011053 GLP Not published Syngenta File N GS23158/0020	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2002	GS23158 tech. (metabolite of GS13529): 90-days acute oral toxicity study in the rat (administration in food) Syngenta Crop Protection AG, Basell Report No 20011053 GLP Not published Syngenta File N GS23158/0010	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2001	GS23158 tech. (metabolite of GS13529): *Salmonella* and *Escherichia*/ mammmalian microsome mutagenicity test Syngenta Crop Protection AG, Basell Report No 20011054 GLP Not published Syngenta File N GS23158/0012	Y		-	SYNGENTA

KIIA 5.8.1	xxxx	2001	GS23158 tech. (metabolite of GS13529): L5178Y TK+/- mouse lymphoma mutation assay Syngenta Crop Protection AG, Basell Report No 20011054 GLP Not published Syngenta File N GS23158/0012	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2002	GS23158: *In vitro* Cytogeenetic assay in human lymphocytes Syngenta Crop Protection AG, Basell Report No CTL/SV1087 GLP Not published Syngenta File N GS23158/0013	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2000	GS28620 tech. (metabolite of GS13529): Acute Oral Toxicity in the Rat (limit test) Syngenta Crop Protection AG, Basell Report No 20001004	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2001	GS28620 tech. (metabolite of GS13529): 90-days acute oral toxicity study in the rat (administration in food) Syngenta Crop Protection AG, Basell Report No 20001005	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2000	GS28620 tech. (metabolite of GS13529): *Salmonella* and *Escherichia*/ mammmalian microsome mutagenicity test Syngenta Crop Protection AG, Basell Report No 252/268-D5140/ 20001002	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2000	GS28620 tech. (metabolite of GS13529): Mutation at the thymidine kinase (TK) locus of mouse lymphoma L5178Y cells (MLA) using the microtitre fluctuation Syngenta Crop Protection AG, Basell Report No 252/268-D5140/ 20001002	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2001	GS28620 tech. (metabolite of GS13529): Induction of chromosome aberrations in cultured chinese hamsternovary (CHO) cells Report No 252/268-D6171/ 20001003	Y		-	SYNGENTA

KIIA 5.8.1	xxxx	2009	CSCD692760/LM3 *Salmonella typhimurium* and *Escherichi coli* reverse mutation assay Syngenta Crop Protection AG, Basell GLP Not published File No GS13529_10139	Y		-	OXON/ SYNGENTA
KIIA 5.8.1	xxxx	2009	CSCD692760/LM3 Chromosome aberration test in human lymphocytes *in vitro* Syngenta Crop Protection AG, Basell GLP Not published File No GS13529_10142	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2009	GS16984/LM5 *Salmonella typhimurium* and *Escherichi coli* reverse mutation assay Syngenta Crop Protection AG, Basell GLP Not published File No SYN545666_10000	Y		-	SYNGENTA/ OXON
KIIA 5.8.1	xxxx	2009	CSCD648241/LM6 *Salmonella typhimurium* and *Escherichi coli* reverse mutation assay Syngenta Crop Protection AG, Basell GLP Not published File No GS13529_10005	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2009	CSCD648241/LM6 Cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells Syngenta Crop Protection AG, Basell GLP Not published File No SYN545666_10002	Y		-	SYNGENTA
KIIA 5.8.1	xxxx	2009	CSCD648241/LM6 Chromosome aberration test in human lymphocytes in vitro Syngenta Crop Protection AG, Basell GLP Not published File No GS13529_10140	Y		-	SYNGENTA

KIIA 5.8.1	xxxx	2006	CSCD648241/LM6 Micronucleus test in the mouse Syngenta Crop Protection AG, Basell Oxon Italia S. p. A. GLP Not published File No GS13529_10141	Y		-	SYNGENTA
KCP 7.2.1	Giannone, C.	1998	Stability or residues of terbuzhylazine (GS 13529) and GS 26379 (metabolite of terbuthylazine) in plant materials (analytical specimens on wheat grain and wheat straw) stored under deep freeze conditions Novartis Crop Protection AG, Basel Switzerland Report No 136/96 GLP, Not Published Syngenta File N°GS13529/1557	N	N	-	Syngenta
KCP 7.2.1	Giannone, C.	2003	Stability of residues of GS 28260 (Metabolite of terbuthylazine) in deep freeze stored analytical specimens of wheat grain, beans and sunflowers seeds Syngenta Crop Protection AG, Basel, Switzerland Report No 302/01 GLP, Not Published Syngenta File N°GS13529/1854	N	N	-	Syngenta
KCP 7.2.2	Nicollier, G.	1997	Behaviour and metabolism of GS 13529 in field grown corn after soil application of [Triazine-(U)-^{14}C] labelled material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No CMR 07/97 GLP, Not published Syngenta File N° GS13529/1486	N	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: yes Published: no	N	N	-	OXN
KCP 7.2.2	Salvi, M.	2002a	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France, Report No 3002/00	N	N	-	Syngenta

			GLP, Not Published Syngenta File N° GS13529/1754				
KCP 7.2.2	Salvi, M.	2002b	Residue study with terbuthylazine (GS 13529) and S-Matalochlor (CGA 77102) in or on maize in Switzerland Syngenta Crop Protection AG, Basel, Switzerland ADME -Bioanalysis, Vergéze, France, Report No 3003/00 GLP, Not Published Syngenta File N° GS13529/1755	N	N	-	Syngenta
KCP 7.2.2	Stolze, K.	1997a	Residues of CGA 77102 and Terbuthylazine (GS 13529) in maize Novartis Crop Protection AG, Basel Switzerland Novatoris Agro GmbH, Frankfurt, Germany, Report No GR 15596 GLP, Not Published Syngenta File N°GS13529/1500	N	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	N	-	Syngenta
KCP 7.2.2	Luetolf, W.	1999a	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP, Not Published Syngenta File N° GS13529/1607	N	N	-	Syngenta
KCP 7.2.2	Luetolf, W.	1999b	Residue study with terbuthylazine (GS 13529) in or on maize in Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 3004/96 GLP, Not Published Syngenta File N° GS13529/1608	N	N	-	Syngenta
KCP 7.2.2	Stolze, K.	2004a	Determination of Residues of CGA 77102 and GS 13529 in maize after application of A 12310 A in Germany, 2000 Syngenta Crop Protection AG, Basel, Switzerland	N	N	-	Syngenta

			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	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	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	N	-	Syngenta
KCP 7.2.2	Stolze, K.	2004e	Determination of residues of CGA 77102 and GS 13529 in maize and rotational crop Winter Barley, Winter Oilseed Rape and Sugar Beet after application of A 9476 B in Germany, Seasons 2000 and 2001 Syngenta Crop Protection AG, Basel, Switzerland Syntenta Agro GmbH, Maintal, Germany, Report No gr 10200 GLP, Not Published Syngenta File N° GS13529/1917	N	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	N	N	-	Syngenta

			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				
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	N	-	Syngenta
KCP 7.7.2	Kuehne-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	N	-	Syngenta
KCP 7.7.2	Kuehne-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	N	-	Syngenta
KCP 7.2.3	Mostert, I.	1997a	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3054/95 GLP, Not Published Syngenta File N° GS13529/1498	N	N	-	Syngenta
KCP 7.2.3	Mostert, I.	1997b	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland,	N	N	-	Syngenta

			Report No 3055/95 GLP, Not Published Syngenta File N° GS13529/1499				
KCP 7.2.3	Mostert, I.	1997c	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3052/96 GLP, Not Published Syngenta File N° GS13529/1489	N	N	-	Syngenta
KCP 7.2.3	Mostert, I.	1997d	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3085/95 GLP, Not Published Syngenta File N° GS13529/1490	N	N	-	Syngenta
KCP 7.2.3	Mostert, I.	1997e	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3053/96 GLP, Not Published Syngenta File N° GS13529/1491	N	N	-	Syngenta
KCP 7.2.3	Mostert, I.	1997f	Magnitude of Residues in maize and soil after application of CGA 77102 and terbuthylazine (GS 13529) as formulation SC 500 (A-9476 B) Novatoris Crop Protection AG, Basel, Switzerland Novatoris Crop Protection AG, Basel, Switzerland, Report No 3051/96 GLP, Not Published Syngenta File N° GS13529/1492	N	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	N	N	-	Syngenta

			Novatoris Crop Protection AG, Basel, Switzerland, Report No 3083/95 GLP, Not Published Syngenta File N° GS13529/1493				
KCA 6.6.1	Krauss, J.	2000	Outdoor confined accumulation study on rotational crops after bareground application of [Triazine-(U)-^{14}C]GS 13529 Novartis Crop Protection AG, Basel, Switzerland, Report No 96GN32 GLP, Not Published Syngenta File N° GS13529/1663	N	N	-	Syngenta
KCP 9.1	Anon	2002	Groundwater Survey 2002, Part 5: Pesticides and Degradation Products Pages 57-74 Syngenta Crop Protection AG, Syngenta File No ICI224/0922 Non-GLP published	N	N	-	Syngenta
KCP 9.1	Bader, U.	1990	GS 13529, Report on the teste for ready biodegradability in the Modified Sturm Test Novartis Crop Protection AG, Basel Report No 901360 GLP Unpublished	N	N	-	Syngenta
KCP 9.1	Glaenzel, A.	1998	Rate of degradation S135ne under various conditions Novartis Crop Protection AG, Basel Report No 97RP02 GLP Unpublished	N	N	-	Syngenta
KCP 9.1	James, T., et al.	1998	Degradation and movement of terbuthylazine in soil Published Syngenta File No GS13529/1683	N	N	-	---
KCP 9.1	Kjaer, J.	2003	The Danish Pesticide Leaching Assesment Programme. Monitoring Results May 1999 – June 2002. Third Repot Geological Survey of Denmark and Greenland, the Danish Institute of Agricultural Science and the National Environmental Research Institute Non GLP Published	N	N	-	Published Reference
KCP 9.1	Kjaer, J.	2004	The Danish Pesticide Leaching Assesment Programme. Monitoring Results May 1999 – June 2003. Geological Survey of Denmark and Greenland, the Danish Institute	N	N	-	Published Reference

			of Agricultural Science and the National Environmental Research Institute Non GLP Published				
KCP 9.1	Schmidt, B., Zietz, E.	2000	Monitoring site-related evaluation of terbuthylazine findings in Groundwater Novartis Crop Protection AG, Basel Report No 100-1522-1738 Non GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Abildt, U.	1991	Aerobic degradation of GS 13529 in soil under various test conditions Novartis Crop Protection AG, Basel Report No 38-90 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Galicia, H., Margenroth, U.	1993	Degradation of 14C-Terbuthylazin Technical (GS 13529): in Four Soils Incubated under Aerobic Conditions Novartis Crop Protection AG, Basel Report No 243224 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Glaenzel, A.	2000a	Rate of degradation of 14C-triazine labelled GS 23158 in three soils under laboratory conditions at 20°C Novartis Crop Protection AG, Basel Report No 99AG05 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Morgenroth, U.	2000a	Degradation of [triazine-U-14C]-labelled GS 13529 in two soils under aerobic conditions at 20 C Novartis Crop Protection AG, Basel Report No 99MO06 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Offizorz, P., Resseler, H.	1990a	Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel Report No 170425 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Phaff, R.	2000a	Degradation of 14C-triazine labelled GS 28620 in four soils under aerobic conditions at 20°C Novartis Crop Protection AG, Basel Report No 99RP05 GLP Unpublished	N	N	-	Syngenta

KCP 9.1.1	Purghart, V.	2000	Terbuthylazine (GS 13529): soil photolysis Novartis Crop Protection AG, Basel Report No 1047.102.720 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Reischmann, F.	2000a	Rate of degradation of Triazine-U-14C) labelled GS 26379 in three soils under aerobic laboratory conditions at 20°C Novartis Crop Protection AG, Basel Report No 99RF04 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Schaffer, A. and Nicollier, G.	1997a	Degradation of ^{14}C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG Study no 96AS01 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1	Schaffer, A. and Nicollier, G.	1997b	Degradation of ^{14}C-labelled GS13529 in Gartenacker loam soil under aerobic conditions at 10 and 20 C and under anaerobic/sterile conditions at 20 C. Syngenta Crop Protection AG Study no 96AS05 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Edwards, P., Evans, P.	2004	Terbuthylazine: Residue Stability Study for Terbuthylazine (GS13529) and its Metabolites (GS26379, GS23158 and GS28620) in Soil under Freezer Storage Conditions – Interim Report Syngenta Crop Protection AG, Report No RJ3492B GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Evans, P.	2004a	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine (GS13529) and Metolachlor (CGA77102) in or on Cultivated Soil in France (South) Syngenta Crop Protection AG, Report No RJ3521B GLP Unpublished	N	N	-	Syngenta

KCP 9.1.1.2	Evans, P.	2004b	Terbuthylazine (GS13529) and S-Metolachlor (CGA77102): Dissipation Study with Terbuthylazine and Metolachlor (CGA77102) in or on Cultivated Soil in Italy Syngenta Crop Protection AG, Report No RJ3522B GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Klosowski, R., Siebes, J., Nolting, H.	1990	Investigations into the infiltration behaviour of active ingredient Terbuthylazine and the metabolite Desethyl-Terbuthylazine. GLP Published	N	N	-	Published reference
KCP 9.1.1.2	Offizorz, P., Resseler, H.	1990b	Field soil, Dissipation rate determination of terbuthylazine Novartis Crop Protection AG, Basel Report No 170414 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Offizorz, P., Resseler, H.	1991a	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 51-90B) Novartis Crop Protection AG, Basel Report No 223740 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Offizorz, P., Resseler, H.	1991b	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 25-90B) Novartis Crop Protection AG, Basel Report No 223727 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Offizorz, P., Resseler, H.	1991c	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 24-90B) Novartis Crop Protection AG, Basel Report No 223716 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1. 1.2	Offizorz, P., Resseler, H.	1991d	Field soil, dissipation rate determination of terbuthylazine (Exp.-No. 50-90B) Novartis Crop Protection AG, Basel Report No 223738 Not GLP Unpublished	N	N	-	Syngenta
KCP 9.1.1.2	Nicollier, G.	1997	Field dissipation of GS 13529 after bareground application of [triazine-(U)-14C] labelled material Novartis Crop Protection AG, Basel Report No CMR	N	N	-	Syngenta

			08/97 GLP Unpublished				
KCP 9.1.2	Adam, D.	2000a	Adsorption/desorption of GS 23158 in Borstel soil Novartis Crop Protection AG, Basel Report No 99DA11 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Ellgenhausen, H.	1988	Leaching model study with GS 13529 in four soil types Novartis Crop Protection AG, Basel Report No 14-88 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Haamann, H., Gramatte, A., Brodsky, J.	1993	Experimental examinations of the behaviour of terbuthylazine in soil Novartis Crop Protection AG, Basel Report No BE-FLA-20-89-1 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Hassink, J.	1992	Outdoor lusimeter study on Terbuthylazine Novartis Crop Protection AG, Basel Report No CIB-04/7-11 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Luetolf, W., Haamann, H.	1998	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1994/95 Novartis Crop Protection AG, Basel Report No 3053/94 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Luetolf, W.	1999	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1994/95 Novartis Crop Protection AG, Basel Report No 3060/95 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Luetolf, W.	2000a	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1996/97 Novartis Crop Protection AG, Basel Report No 3070/96 GLP	N	N	-	Syngenta

			Unpublished				
KCP 9.1.2	Luetolf, W.	2000b	Experimental studies on the behaviour of terbuthylazine in soil – study on potential leaching into groundwater – 1997/98 Novartis Crop Protection AG, Basel Report No 3140/97 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	McLaughlin, S., Galicia, H.	1996a	GS 26379: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel Report No 95-058-1008 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	McLaughlin, S., Galicia, H.	1996b	GS 23158: Determination of adsorption and desorption in three soils Novartis Crop Protection AG, Basel Report No 95-059-1008 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Morgenroth, U.	2000b	Adsorption/desorption of Triazine-U-14C labelled GS 28620 in various soils Novartis Crop Protection AG, Basel Report No 00MO01 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Mueller, J.	1991a	Determination the adsorption and desorption of terbuthylazine. Novartis Crop Protection AG, Basel Report No CIB-004/7-13 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Mueller, J.	1991b	Determination of adsorption/desorption of desethyl-terbuthylazine. Novartis Crop Protection AG, Basel Report No GS26379/0006 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2	Phaff, R.	2000b	Adsorbtion/Desorbtion of GS 13529 in various soils Novartis Crop Protection AG, Basel Report No 99RP04 GLP	N	N	-	Syngenta

			Unpublished				
KCP 9.1.2	Reischmann, F.	2000b	Adsorbtion/Desorbtion of Triazine-U-14C-labelled GS 26379 in soil lorsh Novartis Crop Protection AG, Basel Report No 00RF04 GLP Unpublished	N	N	-	
KCP 9.1.2	Ricker, I., Haamann, H.	1993	Experimental studies on the behaviour of terbuthylazine in soil – 1992 Novartis Crop Protection AG, Basel Report No BE-FLA-20-89-1 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2.3	Burgener, A.	1995	14C-Terbuthylazine/14C-Atrazine: Mobility and Degradation in Soil in Outdoor Lysimeters Novartis Crop Protection AG, Basel Report No 321581 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2.3	Luetolf, W.	2002	Study on potential leaching into groundwater – 1999/2000 – Field experiment section. Novartis Crop Protection AG, Basel Report No 3091/99 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2.3	Mamouni, A.	1996	14C-Terbuthylazine: mobility and Degradatioon in Soil in Outdoor Lysimeters RCC AG, Itingen, Switzerland, Report No. 348794 GLP Unpublished	N	N	-	OXON
KCP 9.1.2.3	Resseler, H.	2004	Leaching behaviour of terbuthylazine in a long term field experiment from 1990 to 2001 in Germany Syngenta Crop Protection AG, Report No HR012004 Non-GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2.3	Tribolet, R.	2003	Study on potential leaching into groundwater – 1999/2000 – Field experiment section. Novartis Crop Protection AG, Basel Report No 3040/00 GLP Unpublished	N	N	-	Syngenta
KCP 9.1.2.3	Zietz, E.	2000	Monitoringof GS13529 (Terbuthylazine) in Surface Water adjecent Field susceptible to run-off. Trial Sites	N	N	-	Syngenta

			Ramholz (Hesse) and Kemading (Bavaria) Novartis Agro, Report No IF-99/07972-00 GLP Unpublished				
KCP 9.2	Adam, D.	2000b	Hydrolysis of [triazine-U-14C]-labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel Report No 00DA01 GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Bourry, R.	2003	Stability of Residues of GS 28620 and GS 23158 (Metabolites of Terbuthylazine) in Deep Freeze Stored Analytical Specimens of Potable Water Syngenta Crop Protection AG, Report No 301/01 Non-GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Doyle, R.	1991	Hydrolysis of 14C-Terbuthylazine Novartis Crop Protection AG, Basel Report No IITRI-VTC-9004 GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Glaenzel, A.	2000b	Aqueous photolysis of 14C-triazine labelled GS 26379 under laboratory conditions Novartis Crop Protection AG, Basel Report No 99AG06 GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Mamouni,A.	1998	14C-Terbuthylazine: degradation and metabolism in aquatic systems Novartis Crop Protection AG, Basel Report No 608207 GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Mamouni,A.	2002	Aqueous Photolysis of 14C-Triazine Ring Labelled GS 13529 under :aboratory Conditions Syngenta Crop Protection AG, Syngenta File No 820642 Non-GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Reese-Staehler, G.	2000	Monitoring of GS13529 (Terbuthylazine) in Surface Water in the Area of Fields Endangered by Run off. Sites: Adenstedt (Lower Saxony) and Suplingen (Sachsen Anhalt)	N	N	-	Syngenta

			Novartis Crop Protection AG, Basel Report No OC9902 GLP Unpublished				
KCP 9.2	Van, der Gaaw A.	2002	14C-Triazine Ring labelled GS23158 Hydrolysis at three different pH values Syngenta Crop Protection AG, Syngenta File No GS13529/1732 Non-GLP Unpublished	N	N	-	Syngenta
KCP 9.2	Zetzsch, C., Palm, W.	1993	GS 13529 UV – Absorption sprectra of Terbuthylazin – estimation of aqueous photolysis maximum rate constant and minimum half-life in sunlight Novartis Crop Protection AG, Basel Report No PC91-3 GLP Unpublished	N	N	-	Syngenta
KCP 9.3	Reischmann, F.	1992	Volatilization of GS 13529 from soil surface under controlled laboratory conditions Novartis Crop Protection AG, Basel Report No 95RF14 GLP Unpublished	N	N	-	Syngenta
KCP 9.3	Reischmann, F.	1995	Volatilization of GS 13529 from water (calculation) Novartis Crop Protection AG, Basel Report No 95RF14 GLP Unpublished	N	N	-	Syngenta
KCP 9.3	Sandmeier, P.	1992	GS 13529 Volatility from plant and soil surfaces Novartis Crop Protection AG, Basel Report No 92PSA06 GLP Unpublished	N	N	-	Syngenta
KCP 9.3	Sandmeier, P.	1993	Volatilization of GS 13529 from Plant and Soil ofter Posemergent Spray Application of 14C-labelled Material on Maize under Indoor Conditions Novartis Crop Protection AG, Basel Report No 93PSA17 GLP Unpublished	N	N	-	Syngenta
KCP 9.3	Stamm, E.	1997	Atmosphere oxidation of terbuthylazine GS 13529 by hedroxyl radicals; rate estimation Novartis Crop Protection AG, Basel Report No 95A97007SM GLP	N	N	-	Syngenta

			Unpublished				
KCP 9.3	Zetzsch, C., Palm, W.	1994	Determination of the OH-rate constant of terbuthylazine lazine adsorbed on aerosols Novartis Crop Protection AG, Basel Report No PC92-4 GLP Unpublished	N	N	-	Syngenta
KCP 10.1.1	xxxx	1989	Bobwhite quail acute oral toxicity study OXON	Y	N	-	Syngenta
KCP 10.1.1	xxxx	1988	Bobwhite quailshort-term dietary toxicity study OXON	Y	N	-	Syngenta
KCP 10.1.1	xxxx	1995	Japanese quail reproductive toxicity Syngenta and OXON	Y	N	-	Syngenta
KCP 10.1.2	xxxx	1991	DACT Technical Ground FL-871776: Acute Oral Toxicity Study in Rats Syngenta Unpublished Report No. 7801-91 GLP	Y	N	-	Syngenta
KCP 10.1.2	xxx	2008	Determination of terbuthylazine initial residue and DT50 in maize plant following application of gardo gold^{tm} (187.5 terbuthylazine/L and 312.5 g S-metolachlor/L) Oxon Italia S.P.A, Pero, Italy, Syngenta CP AG, Basel, Switzerland GLP, not published File No A9476C_11126	Y	N	-	Oxon / Syngenta
KCP 10.1.2	xxxx	1991a	TK 12 669/1: Test To Evaluate the Acute Toxicity Following a Single Oral administration (LD50) in the Rat Syngenta Unpublished Report No. 012333 GLP	Y	N	-	Syngenta
KCP 10.1.2	xxxx	2000	GS 28620 Tech. (Metabolite Of GS 13529): Acute Oral Toxicty in the Rat (Limit test Syngenta Unpublished Report No. 20001004 GLP	Y	N	-	Syngenta
KCP 10.1.2	xxxx	2001	GS 23158 Tech (Metabolite of GS 13529): Acute Oral Toxicity in the Rat (Limit test Syngenta Unpublished Report No. 20001014 GLP	Y	N	-	Syngenta
KCP 10.1.2	xxxx	2003	GS 26379: Acute Oral Toxicity Study in the Rat: Up and Down Procedure Syngenta Unpublished Report No. CTL/AR7315 GLP	Y	N	-	Syngenta

KCP 10.1.2	xxxx	1998	Two generation reproduction toxicity studies Syngenta	Y	N	-	Syngenta
KCP 10.1.2	xxxx	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria Report no.: WFC/FS 017 GLP	Y	N	-	---
KCP 10.2	Dengler, D.	2001	Assessment of Toxic Effects of Terbuthylazine Technical on the Duckweed Lemna gibba in a Semi Static Test and a Recovery Period, Oxon Italia S.P.A, Pero, Italy Report-no. 20001420/01-ARLg, GLP, Not published	N	N	-	Oxon
KCP 10.2	Grade, A.	2000a	Acute toxicity of GS 23158 (Metabolite of GS 13529) to the cladoceran Daphnia magna Straus in the static system, Novartis Crop Protection AG, Basel, Switzerland, Report No 2001569, GLP, Not Published	N	N	-	Syngenta
KCP 10.2	Grade, A.	2000b	Growth inhibition of GS 23158 (metabolite of GS 13529) to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 2001571, GLP, Not Published	N	N	-	Syngenta
KCP 10.2	Grade, R.	1997	Growth inhibition test of GS 14260 tech. to green algae (Selenastrum capricornutum) under static conditions, Novartis Crop Protection AG, Basel, Switzerland, Report No 961714, GLP, Not Published	N	N	-	Syngenta
KCP 10.2	Kelly, C.	1996	Terbuthylazine Technical Algal Growth Inhibition, Oxon Italia S.P.A, Pero, Italy Report-no. OXN 180/962297, GLP, Not published:	N	N	-	Oxon
KCP 10.2	Memmert, U.	1998	Effects of 14C-labelled GS 13529 (Terbuthylazine tech.) on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system. Syngenta File No GS13529/1579 GLP	N	N	-	Syngenta
KCP 10.2	Palmer, S, Kendall, T, Krueger, H A	2001	96-Hour Growth Inhibition Test of GS-26379 (Metabolite of GS-13529) to the Green Alga, Selenastrum capricornu-	N	N	-	Syngenta

			tum, Syngenta Crop Protection AG, Basel, Switzerland, Report No 528A-109, GLP, Not Published,				
KCP 10.2	xxxx	2000	Acute toxicity of GS 23158 to Rainbow trout (Oncorhynchus mykiss) in a 96-hour static test. Novartis Crop Protection AG, Basel, Switzerland, Report No 765562, GLP Not Published	Y	N	-	Syngenta
KCP 10.2	Shillabeer, N., Maynard, S.J., Woodyer, J.M.	2002	GS13529 (Terbuthylazine technical) Chronic toxicity to Daphnia magna Syngenta File No GS13529/1783 GLP	N	N	-	Syngenta
KCP 10.2	xxxx	1982	Acute toxicity of Terbutryn technical to Rainbow trout (Salmo Gairdneri) Novartis Crop Protection AG, Basel, Switzerland. , Report No BW-82-8-1241 Not GLP, Not Published,	Y	N	-	Syngenta
KCP 10.2	xxxx	2002	GS13529 (Terbuthylamine technical): Acute toxicity to rainbow trout (Oncorhynchus mykiss) Syngenta Report No BL7395/B GLP Not Published	Y	N	-	Syngenta
KCP 10.2	xxxx	1996	Prolonged Toxicity Test of CGA 293343 tech. to Rainbow Trout (Oncorhynchus mykiss) in the Flow-Through System	Y	N	-	Syngenta
KCP 10.2	xxxx	1991a	Report on the acute toxicity test of GS 26379 to Rainbow trout (Salmo gairdneri) Novartis Crop Protection AG, Basel, Switzerland, Report No 918144 GLP, Not Published	Y	N	-	Syngenta
KCP 10.2	Vial, A.	1991d	Report on the acute toxicity test of GS 26379 to Daphnia (Daphnia magna STRAUS 1820), Novartis Crop Protection AG, Basel, Switzerland, Report No 918142, GLP Not Published,	N	N	-	Syngenta
KCP 10.3	Petto, R., Klepka, S.	1994	Laboratory testing for toxicity (acute contact and oral LD50) of GS 13529 to honey bees (Apis mellifera L.) Syngenta File No GS13529/1239	N	N	-	Syngenta

			GLP Not Published				
KCP 10.4	Corboli, M,	2009	Effect on earthworms (Eisenia foetida) reproduction of 2-hydroxy-terbuthylazine (MT13). Flie no. GS13529_10039) GLP	N	N	-	Syngenta
KCP 10.4	Klein, O.	2006	S-metolachlor (A9396C), terbuthylazine (A5435E) and s-metolachlor + terbuthylazine (A9476C): A field study to evaluate effects on the earthworm fauna a maize field in southern Germany. GAB Biotechnologie GmbH & GAB Analytik GmbH, Germany Report No. 20051078/G1-NFEw. GLP, Not published, Syngenta file no CGA77102/1003	N	N	-	Syngenta
KCP 10.4	Muther	2004a	GS26379 (a Metabolite of GS13529): Sublethal Toxicity to the Earthworm *Eisenia Andrei* in Artificial Soil. Syngenta Unpublished report No: 20041056/01 GLP	N	N	-	Syngenta
KCP 10.4	Pease, G., et al.	2006	S-metolachlor (A9396C), terbuthylazine (A5435E) and s-metolachlor + terbuthylazine (A9476C): A field study to evaluate effects on the earthworm fauna a maize field in Denmark. Ecotox Limited, Devon, UK. Report No. ER-06-KCB 215. Non GLP report from GLP study, Not published, Syngenta file no CGA77102/1002	N	N	-	Syngenta
KCP 10.5	Kolzer, U.	2002	Assessment of the side effects of 2-hydroxy-terbuthylazine on the Activity of the Soil Microflora Oxon Italia S.P.A, Report No 20011377/01-ABMF GLP, Not published	N	N	-	Oxon
KCP 10.5	Kolzer, U.	2003	Assessment of the side effects of desethyl terbuthylazine on the Activity of the Soil Microflora Oxon Italia S.P.A, Report No 20021389/01-ABMF GLP, Not published	N	N	-	Oxon

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-