REGISTRATION REPORT

Part A

Risk Management

Product code: ADM.09050.H.1.A

Product name(s): **STEMPER**

Chemical active substances:

Trinexapac-ethyl, 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **ADAMA**

Submission date: May 2022

Evaluation date: March 2023

Version history

When	What
January 2021	dRR version 1 submitted by applicant
March 2023	Version evaluated by zRMS

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application under article 33 of regulation 1107/2009 submitted by the applicant in January 2021 is for first authorisation of the product ADM.09050.H.1.A, an emusifiable concentrate containing 175 g/L trinexapac-ethyl for use in cereals and grass for seeds, with max. 0.8 L/ha and at latest BBCH 39.

The zRMS for the central zone dossier is Poland.

An application was also submitted in Lituania (Northern zone zRMS) and Italy (Southern zone zRMS).

1.2 Letters of Access

Business Confidential.

1.3 Justification for submission of tests and studies

All reports submitted are needed for the first registration of ADM.09050.H.1.A in accordance to the data requirements laid down in Regulation (EC) No. 284/2013.

1.4 Data protection claims

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company, the Applicant claims data protection for the studies submitted with this application. The list of the studies for which the applicant requests data protection are reported in the appendix 4 of Part A. The Applicant confirms that no period of data protection has previously been granted in respect of the study or has been granted and not yet expired.

2 Details of the authorization decision

2.1 Product identity

Product code	ADM.09050.H.1.A (formerly AG-T3-175 EC1)
Product name in MS	Stemper
Authorization number	new product
Function	herbicide
Applicant	ADAMA Poland Sp. z o. o.
Active	trinexapac-ethyl; 175 g/L

substance(s) (incl. content)	
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	5 L and 10 L COEX containers, professional user
Coformulants of concern for national authorizations	not applicable
Restrictions related to identiy	not applicable
Mandatory tank mixtures	not applicable
Recommended tank mixtures	not applicable

2.2 Conclusion

The evaluation of the application for STEMPER 175 EC resulted in the decision to grant the authorization of this plant growth regulator to prevent or reduce the lodging of cereal crops (the accepted national GAP: 2.6)

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

Not applicable.

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:	Skin irritation Category 2 ~~3~~ Eye irritation Category 2 Skin sensitization Category 1 STOT RE 2 Aquatic Chronic ~~3~~ 2

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 GHS09**
Signal word:	**Warning**
Hazard statements:	**H315** **H317**

	H319 **H373 (GI tract)** **H411** ~~**H412**~~
Precautionary statements:	~~**P102, P280, P302+P352, P305+P351+P338, P501**~~ P261 Avoid breathing spray. P264 Wash hands and face thoroughly after handling P272 Contaminated work clothing should not be allowed out of the workplace P280 Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention P332 + P313 If skin irritation occurs: Get medical advice/attention. P362 Take off contaminated clothing and wash before reuse. P314 Get medical advice/attention if you feel unwell. P501 Dispose of contents/container to …in accordance with local/ regional/ national/international regulation P391 Collect spillage
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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).

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

Refer to national product label.

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	none
Worker protection:	
respective code if available	none
Integrated pest management (IPM)/sustainable use:	
respective code if available	none
Environmental protection	

respective code if available	none

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):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 28.05.2020

PPP (product name/code):	ADM.09050.H.1.A	Formulation type:	EC
Active substance 1:	Trinexapac-ethyl	Conc. of as 1:	175 g/L
Safener:	not relevant	Conc. of safener:	not relevant
Synergist:	not relevant	Conc. of synergist:	not relevant
Applicant:	ADAMA Registrations B.V.	Professional use:	X
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Plant growth regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ syner-gist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					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	Winter wheat (TRZAW)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring, BBCH ~~29~~ 30-39	a)1 b)1	n/a	a) 0.4-0.6 l//ha b) 0.4-0.6 l//ha	a) 70-105 g a.s./ha b) 70-105 g a.s./ha	200-300	n/a	Due to the assump-tions used in the assessment for winter cereals in B8 and B9	
2	PL	Winter wheat (TRZAW)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring, A: BBCH 31-32 B: BBCH 37-39	a)2x50% b)2x50%	14-32	a) 2x 0.3 l//ha b) 2x 0.3 l//ha	a) 2x 52.5 g a.s./ha b) 2x 52.5 g a.s./ha	200-300	n/a	Split dose: 2 x 50% max. rate for TRZAW	
~~3~~	~~PL~~	~~Spring oat~~	~~F~~	~~Plant Growth Regulator~~	~~Spray,~~	~~Spring,~~	~~a)1~~	~~n/a~~	~~a) 0.4-0.6 l//ha~~	~~a) 70-105 g~~	~~200-300~~	~~na~~		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ syner-gist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					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			
		~~(AVESA)~~		~~PGR~~	~~medium sprayer~~	~~BBCH 31-33~~	~~b)1~~		~~b) 0.4-0.6 l//ha~~	~~a.s./ha b) 70-105 g a.s./ha~~				
4	PL	Spring barley (HORVS)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring BBCH 30-34	a)1 b)1	n/a	a) 0.4-0.6 l//ha b) 0.4-0.6 l//ha	a) 70-105 g a.s./ha b) 70-105 g a.s./ha	200-300	n.a		
5	PL	Winter barley (HORVW)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring BBCH 31-39	a)1 b)1	n/a	a) 0.6-0.9 l//ha b) 0.6-0.9 l//ha	a)105 – 157.5 gas/ha b) 105 – 157.5 gas/ha	200-300	n.a		
6	PL	Winter rye (SECCW)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring BBCH 31-39	a)1 b)1	n/a	a) 0.6 l//ha b) 0.6 l//ha	a)105 gas/ha b) 105 gas/ha	200-300	n.a		
7	PL	Winter triticale (TTLWI)	F	Plant Growth Regulator PGR	Spray, medium sprayer	Spring BBCH 31-32	a)1 b)1	n/a	a) 0.6 l//ha b) 0.6 l//ha	a)105 gas/ha b) 105 gas/ha	200-300	n.a		

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

** 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

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 ADM.09050.H.1.A is that of an amber liquid with an aromatic odor. It is not explosive, has no oxidising properties. The product has a flash point of >150 °C. It has a self-ignition temperature of 374°C. The pH value of the formulation (1% w/w) is 3.7 at 25°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 content of the active ingredient nor the technical properties were changed. Also the 2 years shelf life study confirms the high quality and stability of ADM.09050.H.1.A when stored at ambient temperature in HDPE/PA or HDPE/EVOH commercial containers. Its technical characteristics are acceptable for an EC formulation.
The intended concentration of use in the Central Zone is 0.0625%v/v to 0.6% v/v.
The product will not be used in tank mixtures.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Experimental results on the product ADM.09050.H.1.A (Trinexapac-ethyl 175 g/L) with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	Expert statement	Not explosive	None
Oxidising properties	Expert statement	Not oxidizing	None
Flammability	--	Not applicable for EC-formulation	--
Flash point	EEC A.9	> 150°C	None
Auto-flammability	EEC A.15	Self-ignition temperature = 374 ± 5°C	None
pH	CIPAC MT 75.3	3.7	None
Viscosity	ISO 2431:1993(E) and OECD 114	Dynamic viscosity at 20°C 25.9 mPa*s at 61.2 s^{-1} 25.9 mPa*s at 73.4 s^{-1} and 25.9 mPa*s at 110.0 s^{-1} Dynamic viscosity at 40°C 25.9 mPa*s at 61.2 s^{-1} 25.9 mPa*s at 73.4 s^{-1} and 25.9 mPa*s at 110.0 s^{-1} Kinematic Viscosity at 20°C 26.0 mPa*s at 61.2 s^{-1} 26.0 mPa*s at 73.4 s^{-1} and 26.0 mPa*s at 110.0 s^{-1}	None
Surface tension	EEC A.5	32.2 mN/m for 0.8% (v/v) solution of the test item in water at 20°C	None
Relative density	EEC A.3	0.997 g/mL	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

Compliance with FAO specifications:

The product ADM.09050.H.1.A, Trinexapac-ethyl 175 EC has not FAO specifications.

3.2 Efficacy (Part B, Section 3)

Introduction

This document summarises the information related to the efficacy of the plant protection product **ADM.09050.H.1.A** (commercial name STEMPER) containing 175 g/L of Trinexapac-ethyl.
Authorizations to control lodging in cereals in the European Central registration zone were already obtained under several commercial names such as OPTIMUS (PL). In 2018. those authorizations were transferred from Adama to NUFARM without changes.
ADAMA is now submitting this dossier to register the product with extended GAP as previously authorised.
Trinexapac-ethyl was included into Annex I of Regulation (EC) no 1107/2009 (Reg. (EU) 2020/421). The SANCO report for active substance (SANCO/10011/06 – 04/04/2006) is considered to provide the relevant review information or a reference to where such information can be founded.

The Annex I Inclusion Directive for active substance (Reg. (EU) 2020/421) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

This document is submitted in view to a first authorization of the product.

This document will be evaluated by Poland as Zonal Rapporteur Member State (zRMS).

In most of trials this product has the formulation code AG-T3-175 EC. AG-T3-175 EC and **ADM.09050.H.1.A** are the same formulation and have the same composition without affecting the efficacy or crop safety of the product. However as the code used in most trials is AG-T3-175 EC. as a matter of simplification this is the code used throughout this document

Description of active substances

AG-T3-175 EC is an emulsifiable concentrate (EC) containing 175 g/L of Trinexapac-ethyl for use as a plant growth regulator on winter wheat. spring wheat. wnter barley. spring barley. oat. triticale. spelt. rye and grass for seed.
Trinexapac-ethyl belonging to the cyclohexandione group is a dioxocyclohexane carboxylic acid derivative.
Trinexapac-ethyl is the precursor of the biologically active acid metabolite Trinexapac-acid.

Mode of action

Trinexapac-ethyl is predominately taken up by the leaves and shoots. while the uptake via roots is limited. It is transported acropetal in plants. largely to areas of rapid vegetative growth. Trinexapac-ethyl inhibits the gibberellin biosynthesis which leads to a reduced elongation of the basal or upper inter-nodes and thus a reduction of crop height. This together with increased stem diameter results in reduc-tion of lodging and maintains high quality of yield. Depending on the application timing. Trinexapac-ethyl applied in early growth stages (BBCH 20 – 30) increases the growth of crown roots and prevents root lodg-

ing while applications in later stages of development (BBCH 30 – 39) reduces the length of the lower part of the stem.

3.3 Efficacy data

ADM.09050.H.1.A is a plant growth regulator developed for use in cereals.

Winter wheat
Total of 12 efficacy trials in winter wheat were conducted in Poland (NE) are available to support the evaluation of AG-T3-175 EC against lodging on winter wheat.
Application of AG-T3-175 EC at dose rates: 0.4-0.6 l/ha was performed at 2 application terms:
BBCH 31-32 (A/B) and BBCH 31-39 (B/C)
Application of AG-T3-175 EC at dose rate: 0.2 l/ha was performed at BBCH 29. application code: A*
Application of AG-T3-175 EC at dose rate: 0.3 l/ha was performed at BBCH 31-32.application code: B*
Applications of AG-T3-175 EC at dose rate: 0.6 l/ha was performed at 2 application terms: BBCH 31-32: code A/B and BBCH 31-39 code BC
Applications of AG-T3-175 EC at split dose rates pattern: 0.3 l/ha+ 0.3 l/ha. first application at BBCH 31-32 second application at BBCH 31-39. application code: A/B/C

Oats
In 2016-2017 total of 3 efficacy trials were conducted in Poland (NE) to evaluate the growth regulatory activity of the formulation AG-T3-175 EC
AG-T3-175 EC was tested at several dose rates: 0.4-0.5-0.6 l/ha.
Lodging was observed on all 3 trials.

Spring barley
In total 5 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on spring barley. 2 trials were conducted in Poland (NE). 2016. other 3 trials were conducted in Czech Republic (MAR) in 2104-2017.
In 2 trials conducted in Poland. AG-T3-175 EC was tested at dose rates: 0.4 l/ha. 0.5 l/ha. 0.6 l/ha.
Application: BBCH 31-32
In 3 trials conducted in Czech Republic(MAR) AG-T3-175 EC was tested at dose rates: 0.25 l/ha. 0.3 l/ha. 0.4 l/ha. 0.5 l/ha. 0.6 l/ha. Application: BBCH 21-34.

In 3 trials conducted in Czech Republic(MAR) AG-T3-175 EC was tested at dose rates: 0.25 l/ha. 0.3 l/ha. 0.4 l/ha. 0.5 l/ha. 0.6 l/ha. Application: BBCH 21-34.

Winter barley
In total 6 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter barley.
2 trials were conducted in Poland (NE). 2016. 2 trials were conducted in Czech Republic (MAR) in 2017 and 2 trials were conducted in Germany (MAR) in 2017.
In 2 trials conducted in Poland. AG-T3-175 EC was tested at dose rates: 0.4 l/ha. 0.6 l/ha. 0.9 l/ha.
One application was performed at 2 terms:
treatments with dose rates: 0.4 l/ha and 0.6 l/ha – BBCH 31-32 (A)
treatment: 0.9 l/ha - BBCH 37-39 (B)
In total 4 trials were conducted in Maritime EPPO zone. 2 in Czech Republic and 2 in Germany.
AG-T3-175 EC was tested at dose rates: 0.4 l/ha .6 l/ha; 0.8 l/ha
Application: BBCH 31-34.

Winter rye
In total 6 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter rye. 3 trials were conducted in Poland (NE). 2016. 3 trials were conducted in Germany (MAR) in 2016-2017. In 3 trials conducted in Poland. AG-T3-175 EC was tested at dose rates: 0.3l/ha. 0.4l/ha. 0.6 l/ha.

Application: 31-32
In total 3 trials were conducted in Maritime EPPO zone (Germany). AG-T3-175 EC was tested at dose rates: 0.3 l/ha. 0.4 l/ha. 6 l/ha.
Application: BBCH 32-39.

Winter triticale
In total 5 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter triticale. 2 trials were conducted in Poland (NE) in 2016. 3 trials were conducted in Germany (MAR) in 2014-2016.
In 2 trials conducted in Poland. AG-T3-175 EC was tested at dose rates: 0.3l/ha. 0.4l/ha. 0.6 l/ha.
Application: 31-32
In total 3 trials were conducted in Maritime EPPO zone (Germany). AG-T3-175 EC was tested at dose rates: 0.25l/ha. 0.3 l/ha. 0.4 l/ha. 6 l/ha.
Application: BBCH 31-32.

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

AG-T3-175 EC is a plant growth regulator containing the active substance Trinexapac-ethyl.
Trinexapac-ethyl acts as an inhibitor of the action of a key enzyme in the formation of gibberellic acid (GA1), preventing the formation of the plant growth regulator gibberellins, which promotes cell elongation. In the absence of gibberellins the internodes of the plants fail to grow and prevent the plant from growing taller.
No case of resistance (or in this case, rather increased tolerance) was reported in the literature so far.

3.3.2 Adverse effects on treated crops

Oats
In total 3 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on oats.
In 2 of these trials, AG-T3-175 EC was tested at dose rates: from 0,4 l/ha, 0,5 l/ha, 0,6 l/ha and 1,2 l/ha.
In trial: PL17GEAVESA040A, AG-T3-175 EC was tested only in dose rates 0,6 l/ha and 1,2 l/ha.
Application of AG-T3-175 EC at dose rates: 0,4-0,6 l/ha was performed at BBCH 31-33.
AG-T3-175 EC did not induce phytotoxicity symptoms at any of assessment intervals.

Spring barley
In total 5 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on spring barley. 2 trials were conducted in Poland (NE) in 2016, other 3 trials were conducted in Czech Republic (MAR) in 2104-2017.
In 2 trials conducted in Poland, AG-T3-175 EC was tested at dose rates: 0,4 l/ha, 0,5 l/ha, 0,6 l/ha.
Application: BBCH 31-32
In 3 trials conducted in Czech Republic(MAR) AG-T3-175 EC was tested at dose rates: 0,25 l/ha, 0,3 l/ha, 0,4 l/ha, 0,5 l/ha, 0,6 l/ha. Application: BBCH 21-34.
In Poland there were observed some phytotoxicity symptoms on tested product and standard.
The phytotoxicity was transient and did not cause any effect at yield. AG-T3-175 EC may cause phytotoxicity on sensitive varieties of spring barley.
No phytotoxicity observed on trials in Czech Republic.

Winter barley
In total 6 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter barley.
2 trials were conducted in Poland (NE) in 2016, 2 trials were conducted in Czech Republic (MAR) in 2017 and 2 trials were conducted in Germany (MAR) in 2017.
In 2 trials conducted in Poland, AG-T3-175 EC was tested at dose rates: 0,4 l/ha, 0,6 l/ha, 0,9 l/ha.

One application was performed at 2 terms:
0,4 l/ha and 0,6 l/ha – BBCH 31-32 (A)
0,9 l/ha - BBCH 37-39 (B)
In total 4 trials were conducted in Maritime EPPO zone, 2 in Czech Republic and 2 in Germany.
AG-T3-175 EC was tested at dose rates: 0,4 l/ha, 6 l/ha; 0,8 l/ha
Application: BBCH 31-34 .
The phytotoxicity was transient and did not cause any effect at yield.
AG-T3-175 EC may cause phytotoxicity on sensitive varieties of winter barley in situation of high temperature amplitudes between days and nights.
No phytotoxicity observed on trials in Czech Republic and Germany

Winter rye
In total 6 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter rye. 3 trials were conducted in Poland (NE) in 2016, 3 trials were conducted in Germany (MAR) in 2016-2017.
In 3 trials conducted in Poland, AG-T3-175 EC was tested at dose rates: 0,3l/ha, 0,4l/ha, 0,6 l/ha.
Application: BBCH 31-32
In total 3 trials were conducted in Maritime EPPO zone (Germany). AG-T3-175 EC was tested at dose rates: 0,3 l/ha, 0,4 l/ha, 6 l/ha.
Application: BBCH 32-39
No phytotoxic effect observed on any of the trial at assessment intervals.

Winter triticale
In total 5 efficacy trials are available for efficacy evaluation of AG-T3-175 EC against lodging on winter triticale. 2 trials were conducted in Poland (NE) in 2016, 3 trials were conducted in Germany (MAR) in 2014-2016. In 2 trials conducted in Poland, AG-T3-175 EC was tested at dose rates: 0,3l/ha, 0,4l/ha, 0,6 l/ha.
Application: BBCH 31-32
In total 3 trials were conducted in Maritime EPPO zone (Germany). AG-T3-175 EC was tested at dose rates: 0,25l/ha, 0,3 l/ha, 0,4 l/ha, 6 l/ha.
Application: BBCH 31-32
No phytotoxic effect observed on any of the trial at assessment intervals.

Winter wheat
Application of AG-T3-175 EC at dose rates: 0,4-0,6 l/ha was performed at 2 application terms:
BBCH 31-32 (A/B) and BBCH 31-39 (B/C)
Application of AG-T3-175 EC at dose rate: 0,21 l/ha was performed at BBCH 29, application code: A*
Application of AG-T3-175 EC at dose rate: 0,3 l/ha was performed at BBCH 31-32,application code: B*
Applications of AG-T3-175 EC at dose rate: 0,6l/ha was performed at 2 application terms: BBCH 31-32: code A/B and BBCH 31-39 code BC
Applications of AG-T3-175 EC at split dose rates pattern: 0,3 l/ha+ 0,3 l/ha, first application at BBCH 31-32 second application at BBCH 31-39, application code:A/B/C
Evaluation is focussing on the plant growth regulator effect sprayed at:
AG-T3-175 EC – 0,2 l/ha application term: 29 BBCH – 4 trials
AG-T3-175 EC – 0,3 l/ha application term: 31 BBCH – 6 trials
AG-T3-175 EC – 0,4 l/ha application term: 31-32 BBCH (A/B) – 11 trials
AG-T3-175 EC – 0,4 l/ha application term: 31-39 BBCH (B/C) – 9 trials
AG-T3-175 EC – 0,6 l/ha application term: 31-32 BBCH (A/B) – 12 trials
AG-T3-175 EC – 0,6 l/ha application term: 31-39 BBCH (B/C) – 9 trials
AG-T3-175 EC – 0,6 l/ha application term: 31-32 BBCH (A/B) – 12 trials
AG-T3-175 EC – 0,3 l/ha+ 0,3 l/ha (split dose pattern) application term: first application at BBCH 31-32 second application at BBCH 31-39- 9 trials.

The phytotoxicity was transient and did not cause any effect at yield. AG-T3-175 EC may cause phytotoxicity on sensitive varieties of winter wheat.

3.3.3 Observations on other undesirable or unintended side-effects

Products containing Trinexapac-ethyl (for example MODDUS products) have been registered for several years in several European countries (almost 30 years in France) and no phytotoxicity issues with were observed on succeeding crops within a classical rotation.
Nevertheless, an evaluation risk in case of crop failure was carried out in France in 2009 through one trial on garden peas and maize. Moreover, an evaluation was also conducted on winter rape within a classical rotation.

In case of crop failure on cereal crops treated with ADM.09050.H.1.A up to 1.2 L/ha (210 g ai/ha of Trinexapac-ethyl), the substitution by peas or maize can be safely sown with shallow cultivation or ploughing.
In the case of a carry over of a cereal crop treated with ADM.09050.H.1.A up to 1.2 L/ha (210 g ai/ha of Trinexapac-ethyl), winter oilseed rape can be sown safely with a superficial preparation or ploughing.
Therefore, no impact of ADM.09050.H.1.A applied up to 1.2 L/ha (210 g ai/ha of Trinexapac-ethyl) is expected on succeeding crops if applied according to the GAP recommendations.

No drift effect damageable to adjacent crops have been recorded so far in the numerous countries which have been using products containing Trinexapac-ethyl. However, two GEP trials were carried out in France in 2009 on the main crops likely to be concerned: peas, maize, sugarbeet, flax, pota-to, winter rape in the first trial, and fodder peas, maize, sunflower and winter rape in the second trial.

Regarding the results obtained in both trials, it can be concluded that ADM.09050.H.1.A is totally selective to peas, sugar beet, potatoes, maize, flax, winter rape and sunflower.
Therefore, no impact of ADM.09050.H.1.A applied up to 0.8 L/ha (140 g ai/ha of Trinexapac-ethyl) is expected on adjacent crops if applied according to the GAP recommendations.
Nevertheless, ADM.09050.H.1.A is intended to be applied up to 1.2 L/ha (210 g ai/ha of Trinexapac-ethyl) on some crops. Considering that no adverse effect was observed on the target crops when applied up to 1.2 L/ha (see paragraph KCP 6.4.1), it is deduced that ADM.09050.H.1.A will not have any impact on adjacent crops when applied up to 1.2 L/ha (210 g ai/ha of Trinexapac-ethyl).

Methods of analysis (Part B, Section 5)

3.3.4 Analytical method for the formulation

The analysis of trinexapac-ethyl in the plant protection product trinexapac-ethyl 175 EC (ADM.09050.H.1.A, formerly AG-T3-175 EC1) was done by high performance liquid chromatograph (HPLC) with UV detection using external standard technique.

3.3.5 Analytical methods for residues

zRMS:
Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
The applicant, as the TaskForce member has an access to the adequate analytical methods.
The residue definition for monitoring in plant and animal matrices was defined as sum of trinexapac and its salts, expressed as trinexapac. The quick, easy, cheap, effective, rugged and safe (QuEChERS) multi-residue enforcement method and also single residue methods with liquid chromatography with tandem mass spectrometry (LC–MS/MS) can be used for the determination of residues of trinexapac in food and feed of plant and animal origin with a limit of quantification (LOQ) of 0.01 mg/kg in each commodity

group and in each animal matrix (EFSA Journal 2018;16(4):5229).
Moreover in the context of the authorization request the applicant submitted several acceptable analytical methods for the determination of residues in support of ecotoxicological studies (see B5 Appendix 2).

Validated methods for the generation of post-authorisation data

Studies indicated as new data are currently under EU evaluation (reviewed by Lithuania, 2018 and EFSA, 2018).

Component of residue definition: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac)				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing / EU agreed**
High water content - *Lettuce*	Primary	0.01 mg/kg	HPLC-MS/MS (data generation or monitoring)	Campbell, A.J and Crook, S.J. 2004 Syngenta Report no. REM 137.13 Nichols, C. Kwiatkowski, A., 2004 Syngenta Report no. 03-3001 ILV: Benazeraf, L. 2004a Syngenta Report no. SYN/TRIN/04091 *EU agreed (DAR Addendum, 2005 and EFSA Scientific Report (2005)*
	ILV	0.01 mg/kg		
High oil content - *Sunflower seed*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
High protein/ high starch content (dry) - *Barley grain*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
Difficult (if required, depends on intended use) - *Barley hay and straw*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
	Confirmatory (if required)	--	Not required, highly specific detection system was used (HPLC- MS/MS)	
High protein/ high starch content (dry) - *Barley grain*	Primary	0.01 mg/kg	HPLC-MS/MS	GRM020.05A Hargreaves, 2008 **New data** *EU agreed (RAR 2017 Volume 3 – B.5 (AS))*
High water content - *Lettuce*				
High oil content - *Sunflower seed*				
	Confirmatory (if required)	--	Not required, highly specific detection system was used (HPLC- MS/MS)	
Dry matrix - *Barley hay and straw*	Data generation or monitoring	0.01 mg/kg	HPLC-MS/MS	Supercedes REM 137.13 Validation: Mayer L, 2008, (amended 2016) **New data** *EU agreed (RAR 2017 Volume 3 – B.5 (AS))*
	Confirmatory (if required)	--	Not required, highly specific detection system was used (HPLC- MS/MS)	
High oil content	Primary	0.01 mg/kg	QuEChERS	Richter, 2015a

Component of residue definition: Trinexapac (sum of trinexapac (acid) and its salts, expressed as trinexapac)				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing / EU agreed**
- - *Sunflower seed*	ILV	0.01 mg/kg	(LC-MS/MS) (monitoring)	Report: P 3685 G and amendment to report (Syngenta File No. CGA179500_10993) Brown, 2015a (ILV) Report RES-00008; TK0255738 (Syngenta File No. CGA179500_11005) **New data** *EU agreed (RAR 2017 Volume 3 – B.5 (AS))*
High oil content - *Sunflower seed*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
High protein/high starch content (dry) - *Wheat, grain* - *Broad bean, dried*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
High acid content - *Orange*	Primary	0.01 mg/kg		
	ILV	0.01 mg/kg		
	Confirmatory (if required)	--	Not required, highly specific detection system was used (HPLC- MS/MS)	
Difficult to analyse None	Primary	-	-	-
	ILV	-		

'Two analytical methods (REM 137.13 and REM 137.14) have been previously assessed in the framework of Directive 91/414/EEC. In order to cover all types of matrices, further validation of REM 137.13 has been conducted; the method has been renamed GRM020.05A.'

3.4 Mammalian toxicology (Part B, Section 6)

For the toxicological evaluation of ADM.09050.H.1.A, bridging to data produced with product trinexapac-ethyl 175 EC (AG-T3-175 EC) has been performed. A detailed comparison of both formulation compositions is presented in the confidential Part C of this dossier. It is concluded that the acute endpoints gained for trinexapac-ethyl 175 EC (AG-T3-175 EC) are also valid for the product ADM.09050.H.1.A.

3.4.1 Acute toxicity

Following studies with trinexapac-ethyl 175 EC (AG-T3-175 EC) were performed: Acute oral, acute dermal, skin irritation, eye irritation and skin sensitisation maximisation test. All studies were considered acceptable. An acute inhalation study was not considered necessary.

Trinexapac-ethyl 175 EC (AG-T3-175 EC) was not acutely toxic with respect to oral and dermal application. Trinexapac-ethyl 175 EC (AG-T3-175 EC) was irritant to both skin and eye and showed a skin sensitising potential. These acute endpoints gained for trinexapac-ethyl 175 EC (AG-T3-175 EC) are also valid for the product ADM.09050.H.1.A. Consequently, the product ADM.09050.H.1.A. needs to be classified with skin irritation Category 2 (H315), eye irritation Category 2 (H319) and skin sensitization Category 1 (H317) according to Regulation (EC) No.1272/2008.

zRMS:
Based on data presented in part B 6 of this report product ADM.09050.H.1.A require classification as

Skin Irrit. 2: H315; Eye Irrit. 2: H319; Skin Sens. 1: H317 and STOT RE 2, H373 (GI tract)

3.4.1 Operator exposure

The operator exposure estimations were based on the EU agreed AOEL of trinexapac-ethyl of 0.34 mg/kg bw/day. An AAOEL was not considered necessary and was not derived. Dermal absorption rates of trinexapac-ethyl of 3.1% for the concentrate and 66% for the dilutions were based on the results of a dermal absorption study *in vitro* on human skin with ADM.09050.H.1.A (AG-T3-175 EC1).

The potential total systemic exposures of an operator, who is dressed in work wear that covers body, arms and legs and not considering the use of protective gloves corresponds to about 10% of the AOEL.

Estimated operator exposure

			Trinexapac-ethyl	
Model data		**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.210 kg a.s./ha				
EFSA Operator Model (75th quantile regression) Body weight: 60 kg		Potential exposure (no clothing)	0.0526	15.5%
		+ Work Wear (arms, body, legs covered)	0.0337	9.9%

It is concluded that the use of ADM.09050.H.1.A is at an acceptable risk for the operator.

zRMS:
The potential exposure to Trinexapac-ethyl of operator not wearing a work clothing (long sleeved shirt, long trousers) and applying formulation ADM.09050.H.1.A (STEMPER) on cereals at maximal dose of 1.2 L product/ha (0.210 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 15.5% of AOEL. In case the operator is using a work clothing (long sleeved shirt, long trousers) during mixing/loading and application the exposure to Trinexapac-ethyl is reduced to 9.9% of AOEL.

Since the potential systemic exposures and systemic exposure of operator wearing a work clothing (long sleeved shirt, long trousers) during mixing/loading and application to active substance expressed as percentage of its AOEL is well below 100%, the application of product STEMPER (ADM.09050.H.1.A) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of operator

Since the product STEMPER (ADM.09050.H.1.A) is classified as Skin Irrit. 2, Eye Irrit. 2 and Skin Sens. 1 the operator should wear protective clothing covering body, legs and arms, sturdy shoes, protective gloves and eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

3.4.2 Worker exposure

The estimated exposure of a worker dressed in work wear (arms, body and legs covered, no gloves) was estimated to account for about 6% of the AOEL.

Estimated worker exposure

		Trinexapac-ethyl	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate:		1 x 0.210 kg a.s./ha	
EFSA Worker Model **Body weight: 60 kg,** **DFR: 3 µg/cm²/kg a.s./ha** 2 hours/day Body weight: 60 kg	Potential(1) TC:12500 cm^2/person/h	0.1733	51%
	Work cloth (2) TC: 1 400 cm^2/person/h	0.0194	5.7%

(1) Potential exposure: no clothing considered
(2) Work cloth: Worker wearing long sleeved shirt, long trousers ("permea ble") but no gloves

Therefore, it is concluded that there is no unacceptable risk, when a worker re-enters crops treated with ADM.09050.H.1.A.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

zRMS:
The potential exposure to Trinexapac-ethyl of worker not wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours inspection a field of cereals treated with formulation ADM.09050.H.1.A (STEMPER) at maximal dose of 1.2 L product/ha (0.210 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 51% of AOEL. In case the worker is wearing a work clothing (long sleeved shirt, long trousers) the exposure to Trinexapac-ethyl is reduced to 5.7% of AOEL.

Since the potential systemic exposures and systemic exposure of worker wearing a work clothing (long sleeved shirt, long trousers) during 2 hrs inspection to active substance expressed as percentage of its AOEL is well below 100%, the application of product STEMPER (ADM.09050.H.1.A) according to its intended use within good agricultural practice does not pose an unacceptable risk to the health of worker . The treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.4.3 Bystander and resident exposure

According to the EFSA-OPEX guidance, a bystander risk assessment is required for plant protection products that have significant acute toxicity or the potential to exert toxic effects after a single exposure, based on the 95th percentile data values.

For trinexapac-ethyl no AAOEL and no ARfD have been established. Therefore, a risk assessment for bystanders was not performed. The chronic risk for bystanders, however, is covered by the chronic risk assessment for residents.

The estimated resident exposure accounts for about 9% and 4% of the established AOEL for the child and adult scenario, respectively.

Estimated resident exposure

	Trinexpac-ethyl	
Route of exposure	**75th centile** (mg/kg bw/day)	**in % of AOEL (RVNAS)**
Tractor mounted boom spray application outdoors to low crops (cereals) Application rate: 0.21 kg trinexapac-ethyl/ha water volume 200 L/ha Drift rate: 5.60/4.10 % Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days; DFR: 3 µg/cm²/kg a.s./ha		
Resident child (body weight 10 kg)		
Spray drift	0.0186	5.47%
Vapour	0.0011	0.31%
Surface deposits	0.0022	0.64%
Entry into treated crops (= exposure to soil borne residues)	0.0234	6.88%
Sum of all pathways: Mean	0.0316	9.28%
Resident adult (body weight 60 kg)		
Spray drift[1]	0.0045	1.31%
Vapour	0.0002	0.07%
Surface deposits	0.0009	0.28%
Entry into treated crops (= exposure to soil borne residues)	0.0130	3.82%
Sum of all pathways: Mean	0.0134	3.94%

It is concluded that resident exposure to ADM.09050.H.1.A is acceptable in cereals.

zRMS:
The exposure estimation of resident (adult and child) to Trinexapac-ethyl, an active substance of a product STEMPER (formulation ADM.09050.H.1.A) applied on a field of cereals at maximal dose of 1.2 L product/ha (0.210 kg a.s./ha) as foreseen in GAP, using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM demonstrates that such a exposure for adult resident is 3.94 % of AOEL and for child resident 9.28 %% of AOEL, therefore the risk would be acceptable, and no risk refinement is needed using relevant risk management measures such as increased buffer zone or drift reduction technology.

No bystander acute exposure estimation for Trinexapac-ethyl is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Trinexapac-ethyl as a result of application of a product STEMPER (formulation ADM.09050.H.1.A) with accordance with intended use within good agricultural practice.

Summing up application of a product STEMPER (formulation ADM.09050.H.1.A) in line with GAP on low crops at maximal dose of 1.2 L product/ha, using tractor-mounted/trailed boom sprayer does not pose an unacceptable health risk for residents and bystanders.

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

zRMS:
The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 3.0 mg/kg for trinexapac-ethyl in barley, wheat (including triticale and spelt) and oat and of 0.5 mg/kg in rye as laid down in Regulation (EU) 2017/1016 is not expected. The chronic intake of trinexapac-ethyl residues are unlikely to present a public health concern. As far as consumer health protection is concerned, the zRMS agrees with the authorization of the intended uses.

This dossier is presented to support the product ADM.09050.H.1.A for the use in cereals (winter barley, oats, winter wheat, rye, triticale and spelt) and in grass for seed production . The supported uses are all within the critical GAP evaluation on EU-level (refer to EFSA Journal 2012;10(1):2511, EFSA Journal 2018;16(4):5229.

The summary for the trinexapac-ethyl is given hereafter:

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
14	Barley	Yes	Yes (18 trials including scaled wheat data)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
19	Wheat	Yes	Yes (11 trials)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
6	Spelt	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
18	Triticale	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
24	Oats	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
17	Rye	Yes	Yes (extrapolation from wheat)	N/A (determined by growth stage at last application)	Yes	Yes	No	No
3	Grass (seed production)	Yes	Not required as not intended as a	N/A (determined by	N/A	N/A	N/A	N/A

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
			food/feed item and therefore not relevant for human consumption	growth stage at last application)				

3.5.1 Residues

Barley
Barley is a major crop in Central/Northern Europe and 8 trials are required. Five valid trials have been evaluated by Lithuania (RAR, 2018) and EFSA (2018) that correspond to the intended GAP for ADM.09050.H.1.A in Central Europe. Two further trials (study TK0178789) that had been excluded from evaluation due to lack of storage stability data have now been included as storage stability in grain over a period of 26 months has been shown in a newly submitted study.
As the last application according to the intended GAP for ADM.09050.H.1.A is done before edible parts are formed (i.e. before BBCH 51), data on wheat can be extrapolated to barley (SANTE/2019/12752). Furthermore, the proportionality concept can be applied for plant growth regulators such as trinexapac-ethyl to between x0.3 and x4 of the GAP dose rate where quantifiable residues occur[1].
Residue data for wheat grain and straw were scaled up to the maximum GAP rate for barley and extrapolated to barley (see **Błąd! Nie można odnaleźć źródła odwołania.**). When including the scaled wheat data, there is a total of 18 trials data available for barley grain and 11 trials data for barley straw that comply with the residue definition for enforcement.
It is concluded that sufficient data are available to support the intended uses on barley. The data show that no exceedance of the current MRL will occur.

Wheat, spelt, triticale
Wheat is a major crop in Central/Northern Europe and 8 trials are required. Eleven valid trials have been evaluated by Lithuania (RAR, 2018) and EFSA (2018) that correspond to the intended GAP for ADM.09050.H.1.A in Central Europe.
It is concluded that sufficient data are available to support the intended uses on wheat, spelt and triticale. The data show that no exceedance of the current MRL will occur.

Oat, rye
According to SANTE/2019/12752 for applications before BBCH 51 (i.e. before edible parts are formed), data for wheat can be extrapolated to oat and rye as the GAPs for these crops are comparable to or less critical than the GAP for wheat. In line with the EFSA (2018) assessment, where data from N-EU/C-EU and S-EU regions were combined for rye, combined N-EU/S-EU data were used here for extrapolation to both, oat and rye.
Sufficient data are therefore available to extrapolate the existing data to oat and rye. The data show that no exceedance of the current MRLs for oat and rye will occur.

Grass (seed production)
Grass for seed production will not be consumed by humans or livestock. Residue trials for MRL setting or

[1] EFSA (European Food Safety Authority), 2018. Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues. EFSA supporting publication 2017:EN-1503. 18 pp. doi:10.2903/sp.efsa.2017.EN-1503

for consumer risk assessment are therefore not needed.

3.5.2 Consumer exposure

Dietary risk assessment for the active substance trinexapac-ethyl was carried out using EFSA PRIMo revision 3.1. The results are presented in Point B7.2.8. Calculations were done using MRLs and performed taking into account all categories of crops for the chronic risk assessment and only the intended used for acute risk assessment.

The TMDI calculation gave a maximum exhaustion of the ADI of ~~8~~ 3%, based on the GEMS/Food G06 diet. The estimated chronic consumer intake levels is therefore well below the EU agreed ADI of 0.32 mg/kg bw per day for trinexapac-ethyl. It can therefore be concluded that acceptable margins of safety exist for consumers.

~~The results of the IESTI calculation demonstrates that in no case the IESTI is above the acute reference dose (ARfD) of 0.34 mg/kg bw including a safety factor of 100. Thus, the acute risk to the consumer based on the short-term intake of residues of the active substance trinexapac-ethyl is considered to be acceptable.~~

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

No new experimental studies were submitted to the List of Endpoints of trinexapac-ethyl. The appropriate endpoints were used to calculate PECs for the active substance and its relevant metabolites in soil, groundwater and surface water/sediment. ~~for the single applications on winter barley (80% interception) and grass for seed (60% interception). The respective worst-case application rate for the active substance is 140 g a.s./ha for both uses.~~

3.6.1 Predicted environmental concentrations in soil (PEC_{SOIL})

Predicted environmental concentrations in soil (PEC_{SOIL}) values were calculated in the core assessment covering all uses in the Central European Union for trinexapac-ethyl and its relevant soil metabolites, taking into account the molar weight factor and their maximum observed occurrence in soil.

PEC_{SOIL} values were calculated for trinexapac-ethyl and its metabolites CGA179500, CGA300405 and CGA275537. The formulation PEC_{SOIL} of ADM.09050.H.1.A was calculated with application rates of 1 × 598.2 (spring cereals), 1 x 1196.4 g/ha (winter cereals) and 1 × 797.6 g/ha (grass), assuming a density of 0.997 g/mL.

All calculations were carried out using a dry soil bulk density of 1.5 g/cm^3 and a 5 cm soil depth, in accordance with SANCO/10058/2005 v.2.0, 2006.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{GW})

Predicted concentration in groundwater for trinexapac-ethyl and its relevant metabolites were calculated using FOCUS PEARL 4.4.4 with the respective FOCUS groundwater scenarios for winter cereals, spring cereals and grass. According FOCUS DG SANTE for active substances and their relevant metabolites PEC_{GW} calculations after 1 January 2022 should be performed with new versions of models: FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. Nevertheless, as PECgw values for the active substance and its metabolites are extremely low (<0.001 µg/L in all scenarios of three models), thus the calculation performed with FOCUS MACRO 5.5.4, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 were accepted (KCP 9.2.4-01, Hicks 2020, TXP-EFA-01CEU).

Input data and results of the calculations in the core assessment are fully applicable for the Poland ~~PO-land~~.

In accordance with the active substance renewal assessment, EFSA Journal 2018;16(3):5229, the soil metabolites of trinexapac-ethyl are formed by different processes, therefore different PEC_{gw} calculations are required. Metabolite CGA179500 is formed by microbial degradation in aerobic soil. Metabolites CGA179500, CGA300405 and CGA275537 are formed by photolytic degradation in the soil.

The PEC_{GW} for trinexapac-ethyl and all metabolites (formed by both microbial degradation and photolytic degradation) were < 0.1 µg/L for all scenarios. The threshold of 0.01 µg/L for groundwater protection areas is not exceeded in the relevant scenarios, therefore no restriction regarding groundwater protection areas is indicated.

3.6.3 Predicted environmental concentrations in surface water (PEC_{SW})

Predicted environmental concentrations in surface water were calculated for trinexapac-ethyl and its aquatic metabolites CGA179500 and CGA300405 according to the standard scenario for spring applications.

Additional data were evaluated concerning monitoring in groundwater, monitoring in surface water and the drinking water criterion ~~critierion~~. No concern was indicated by these evaluations.

3.6.4 Predicted environmental concentrations in air (PEC_{AIR})

No further data or calculation are done or required.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The risk assessment for birds and mammals was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

Birds

Effects on birds of ADM.09050.H.1.A were not evaluated as part of the EU assessment of trinexapac-ethyl. However, the provision of further data on the formulation is not considered to be required, because an increased toxicity of the product is not expected compared to the active substance.

An assessment of combined toxicity is not required as there is only one active substance in the formulated product ADM.09050.H.1.A.

An acceptable acute risk is presented with all TERs for dietary exposure of birds towards the active substance exceeding the trigger based on Tier 1 evaluations. Likewise, an acceptable reproductive risk is presented for dietary exposure for all relevant scenarios.

Detailed drinking water assessments are not triggered. Assessments of the potential risks to earthworm-eating birds and fish-eating birds from indirect exposure due to secondary poisoning are not triggered as the log Pow of trinexapac-ethyl amounts to -0.29 at pH 6.9 and thus does not exceed the trigger value of 3.

Terrestrial vertebrates (other than birds)

Effects on mammals of ADM.09050.H.1.A were not evaluated as part of the EU assessment of trinexapac-ethyl. However, the provision of further data on the formulation is not considered to be required, because an increased toxicity of the product is not expected compared to the active substance.

An assessment of combined toxicity is not required as there is only one active substance in the formulated product ADM.09050.H.1.A.

An acceptable acute risk is presented with all TERs for dietary exposure of terrestrial vertebrates other than birds towards the active substance exceeding the trigger based on Screening Step evaluations. Likewise, an acceptable reproductive risk is presented for dietary exposure based on Screening Step evaluations.

Detailed drinking water assessments are not triggered. Assessments of the potential risks to earthworm-eating mammals and fish-eating mammals from indirect exposure due to secondary poisoning are not triggered as the log Pow of trinexapac-ethyl amounts to -0.29 at pH 6.9 and thus does not exceed the trigger value of 3.

3.7.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290). Predicted environmental concentrations in surface water were calculated according to the ~~the~~ standard scenario for spring applications.

Studies were carried out on fish, daphnids, algae and aquatic plants using the formulated product AG-T3-175 EC. This formulation is considered to be comparable to ADM.09050.H.1.A. A comparison of the compositions of the two formulations is provided in Part C of this dossier. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

Acceptable acute and chronic risks for aquatic organisms following exposure to formulation, trinexapac-ethyl and its metabolites from the use of ADM.09050.H.1.A on ~~winter~~ cereals and grass for seed are indicated for all scenarios at Step 1 ~~2~~. No mitigation measures are required.

3.7.3 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).

Acute oral, acute contact, chronic and larval toxicity tests were carried out on honey bees with the formulated products AG-T3-175 EC and Trinexapac-ethyl 175 EC. These formulations are considered to be comparable to ADM.09050.H.1.A. A comparison of the compositions of the three formulations is provided in Part C of this dossier. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The acute risk assessments for the active substance as well as for formulated product with Hazard Quotients well below the trigger for acceptability of effects indicate an acceptable risk for bees exposed in accordance with the intended uses of ADM.09050.H.1.A.

~~It is noted that no chronic effects on adults or juvenile stages of bees are expected for the following rea-~~

~~sons:~~

~~The exposure to honeybees can be caused by the application of plant protection products through direct overspray, by contact with residues on plants or by oral intake of treated food items (nectar or pollen) whilst bees are foraging on food. These sources are highly unlikely in case of the application ADM.09050.H.1.A because cereals and grass are generally considered as of low to moderate attractivity to bees. In addition, the application timing (BBCH until 37) is distinctly before flowering which is at principal growth stage 6 (BBCH Monograph, 2001). Thus, intense foraging on the crop for pollen and nectar can be excluded.~~

~~Furthermore, the results of the chronic feeding studies to adult bees and bee larvae from ADM.09050.H.1.A do not give rise to a specific concern.~~

~~In conclusion, it is reasonable to conclude that the acute and chronic risk for bees can be considered as acceptable, both from the toxicity and the exposure point of view.~~

3.7.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was principally 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.

Glass plate (2D) toxicity tests were carried on *Typhlodromus pyri, Aphidius rhopalosiphi* and *Coccinella septempunctata.* Extended laboratory tests ~~(3D)~~ were carried out on *Typhlodromus pyri, Aphidius rhopalosiphi, Aleochara bilineata, Chrysoperla carnea* and *Coccinella septempunctata.* All tests were undertaken with the formulated product AG-T3-175 EC. This formulation is considered to be comparable to ADM.09050.H.1.A. A comparison of the compositions of the two formulations is provided in Part C of this dossier. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

The in-field risk is indicated to be acceptable based on the available data without the necessity to account for risk mitigation measures. For the in-field risk assessment reference is made to the core assessment.

An acceptable off-field risk is indicated for the standard test species *Typhlodromus pyri* and *Aphidius rhopalosiphi* at Tier 1, using results of the 2D tests.

3.7.5 Effects on soil organisms

The risk assessment was conducted according to the Guidance Document on Terrestrial Ecotoxicology (2002).

Meso- and macrofauna

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of ADM.09050.H.1.A were not evaluated as part of the EU assessment of the active substances trinexapac-ethyl. New tests carried out on *Eisenia andrei, Folsomia candida* and *Hypoaspis aculeifer* were undertaken with the formulated product AG-T3-175 EC. This formulation is considered to be comparable to ADM.09050.H.1.A. A comparison of the compositions of the two formulations is provided in Part C of this dossier. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

Acceptable risks are indicated for soil meso- fauna based on TERs for the active substances, relevant soil

degradation products and the formulated product ADM.09050.H.1.A exceeding the trigger values.

Microbial activity

Effects on soil microbial activity of ADM.09050.H.1.A were not evaluated as part of the EU assessment of the active substances trinexapac-ethyl. A new test was carried out with the formulated product AG-T3-175 EC. This formulation is considered to be comparable to ADM.09050.H.1.A. A comparison of the compositions of the two formulations is provided in Part C of this dossier. Data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

An acceptable risk for soil microbial functions is indicated by predicted environmental concentrations lower than the No Observed Adverse Effect Concentrations (i.e. concentrations causing less than 25% effect on nitrogen transformation after 28 days).

3.7.6 Effects on non-target terrestrial plants

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

Effects on non-target terrestrial plants of ADM.09050.H.1.A were not evaluated as part of the EU assessment of the active substances trinexapac-ethyl. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2 of Part B, Section 9 (Ecotoxicology).

An acceptable off-field risk is indicated for terrestrial non-target plants based on the data for vegetative vigour as well as seedling emergence and growth without the necessity to account for risk mitigation measures.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites CGA179500, CGA300405 and CGA275537 are predicted to occur in groundwater at concentrations **below** 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore **not** required.

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

ADM.09050.H.1.A contains trinexapac which is not identified as Candidates for Substitution (CfS); thus a Comparative Assessment is not required.

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

None.

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

MS assessor to present a copy of the approved product label for MS country.

Appendix 3 Letter of Access

Business Confidential.

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 2.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days (including Amendment No 1) AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd.
KCP 2.2.1/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished	N	Y		ADAMA Agan Ltd.
KCP 2.2.2/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished **Please refer to KCP 2.2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.3.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4,	N	Y		ADAMA Agan Ltd.

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*
			June 2016 GLP, unpublished **Please refer to KCP 2.1/01**				
KCP 2.3.3/01	Atwal, S.S. Tremain, S.P.	2008	Determination of Harzadous Physico-Chemical Properties Celsius Property B.V. Safepharm Laboratories Limited, Shardlow, UK SPL Project no. 2584/0003 October 2008 GLP, unpublished **Please refer to KCP 2.2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.4.1/02	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.5.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.5.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.6.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-	N	Y		ADAMA Agan Ltd.

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*
			02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**				
KCP 2.7.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.7.4/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.7.5/01	Edelson, T.	2018	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) Stored at Ambient Temperature for Two Years AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/5, June 2018 GLP, unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd.
KCP 2.8.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 2.8.6.2/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC (Trinexapac-ethyl 175 EC) Stored at 54ºC for 14 Days and at 0ºC for 7 Days	N	Y		ADAMA Agan Ltd.

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*
			AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/4, June 2016 GLP, unpublished **Please refer to KCP 2.1/01**				
KCP 2.8.6.2/02	Edelson, T.	2018	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) Stored at Ambient Temperature for Two Years AGAN Chemical Manufacturers, Ltd., Israel, Study no. F16-02/5, June 2018 GLP, unpublished **Please refer to KCP 2.7.5/01**	N	Y		ADAMA Agan Ltd.
KCP 4.3/01	Anonymous	2020	Safety Data Sheet – ADM.09050.H.1.A ADAMA Agan Ltd., Ashdod., Israel Report no.: Version 4.01 No GLP Unpublished	N	N		ADAMA Agan Ltd.
KCP 4.4/01	Anonymous	2019	COEX_EVOH (Reyde) - 5 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	N		Reyde
KCP 4.4/02	Anonymous	2019	COEX_PA (Reyde) - 5 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	N		Reyde
KCP 4.4/03	Anonymous	2017	COEX-PA (Pachmas) - 5 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished	N	N		Pachmas
KCP 4.4/04	Anonymous	2017	HDPE (Pachmas) - 5 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel	N	N		Pachmas

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*
			No GLP Unpublished				
KCP 4.4/05	Anonymous	2018	COEX-PA (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	N		Mobilak
KCP 4.4/06	Anonymous	2018	Specification 9813205419E (Mobilak) – 5 L Packaging Information Report no. 9813205419 The Standards Institution of Israel No GLP Unpublished	N	N		Mobilak
KCP 4.4/07	Anonymous	2018	COEX - UN-_2018580 (Mobilak) – 5 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	N		Mobilak
KCP 4.4/08	Anonymous	2019	HDPE and COEX – final drawing (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	N		Reyde
KCP 4.4/09	Anonymous	2019	COEX_EVOH (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	N		Reyde
KCP 4.4/10	Anonymous	2019	COEX_PA (Reyde) - 10 L Packaging information Report no. -- Reyde, S.A., Barcelona, Spain No GLP Unpublished	N	N		Reyde
KCP 4.4/11	Anonymous	2020	COEX-PA (Pachmas) - 10 L Packaging Information Report no. -- State of Israel, Ministry of Transport The Standards Institution of Israel	N	N		Pachmas

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*
			No GLP Unpublished				
KCP 4.4/12	Anonymous	2020	COEX-PA – pmi 2020003 (Pachmas) - 10 L Packaging Information Report no. 7013201083 State of Israel, Ministry of Transport The Standards Institution of Israel No GLP Unpublished	N	N		Pachmas
KCP 4.4/13	Anonymous	2020	COEX-PA and COEX-EVOH (Mobilak) – 10 L Packaging Information Report no. -- The Standards Institution of Israel No GLP Unpublished	N	N		Mobilak
KCP 5.1.1/01	Edelson, T.	2016	Determination of Storage Stability and Phys-Chem Properties in AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) Stored at 54°C for 14 Days and at 0°C for 7 Days ADAMA Agan Ltd., Israel, report no. F16-02/4 and sponsor report no. 90019616 GLP Unpublished **Also filed under KCP 2.1/01**	N	Y		ADAMA Agan Ltd.
KCP 5.1.2/01	xxxxxxxxx	2008	AG-T3-175 EC: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-Hour Static Test xxxxxxxxxxxxx GLP Unpublished **Also filed under KCP 10.2.1/01**	Y	N		ADAMA Agan Ltd.
KCP 5.1.2/02	Höger, S.	2008	AG-T3-175 EC: Acute Toxicity to *Daphnia magna* in a 48-Hour Immobilization Test RCC Ltd., Switzerland, report no. B93082 Celsius Property B.V., report no 90018031_000081126 GLP Unpublished **Also filed under KCP 10.2.1/02**	N	N		ADAMA Agan Ltd.
KCP 5.1.2/03	Bätscher, R.	2008	AG-T3-175 EC: Toxicity to *Anabaena flos-aquae* in a 72-Hour Algal Growth Inhibition Test	N	N		ADAMA Agan Ltd.

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*
			RCC Ltd., Switzerland, report no. B93093 Celsius Property B.V., report no 90018032_000081127 GLP Unpublished **Also filed under KCP 10.2.1/03**				
KCP 5.1.2/04	Höger, S.	2009	AG-T3-175 EC: Toxicity of AG-T3-175 EC to the Aquatic Higher Plant *Lemna gibba* in a 7-Day Growth Inhibition Test RCC Ltd., Switzerland, report no. C45577 Celsius Property B.V., report no 90011801_000066083 GLP Unpublished **Also filed under KCP 10.2.1/04**	N	N		ADAMA Agan Ltd.
KCP 5.1.2/05	Oberrauch, S.	2018a	Trinexapac-ethyl 175 EC: Honey Bee (Apis mellifera L.) Chronic Oral Toxicity Test 10 Day Feeding Test in the Laboratory Eurofins Agroscience Services Ecotox GmbH, Germany, report no. S18-00067 ADAMA Agan Ltd., report no. 90020907 GLP Unpublished **Also filed under KCP 10.3.1.2/01**	N	Y		ADAMA Agan Ltd.
KCP 5.1.2/06	Oberrauch, S.	2018b	Trinexapac-ethyl 175 EC - Honey Bee (Apis mellifera L.) 22 Day Larval Toxicity Test (Repeated Exposure) Eurofins Agroscience Services Ecotox GmbH, Germany, report no. S18-00066 ADAMA Agan Ltd., report no. 90020906 GLP Unpublished **Also filed under KCP 10.3.1.3/01**	N	Y		ADAMA Agan Ltd.
KCP 5.1.2/07	Friedrich, S.	2008a	Terrestrial (non-target) plant test with Trinexapac-ethyl 175 EC: Vegetative vigour test of non-target terrestrial plants BioChem agrar, Germany, report no. 08 10 48 030 S Celsius Property B.V., report no 90018044_000081140 GLP Unpublished **Also filed under KCP 10.6.2/01**	N	N		ADAMA Agan Ltd.
KCP	Friedrich, S.	2008b	Terrestrial (non-target) plant test with Trinexapac-ethyl 175	N	N		ADAMA Agan Ltd.

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*
5.1.2/08			EC: Seedling emergence and seedling growth test of non-target terrestrial plants BioChem agrar, Germany, report no. 08 10 48 029 S Celsius Property B.V., report no 90018045_000081141 GLP Unpublished **Also filed under KCP 10.6.2/02**				
KCP 6.0/01	ADAMA	2021	BAD	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
KCP 6	Katarzyna Furman - Frątczak	2016	Ocena skuteczności i selektywności preparatu Optimus 175 EC stosowanego w uprawie owsa (The evaluation of efficacy and selectivity of Optimus 175 EC on oat) Company Report No: DPE16/943/RZB-01 Trial ID: PL16GEAVESA117A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on spring oats in Poland in 2016 Trial ID: PL16GEAVESA117B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2017	Ocena skuteczności I selektywności preparatu: AG-TC1-292,5 ME1 oraz AG-TC1-292,5 ME stosowanego w uprawie owsa. The evaluation of efficacy and selectivity of AG-TC1-292,5 ME1 and AG-TC1-292,5 ME in oats. Trial ID: PL17GEAVESA040A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Jiri Roslapil	2014	Efficacy evaluation of AG-TC1-292,5 ME on spring barley in the Czech republic in 2014. Trial ID: CZ14GEHORVS005B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Jan Čáp	2017	Efficacy evaluation and comparison to the old formulation of AG-T3-175 EC on spring barley in the Czech republic in	N	Y	Data/study report never submit-ted before to support a product	ADAMA

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*
			2017. Trial ID: CZ17GEHORVS011A GEP Unpublished			authorisation in Poland	
	Jan Čáp	2017	Efficacy evaluation and comparison to the old formulation of AG-T3-175 EC on spring barley in the Czech republic in 2017. Trial ID: CZ17GEHORVS011B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2016	Ocena skuteczności i selektywności preparatu Optimus 175 EC stosowanego w uprawie jęczmienia jarego (The evaluation of efficacy and selectivity of Optimus 175 EC on spring barley) Company Report No: DPE16/940/RZB-01 Trial ID: PL16GEHORVS114A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on spring barley in Poland in 2016 Trial ID: PL16GEHORVS114B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2016	Ocena skuteczności i selektywności preparatu Optimus 175 EC stosowanego w uprawie jęczmienia ozimego (The evaluation of efficacy and selectivity of Optimus 175 EC on winter barley) Trial ID: PL16GEHORVW116A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on winter barley on Poland in 2016 Trial ID: PL16GEHORVW116B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Jiří Hruška	2017	Efficacy evaluation of AG-T3-175 EC on winter barley in the Czech republic in 2017 Trial ID: CZ17GEHORVW015A	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA

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*
			GEP Unpublished				
	Jan Čáp	2017	Efficacy evaluation of AG-T3-175 EC on winter barley in the Czech republic in 2017. Trial ID: CZ17GEHORVW015B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2017	Efficacy evaluation of AG-T3-175 EC and comparison with the old formulation on winter barley in Germany, 2017 Trial ID: DE17WEHORVW500A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2017	Efficacy evaluation of AG-T3-175 EC and comparison with the old formulation on winter barley in Germany, 2017 Trial ID: DE17WEHORVW500B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2017	Efficacy evaluation of AG-T3-175 EC on winter rye in Germany, 2017 Trial ID: DE17WESECSS501B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2016	Efficacy evaluation of AG-T3-175 EC on winter rye in Germany, 2016 Trial ID: DE16WESECSS503B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2016	Efficacy evaluation of AG-T3-175 EC on winter rye in Germany in 2016 Efficacy evaluation of AG-T3-175 EC on winter rye in Germany, 2016 Trial ID: DE16WESECSS503A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2016	Ocena skuteczności I selektywności preparatu Optimus 175 EC w uprawie żyta ozimego The evaluation of efficacy and selectivity of Optimus 175 EC w winter rye Report nr: DPE16/939/RZB-01	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA

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*
			Trial ID: PL16GESECSS113A GEP Unpublished				
	Karolina Felczak	2017	Skuteczność preparatu AG-TC1-292,5 ME w zapobieganiu wylegania w uprawie żyta ozimego, Polska 2017 Efficacy of AG-TC1-292,5 ME in prevention of lodging in winter rye, Poland 2017 Report nr: 39_01_F17_072 Trial ID: PL17GESECSS038A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on winter rye in Poland in 2016 Trial ID: PL16GESECSS113B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2016	Efficacy evaluation of AG-T3-175 EC on winter triticale in Germany in 2016 Trial ID: DE16WETTLSS504B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Udo Zickart	2016	Efficacy evaluation of AG-T3-175 EC on winter triticale in Germany in 2016 Trial ID: DE16WETTLSS504A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Thomas Martin	2014	Efficacy evaluation of AG-TC1-292,5 ME on winter triticale on Triticale, in 2014 Trial ID: DE14GETTLSS515A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2016	Ocena skuteczności i selektywności preparatu Optimus 175 EC stosowanego w uprawie pszenżyta ozimego (The evaluation of efficacy and selectivity of Optimus 175 EC on winter triticale) Report nr: DPE16/941/RZB-01 Trial ID: PL16GETTLSS115A GEP	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA

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*
			Unpublished				
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on winter triticale in Poland in 2016 Trial ID: PL16GETTLSS115B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2017	Badanie skuteczności regulatorów wzrostu AG-TC1-292,5 ME1 oraz AG-TC1-292,5 ME w uprawie zbóż Evaluation of PGR efficacy AG-TC1-292,5 ME1 and AG-TC1-292,5 ME in cereals Trial ID: PL17GETRZAW034B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2017	Badanie skuteczności regulatora wzrostu AG-T3-175 EC w uprawie pszenicy ozimej Efficacy of PGR AG-T3-175 EC in winter wheat Trial ID: PL17GETRZAW049A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2017	Badanie skuteczności regulatora wzrostu AG-T3-175 EC w uprawie pszenicy ozimej Efficacy of PGR AG-T3-175 EC in winter wheat Trial ID: PL17GETRZAW049B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2017	Ocena skuteczności I selektywności preparatu Optimus 175 EC(AG-T3-175 EC) stosowanego w uprawie pszenicy ozimej. The evaluation of efficacy and selectivity of Optimus 175 EC(AG-T3-175 EC) in winter wheat. Trial ID: PL17GETRZAW049C GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2017	Ocena skuteczności I selektywności preparatu Optimus 175 EC(AG-T3-175 EC) stosowanego w uprawie pszenicy ozimej. The evaluation of efficacy and selectivity of Optimus 175 EC(AG-T3-175 EC) in winter wheat. Trial ID: PL17GETRZAW049D GEP	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA

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			Unpublished				
	Adam Pawlak	2017	Ocena skutecznosci AG-T3-175 EC w pszenicy ozimej, Polska 2017 Efficacy evaluation of AG-T3-175 EC on winter wheat, Poland 2017 Trial ID: PL17GETRZAW049E GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Karolina Felczak	2017	Skuteczność preparatu AG-T3-175 EC w zapobieganiu wylegania w uprawie pszenicy ozimej, Polska 2017 Efficacy of AG-T3-175 EC in prevention of lodging in winter wheat, Poland 2017 Report nr: 61-01- F17-110 Trial ID:P L17GETRZAW050A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Karolina Felczak	2017	Skuteczność preparatu AG-T3-175 EC w zapobieganiu wylegania w uprawie pszenicy ozimej, Polska 2017 Efficacy of AG-T3-175 EC in prevention of lodging in winter wheat, Poland 2017 Report nr: 61-01- F17-111 Trial ID:P L17GETRZAW050B GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Katarzyna Furman - Frątczak	2016	Ocena skuteczności I selektywności preparatu Optimus 175 EC stosowanego w uprawie pszenicy ozimej. The evaluation of efficacy and selectivity of Optimus 175 EC in winter wheat. Report nr: DPE16/938/RZB-01 Trial ID: PL16GETRZAW112A GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA
	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on wheat in Poland in 2016 Trial season: 2016 Trial ID: PL16GETRZAW112C GEP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA

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	Łukasz Sobiech	2016	Efficacy evaluation of AG-T3-175 EC on wheat in Poland in 2016 Trial season: 2016 Trial ID: PL16GETRZAW112D GEP Unpublished	N	Y	Data/study report never submitted before to support a product authorisation in Poland	ADAMA
KCP 7.1.1/01	xxxxxxxxxx	2008a	Trinexapac-ethyl 175 EC – Acute Oral Toxicity Study in Rats Report No. B92790 xxxxxxxxxxxxxxxxxx GLP unpublished	Y	N		Celsius Property B.V.
KCP 7.1.2/01	xxxxxxxxxx	2008b	Trinexapac-ethyl 175 EC – Acute Dermal Toxicity Study in Rats Report No. B92801 xxxxxxxxxxxxxxxxxxx GLP unpublished	Y	N		Celsius Property B.V.
KCP 7.1.4/01	xxxxxxxxxx	2008c	Trinexapac-ethyl 175 EC – Primary Skin Irritation Study in Rabbits (4 –Hour Semi-Occlusive Application) Report No. B92812 xxxxxxxx GLP unpublished	Y	N		Celsius Property B.V.
KCP 7.1.5/01	xxxxxxxx	2008d	Trinexapac-ethyl 175 EC – Primary Eye Irritation Study in Rabbits Report No. B92823 xxxxxxxxx GLP unpublished	Y	N		Celsius Property B.V.
KCP 7.1.6/01	xxxxxxxx	2008e	Trinexapac-ethyl 175 EC – Contact Hypersensitivity in Albino Guinea Pigs, Maximisation –Test Report No. B97187 xxxxxxxxxx GLP unpublished	Y	N		Celsius Property B.V.
KCP 7.3/01	xxxxxxxx	2018	*In vitro* percutaneous absorption of Trinexapac-ethyl, formulated as AG-T3-175 EC1, through human skin	N	Y	Data/study report never submitted before to support a product	ADAMA Agan Ltd

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			Report V21000/22; 90020905 xxxxxxxxxxxxxxxxxxx GLP unpublished			authorisation in Poland	
KCA 6.1/01	Brown, D.	2020	Trinexapac-ethyl (CGA163935) - storage stability of residues of trinexapac acid (CGA179500) in crop matrices stored frozen for up to 26 months Charles River Laboratories, Edinburgh, United Kingdom, 227361 GLP not published	N	Y	Data/study report never submitted before to support a product authorisation in Poland	Trinexapac Task Force
KCP 9.2.4/01	Hicks J.	2020a	PECgroundwater Calculations for Trinexapac-ethyl and Metabolites For Submission to Central EU Regulatory Zone TXP/EFA/01 Agrexis AG., Switzerland Sponsor reference number: 000106647 non GLP Unpublished	N	N	Data/study report never submitted before to support a product authorisation in Poland	ADAMA Agan Ltd.
KCP 9.2.5/01	Hicks J.	2020b	PECsurfacewater and PECsediment calculations for Trinexapac-ethyl and Metabolites – FOCUS Steps 1 and 2 For Submission to Central Regulatory Zone TXP/EFA/02 Agrexis AG., Switzerland Sponsor reference number: 000106646 non GLP Unpublished	N	N	Data/study report never submitted before to support a product authorisation in Poland	ADAMA Agan Ltd.
KCP 10.2.1/01	xxxxxxxxxx.	2008	AG-T3-175 EC: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-Hour Static Test xxxxxxxxxxxxxxxxxxxxx GLP Unpublished	Y	N		ADAMA Agan Ltd
KCP 10.2.1/02	Höger, S.	2008	AG-T3-175 EC: Acute Toxicity to *Daphnia magna* in a 48-Hour Immobilization Test RCC Ltd., Switzerland, report no. B93082 Celsius Property B.V., report no 90018031_000081126 GLP Unpublished	N	N		ADAMA Agan Ltd

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KCP 10.2.1/03	Bätscher, R.	2008	AG-T3-175 EC: Toxicity to *Anabaena flos-aquae* in a 72-Hour Algal Growth Inhibition Test RCC Ltd., Switzerland, report no. B93093 Celsius Property B.V., report no 90018032_000081127 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.2.1/04	Höger, S.	2009	AG-T3-175 EC: Toxicity of AG-T3-175 EC to the Aquatic Higher Plant *Lemna gibba* in a 7-Day Growth Inhibition Test RCC Ltd., Switzerland, report no. C45577 Celsius Property B.V., report no 90011801_000066083 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.1.1/01	Jeker, L.	2008a	AG-T3-175 EC: Acute Oral and Contact Toxicityto Honey Bees (*Apis mellifera* L.) RCC Ltd., Switzerland, report no. B93150 Celsius Property B.V., report no 90018033_000081128 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.1.2/01	Oberrauch, S.	2018a	Trinexapac-ethyl 175 EC: Honey Bee (Apis mellifera L.) Chronic Oral Toxicity Test 10 Day Feeding Test in the Laboratory Eurofins Agroscience Services Ecotox GmbH, Germany, report no. S18-00067 ADAMA Agan Ltd., report no. 90020907 GLP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd
KCP 10.3.1.3/01	Oberrauch, S.	2018b	Trinexapac-ethyl 175 EC - Honey Bee (Apis mellifera L.) 22 Day Larval Toxicity Test (Repeated Exposure) Eurofins Agroscience Services Ecotox GmbH, Germany, report no. S18-00066 ADAMA Agan Ltd., report no. 90020906 GLP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd
KCP 10.3.2/01	Schmidt, T.	2009a	AG-T3-175 EC: Toxicity of AG-T3-175 EC to Adults of the Parasitoid Wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) Under Worst-case Conditions in the Laboratory RCC Ltd., Switzerland, report no. B93036	N	N		ADAMA Agan Ltd

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			Celsius Property B.V., report no 90018034_000081129 GLP Unpublished				
KCP 10.3.2/02	Jeker, L.	2008b	AG-T3-175 EC: Toxicity of AG-T3-175 EC to the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) under Worst-Case Laboratory Conditions RCC Ltd., Switzerland, report no. B92970 Celsius Property B.V., report no 90018035_000081130 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.2/03	Schmidt, T.	2009b	AG-T3-175 EC: Toxicity to the Rove Beetle *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae) under Worst-Case Laboratory Conditions RCC Ltd., Switzerland, report no. B92913 Celsius Property B.V., report no 90018036_000081131 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.2/04	Jeker, L.	2009a	AG-T3-175 EC: Toxicity to Larvae of the Seven-Spotted Ladybird *Coccinella septempunctata* (Coleoptera: Coccinellidae) under Worst-Case Laboratory Conditions RCC Ltd., Switzerland, report no. B93025 Celsius Property B.V., report no 90018037_000081132 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.2/05	Schmidt, T.	2009c	AG-T3-175 EC: Toxicity of AG-T3-175 EC to Adults of the Parasitoid Wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) Under Extended Conditions in the Laboratory RCC Ltd., Switzerland, report no. B93047 Celsius Property B.V., report no 90018038_000081133 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.2/06	Jeker, L.	2009b	AG-T3-175 EC: Toxicity of AG-T3-175 EC to the Predatory Mite *Typhlodromus pyri* (Acari: Phytoseiidae) under Extended Laboratory Conditions RCC Ltd., Switzerland, report no. B92968 Celsius Property B.V., report no 90018039_000081134 GLP	N	N		ADAMA Agan Ltd

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			Unpublished				
KCP 10.3.2/07	Schmidt, T.	2009d	AG-T3-175 EC: Toxicity to Larvae of the Green Lacewing *Chrysoperla carnea* (Neuroptera: Chrysopidae) under Extended Laboratory Conditions RCC Ltd., Switzerland, report no. B92957 Celsius Property B.V., report no 90018040_000081135 GLP Unpublished	N	N		ADAMA Agan Ltd
KCP 10.3.2/08	Jeker, L.	2009c	AG-T3-175 EC: Toxicity to Larvae of the Seven-Spotted Ladybird *Coccinella septempunctata* (Coleoptera: Coccinellidae) under Extended Laboratory Conditions RCC Ltd., Switzerland, report no. B93060 Celsius Property B.V., report no 90018041_000081137 GLP Unpublished	N	Y		ADAMA Agan Ltd
KCP 10.4.1.1/01	McCormac, A.	2018	AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) – Determination of chronic toxicity to the earthworm *Eisenia andrei* in an artificial soil substrate Mambo-Tox Ltd., UK, report no. AGAN-17-37 ADAMA Agan Ltd., report no. 90020908 GLP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd
KCP 10.4.2.1/01	Geary, N.	2018	AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) – A laboratory test to determine the effects of fresh residues on the springtail *Folsomia candida* (Collembola, Isotomidae) in an artificial soil substrate Mambo-Tox Ltd., UK, report no. AGAN-17-38 ADAMA Agan Ltd., report no. 90020909 GLP Unpublished	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd
KCP 10.4.2.1/02	Geary, N.	2017	AG-T3-175 EC1 (Trinexapac-ethyl 175 EC) – A laboratory test to determine the effects of fresh residues on the predatory soil mite *Hypoaspis aculeifer* (Acari, Laelapidae) in an artificial soil substrate Mambo-Tox Ltd., UK, report no. AGAN-17-39 ADAMA Agan Ltd., report no. 90020910 GLP	N	Y	Data/study report never submit-ted before to support a product authorisation in Poland	ADAMA Agan Ltd

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*
			Unpublished				
KCP 10.5/01	Seyfried, B.	2009	AG-T3-175 EC: Determinations of Effects on Soil Microflora Activity RCC Ltd., Switzerland, report no. B93227 Celsius Property B.V., report no 90018043_000081139 GLP Unpublished	N	Y		ADAMA Agan Ltd
KCP 10.6.2/01	Friedrich, S.	2008a	Terrestrial (non-target) plant test with Trinexapac-ethyl 175 EC: Vegetative vigour test of non-target terrestrial plants BioChem agrar, Germany, report no. 08 10 48 030 S Celsius Property B.V., report no 90018044_000081140 GLP Unpublished	N	Y		ADAMA Agan Ltd
KCP 10.6.2/02	Friedrich, S.	2008b	Terrestrial (non-target) plant test with Trinexapac-ethyl 175 EC: Seedling emergence and seedling growth test of non-target terrestrial plants BioChem agrar, Germany, report no. 08 10 48 029 S Celsius Property B.V., report no 90018045_000081141 GLP Unpublished	N	Y		ADAMA Agan Ltd

* The sponsor company ADAMA Agan Ltd. is a member of ADAMA Agricultural Solutions. Celsius Property B.V. is a member of the ADAMA group.

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	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
CP 5.1.2	Forrer K.	1989	CGA 163935 Liquid chromatographic determination of residues of parent, Plant material and soil Study Report No. REM 137.01 Ciba-Geigy Ltd., Basel, Switzerland GLP, inpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Forrer K.	1991a	CGA 163935 - Determination of residues of the metabolite CGA 179500 by liquid chromatography, Plant material Study Report No. REM 137.02	N	N	-	Trinexapac Task Force

			Ciba-Geigy Ltd., Basel, Switzerland GLP, unpublished				
CP 5.1.2	Sack St.	1999	Validation (ILV) of method REM 137.02 (validation by analysis of fortified specimens and determination of recoveries), Plant material Study Report No. 304/99 Novartis Crop Protection AG, Basel, Switzerland GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	xxxxxxxx	1995a	Determination of the metabolite CGA 179500 by liquid chromatography, Animal produce (tissue, milk, eggs) Study Report No. REM 137.12 xxxxxxxx GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Gasser A.	2001	Independent Laboratory Validation (ILV) of REM 137.12 Study Report No.312/01 Syngenta Crop Protection AG, Basel, Switzerland GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Lin K.	2008	Validation of Analytical Method GRM020.01A for the Determination of Residues of Trinexapac-ethyl as CGA179500 in Crops by LC-MS/MS GRM020.01A Syngenta Crop Protection, Inc., Greensboro, USA GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Thomas C.	2010	Independent Laboratory Validation (ILV) of Syngenta Analytical Method GRM020.01A – Analytical Method for the Determination of Residues of Trinexapac-Ethyl as CGA179500 in Crops by LC-MS/MS 110.036 Syngenta Crop Protection, Inc., Greensboro, USA North Coast Laboratories, Arcata CA, USA, GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Hargreaves S.	2008	Trinexapac ethyl – Analytical Method for the Determination of Residues of the Metabolite CGA179500 in Crops. Final Determination by LC-MS/MS GRM020.05A, T009081-06 Syngenta – Jealott's Hill, Bracknell, United Kingdom, Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Mayer L.	2008 2016	Trinexapac-Ethyl – Validation of Analytical Method GRM020.05 for the Determination of Residues of Trinexapac-Ethyl Metabolite CGA179500 in Crops by LC-MS/MS GRM020.05, T001300-08 Report has been amended 12 August 2016	N	N	-	Trinexapac Task Force

			Syngenta Crop Protection, Inc., Greensboro, USA GLP, unpublished				
CP 5.1.2	Braid S., Tsui G.	2015 2016	Trinexapac Ethyl –Analytical Method GRM020.09A for the Determination of Residues of CGA179500 in Cereal Grain and Straw by LC-MS/MS GRM020.009A, Report was amended: 22 February 2016 and 2 August 2016 Syngenta - Jealott's Hill,Bracknell, United Kingdom Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Tsui G.	2015	Trinexapac Ethyl - Validation of Analytical Method GRM020.00A for the Determination of Residues of CGA179500 in Cereal Grain and Straw by LC-MS/MS TK0252289, Report has been amended 19 November 2015 Battelle UK Ltd, Chelmsford, Essex, UK GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Braid S., Tsui G.	2016a	Trinexapac Ethyl - Analytical Method GRM020.09B for the Determination of Residues of CGA179500 in Various Crop Matrices by LC-MS/MS Syngenta - Jealott's Hill, Bracknell, United Kingdom GRM020.09B, Report was amended 2 August 2016 Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Tsui G.	2016	Trinexapac Ethyl - Validation of Analytical Methods GRM020.09B and GRM020.16A for the Determination of Residues of CGA179500 in Various Crop Matrices by LC-MS/MS Battelle UK Ltd, Chelmsford, Essex, UK TK0252289 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Braid S., Tsui G.	2016b	Trinexapac Ethyl - Analytical Method GRM020.16A for the Determination of Residues of CGA179500 in Various Crop Matrices by LC-MS/MS Syngenta - Jealott's Hill, Bracknell, United Kingdom GRM020.16A TK0252289 Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	xxxxxxxx	2008	Validation of Residue Method AGR/MOA/TRIN-06 for the Determination of Trinexapac in Animal Matrices xxxxxxxx CHE/TRIN/08003 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Hauck M.	1993	Determination of residues of the metabolite CGA 179500 by liquid chromatography, Plant material Study Report No. REM 137.08 Ciba-Geigy Ltd., Basel, Switzerland GLP, unpublished	N	N	-	Trinexapac Task Force

CP 5.1.2	Watson G.	2016	Trinexapac-ethyl - Analytical Method GRM020.15A for the Determination of CGA224439 (Cyclopropanecarboxylic Acid) in Brewing and Baking Matrices GRM020.15A ResChem Analytical Limited, Derby, UK Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Watson G.	2016a	Trinexapac Ethyl - Validation of a method for the determination of residues of CPCA in processed commodity matrices by LC-MS/MS RES-00026 ResChem Analytical Limited, Derby, UK GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Braid S., Langridge G	2016	Trinexapac Ethyl - Analytical Method GRM020.013A for the Determination of the Metabolite CGA313458 in Brewing and Baking Commodities GRM020.013A Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.1.2	Braid S., Brookes S., Langridge G.	2016	Trinexapac Ethyl - Analytical Method GRM020.014A for the Determination of the Metabolite CGA113745 in Brewing and Baking Commodities GRM020.014A Syngenta - Jealott's Hill, Bracknell, United Kingdom Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Campbell A.J., Crook S.J.	2004	Residue analytical method for the determination of residues of trinexapac acid (CGA 179500) in crop samples. Final determination by LC/MS/MS. Syngenta Ltd, Bracknell, United Kingdom. report no. REM 137.13 Not GPL, Unpublished.	N	N	-	Trinexapac Task Force
CP 5.2	Nichols C., Kwiatkowski A.	2004	Residue Study with Trinexapac-Ethyl (CGA 163935) in or on Broad Beans in France (South). Syngenta Ltd, Bracknell, United Kingdom. report no. 03-3001 GLP, unpublished.	N	N	-	Trinexapac Task Force
CP 5.2	Benazeraf L.	2004a	Independent laboratory validation of residue method REM 137.13 for the determination of trinexapac acid (CGA 179500) in oilseed rape, potato, apple and cereal grain. Syngenta Ltd, Bracknell, United Kingdom. report no. SYN/TRIN/04091 GLP, unpublished.	N	N	-	Trinexapac Task Force
CP 5.2	Hargreaves S.	2008	Trinexapac ethyl Analytical Method for the Determination of Residues of the Metabolite CGA17950 in Crops. Final Determination by LC-MS/MS Syngenta - Jealott's Hill Bracknell, United Kingdom, report no.	N	N	-	Trinexapac Task Force

			GRM020.05A, T009081-06 Not GLP, unpublished				
CP 5.2	Mayer L.	2008	Trinexapac-Ethyl - Validation of Analytical Method GRM020.05 for the Determination of Residues of Trinexapac-Ethyl Metabolite CGA179500 in Crops by LC-MS/MS Syngenta Crop Protection, Inc., Greensboro, USA, report no. GRM020.05, T001300-08, amended 2016 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Richter S.	2015a	Trinexapac– Validation of the QuEChERS Method for the Determination of Trinexapac (Acid) in Crop Matrices by LCMS/MS. Method Validation Report Amendment 1 PTRL Europe GmbH, Germany. Report PTRL Europe ID P 3685 G, Task number TK0255737 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Brown D.	2015a	Trinexapac (acid) – Independent Laboratory Validation of the QuEChERS Analytical Method for the Determination of Trinexapac (acid) Residues in Crops. ResChem Analytical Limited, United Kingdom Report RES-00008; Task number TK0255738 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxx	2004	Residue analytical method for the determination of residues of trinexapac acid (CGA 179500) in animal matrices. Final determination by LC/MS/MS. xxxxxxxxxxxxx 137.14 GLP, unpublished. Syngenta file no. CGA	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxx	2004	Trinexapac Acid (CGA179500): Validation of a Residue Analytical Method REM 137.14 for the Determination of Residues in Animal Products (Milk, Eggs, Muscle, Kidney, Fat and Liver). xxxxxxxxxx report no. RJ3570B GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxx	2004b	Independent laboratory validation of residue method REM 137.14 for the determination of trinexapac acid (CGA 179500) in bovine muscle and bovine Milk. xxxxxxxxxx SYN/TRIN/04092 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxx	2015b	Trinexapac: Validation of the QuEChERS Method for the Determination of Trinexapac (Acid) in Animal Matrices by LC-MS/MS. Method Validation Report Amendment xxxxxxxxxxx, TK0255740 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxx	2015b	Trinexapac (acid) –Independent Laboratory Validation of the QuEChERS Analytical Method for the Determination of	N	N	-	Trinexapac Task Force

			Trinexapac (acid) Residues in animal matrices. xxxxxxxxxxx Report RES-00009, TK0255742 GLP, unpublished				
CP 5.2	Forrer K.	1991c	CGA 163935 Determination of residues of the metabolite CGA 179500 by liquid chromatography, Soil Ciba-Geigy Ltd., Basel, Switzerland, report No. REM 137.03 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Forrer K.	1991d	CGA 163935, Liquid chromatographic determination of residues of parent compound, Soil Ciba-Geigy Ltd., Basel, Switzerland, study report no. REM 137.04 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Sack St.	1995a	Determination of the metabolite CGA 179500 by liquid chromatography, Soil Ciba-Geigy Ltd., Basel, Switzerland, study report no. REM 137.10 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hargreaves S.L.	2004a	Residue Analytical Method for the Determination of Residues of Trinexapac-Ethyl in Soil. Syngenta Ltd., Bracknell, UK, method no. RAM 436/01 Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Nagra B.S.	2004a	Trinexapac-ethyl: Validation of an Analytical Method for the Determination of Residues of Trinexapac-ethyl (CGA163935) in Soil. Syngenta Ltd., Bracknell, UK, report no. RJ3526B, GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hargreaves S.L.	2004b	Residue Analytical Method for the Determination of Residues of CGA 179500 in Soil. Syngenta Ltd., Bracknell, UK, method number RAM 437/01 Not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Nagra B.S.	2004b	Validation of an Analytical Method for the Determination of Residues of CGA 179500 in Soil. Syngenta Ltd., Bracknell, UK, report no. RJ3527B GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hargreaves S.L.	2008a	GRM020.03A – Trinexapac-ethyl – Residue Method for the Determination of trinexapac - ethyl in soil Syngenta Ltd., Jealott´s Hill International Research Centre, UK SYN/TRN/07001, Report No. T010139-04 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Solé C.	2008a	Validation of residue methods GRM020.03A and GRM020.04A for the determination of trinexapac-ethyl (CGA163935) and its metabolite (CGA179500) in soil. Eurofins ADME Bioanalysis, France Report No. T010139-04 GLP, unpublished	N	N	-	Trinexapac Task Force

CP 5.2	Hargreaves S.L.	2008b	GRM020.04A - Trinexapac ethyl - Residue Method for the Determination of Metabolite CGA179500 in Soil - Analytical Method. Syngenta Ltd., Jealott´s Hill International Research Centre, UK Report No. T010139-04, SYN/TRIN/07001 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Braid S.	2015	Trinexapac-ethyl – Analytical Method for the Determination of Metabolite CGA300405 in soil Syngenta Ltd., Jealott´s Hill International Research Centre, UK Report No. GRM020.10A, Task No. TK0253683 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Heinz N.	2015a	Validation of an Analytical Method for the Determination of Trinexapac-ethyl Metabolite CGA300405 in Soil Method/Validation, Report Amendment No. 1 PTRL Europe GmbH, Ulm, Germany. Report No. PTRL Europe ID P 3616G. GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hauck M.	1991	CGA 163935, Determination of residues of the metabolite CGA 179500 by liquid chromatography (LC), Water. Ciba-Geigy Ltd., Basel, Switzerland, study report no. REM137.06 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Sack St.	1995b	Trinexapac-Ethyl (CGA 163935), Determination of the metabolite CGA 179500 by liquid chromatography, Water, Residue method validated Ciba-Geigy Ltd., Basel, Switzerland, study report No. REM 137.09, GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Bourry R.	2000	Validation of Method REM 137.09 Novartis Crop Protection, AG, Basel, Switzerland, study report No. 308/00, GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Ward M.K.	1990	Analytical method for the determination of CGA 163935 in water by HPLC with column switching Ciba-Geigy Corp., Greensboro, United States, study report no. AG558A, GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hargreaves S.L.	2004c	Residue Analytical Method for the Determination of Residues of Trinexapac-Ethyl (CGA 163935) and its Metabolite CGA 179500 In Water Syngenta Ltd, Bracknell, UK, Method No. RAM 438/01 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Nagra B.S.	2004c	Trinexapac-ethyl - Validation of an Analytical Method for the Determination of Residues of trinexapac-ethyl (CGA163935) and	N	N	-	Trinexapac Task Force

			CGA179500 in Water. Syngenta Ltd., Bracknell, UK, report no. RJ3531B GLP, unpublished				
CP 5.2	Hargreaves S.L.	2008c	GRM020.02A Trinexapac ethyl – Residue Method for the Determination of Trinexapac ethyl and its metabolite CGA179500 in water – Analytical Method Syngenta Ltd., Jealott´s Hill International Research Centre, UK Report No. T012479-04 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Solé C.	2007	Validation of residue method GRM020.02A for the determination of trinexapac-ethyl (CGA163935) and its metabolite CGA179500 in water Eurofins ADME Bioanalysis, France Report No. T012479-04, SYN/TRIN/07002 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Foster B. and Mumford J.	2016	Trinexapac-ethyl - Independent Laboratory Validation of Residue Method GRM020.02A for the Determination of Trinexapac ethyl and its Metabolite CGA179500 in Water Method Validation; Report Amendment No. 1 Smithers Viscient (ESG) Ltd., UK Report Number: 3201221, Task Number: TK0281334 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Crook S.	2015	Trinexapac-ethyl – Analytical Method GRM020.11A for the Determination of the Metabolite CGA300405 in Water. Syngenta, Jealotts Hill International Research Centre, UK. Report No. GRM020.113A, Task Number TK0253682 not GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Heinz N.	2015	Heinz N. (2015a). - Trinexapac Ethyl – Validation of an Analytical Method for the Determination of Trinexapac Ethyl Metabolite CGA300405 in Water Method Validation Report Amendment No. 1 PTRL Europe GmbH, Germany Report no. P 3617 G, TK0253685 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Hamberger R.	2015	Trinexapac ethyl – Independent Laboratory Validation of Analytical Method for the Determination of Metabolite CGA300405 in water. CIP Chemisches Institut Pforzheim GmbH, Germany Report No. SYNCGA300405DW, Study no. 15S08142-02-VMWA, TK0253686 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Tribolet R.	1993	Sampling of air and determination of residues of parent compound by high performance liquid chromatography	N	N	-	Trinexapac Task Force

			Ciba-Geigy Ltd., Basel, Switzerland, study report no. REM 137.07 GLP, unpublished				
CP 5.2	Tribolet R.	1996	Validation of Method REM 137.07 in Air; Validation by analysis of fortified specimens and evaluation of recoveries Ciba-Geigy Ltd., Basel, Switzerland, study report no. 151/96 GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Wiltshire K.	2015a	Trinexapac-ethyl – Residue Method GRM020.12A for the Determination of trinexapac –ethyl in Air by LC-MS/MS. CEM Analytical Services Ltd (CEMAS), UK Report No. GRM020.12A, TK0253684 not-GLP, unpublished	N	N	-	Trinexapac Task Force
CP 5.2	Wiltshire K.	2015b	Trinexapac-ethyl – Validation of Draft Residue Method GRM020.12A for the Determination of trinexapac –ethyl in Air by LC-MS/MS. CEM Analytical Services Ltd (CEMAS), UK Report No. CEMR-7011-REG, TK0253684 GLP unpublished	N	N	-	Trinexapac Task Force
CP 5.2	xxxxxxxxxxx	2017	Trinexapac - Validation of the QuEChERS Method for the Determination of Residues of Trinexapac in blood by LC-MS/MS, Final Report – Report Amendment 2 xxxxxxxxxxxxxxx. Report Number: P 4381 G, TK0325240 GLP, unpublished	N	N	-	Trinexapac Task Force
CA 6.1	Sack St.	1998	Stability of residues of CGA 179500 (metabolite of Trinexapac-ethyl, CGA 163935) in deep freeze stored analytical specimens of wheat (grain and straw) and rapeseed Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 105/95 GLP not published Syngenta File No CGA163935/0562	N	N	-	Trinexapac Task Force
CA 6.1	xxxxxxxxx	2000	Residues of CGA 179500 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of CGA 179500 (metabolite of trinexapac-ethyl, CGA 163935) at three dose levels xxxxxxxxxxxxxxx 330/99 GLP not published Syngenta File No CGA179500/0030	N	N	-	Trinexapac Task Force
CA 6.1	Watson G.	2017	Trinexapac-ethyl: Storage Stability of Residues of metabolite CGA224439 (CPCA) in Crop Matrices Stored Frozen for up to Twelve Months. Final Report and Final Report Amendment 1	N	N	-	Trinexapac Task Force

			Syngenta ResChem Analytical Limited Unit 27 Derwent Business Centre, Clarke Street, Derby, DE1 2BU, UK, RES-00030 GLP not published Syngenta File No CA876_10009				
CA 6.1	Langridge G.	2017	Trinexapac-ethyl – Storage Stability of Residues of Metabolites CGA113745 and CGA313458 in Crop Matrices Stored Frozen for up to Twelve Months. CEM Analytical Services Ltd (CEMAS) Berkshire, UK, CEMR-7358 GLP not published Syngenta File No. CGA113745_10003	N	N	-	Trinexapac Task Force
CA 6.2.1	Nicollier G.	1991	Distribution and degradation of ^{14}C-cyclohexyl-CGA 163935 in greenhouse grown spring rape Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 4/91 GLP not published Syngenta File No CGA163935/0209	N	N	-	Trinexapac Task Force
CA 6.2.1	Nicollier G.	1993	Metabolism of [^{14}C-cyclohexyl]-CGA 163935 in greenhouse grown spring rape 90GN15BPR2 (7/93) 90GN15B GLP not published	N	N	-	Trinexapac Task Force
CA 6.2.1	Krauss J. H.	1990	Uptake, distribution and degradation of ^{14}C-cyclohexyl CGA 163935 in field grown spring wheat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 20/90 GLP not published Syngenta File No CGA163935/0086	N	N	-	Trinexapac Task Force
CA 6.2.1	Krauss J. H.	1993	Metabolism of [^{14}C-Cyclohexyl]-CGA 163935 in Field Grown Spring Wheat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 6/93 GLP not published	N	N	-	Trinexapac Task Force

			Syngenta File No CGA163935/0303				
CA 6.2.1	Gross D.	1996	Behaviour and metabolism of CGA 163935 in greenhouse grown paddy rice after application of (3,5- cyclohexadion-1,2,6-^{14}C)labelled material Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 11/96 GLP not published Syngenta File No CGA163935/0482	N	N	-	Trinexapac Task Force
CA 6.2.1	Ray W. J., May-Hertl U.	2003	[1,2,6-^{14}C] Cyclohexyl-CGA-163935: Nature of the Residue in Field Grown Grass Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, 623- 00 GLP not published Syngenta File No CGA163935/0862	N	N	-	Trinexapac Task Force
CA 6.2.1	Piskorski R.	2015a	Trinexapac-ethyl - Metabolism of [^{14}C]-Trinexapac-ethyl in Oilseed Rape Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20120173 GLP not published Syngenta File No CGA163935_10561	N	N	-	Trinexapac Task Force
CA 6.2.1	Piskorski R.	2015b	Trinexapac-ethyl - Metabolism of [^{14}C]-Trinexapac-ethyl in Spring Wheat Syngenta Innovative Environmental Services, Witterswil, Switzerland, 20120098 GLP not published Syngenta File No CGA163935_10644	N	N	-	Trinexapac Task Force
CA 6.2.2	xxxxxxxxxxx	1992a	Distribution and excretion of (1,2 - ^{14}C) - cyclohexyl CGA 163935 after multiple oral administration to laying hens. xxxxxxxxxxxxxxxxxxxxxxx 141798 GLP not published Syngenta File No CGA163935/0277	Y	N	-	Trinexapac Task Force
CA 6.2.2	xxxxxxxxxxx	1993a	The Nature of Metabolites in Eggs, Tissues, and Excreta of Laying Hen after Multiple Oral Administration of [1,2-^{14}C]Cyclohexyl	Y	N	-	Trinexapac Task Force

			CGA 163935 xxxxxxxxxxxxxxx 6/93 GLP not published Syngenta File No CGA163935/0306				
CA 6.2.2	xxxxxxxxxx	2006	[3,5-Cyclohexadione-1,2,6-^{14}C] - labelled Trinexapac-ethyl (CGA163935) - Metabolism in Laying Hens xxxxxxxxxxxxxxx 04JH011, RJ3678B GLP not published Syngenta File No CGA163935/1048	Y	N	-	Trinexapac Task Force
CA 6.2.3	xxxxxxxxxx	1992b	Absorption, distribution and excretion of (1, 2 - ^{14}C) - cyclohexyl CGA 163935 after multiple oral administration to lactating goats. xxxxxxxxxxxxxx 7478, 141782 GLP not published Syngenta File No CGA163935/0276	Y	N	-	Trinexapac Task Force
CA 6.2.3	xxxxxxxxx	1993b	The Nature of the Metabolites in Milk, Tissues, and Excreta of Lactating Goat after Multiple Oral Administration of [1,2-^{14}C]Cyclohexyl CGA 163935 xxxxxxxxxxxxxxxx 5/93 GLP not published Syngenta File No CGA163935/0305	Y	N	-	Trinexapac Task Force
CA 6.2.3	xxxxxxxxxxx	2002	[1,2,6-^{14}C] Cyclohexyl-CGA-163935: Nature of the Residue in Lactating Goats xxxxxxxxxxxxxxxxx GLP not published Syngenta File No CGA163935/0944	Y	N	-	Trinexapac Task Force
CA 6.3.1	Brown D.	2016	Trinexapac-ethyl - Residue Study on Barley in Northern France and the UK in 2014 Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36129 GLP not published Syngenta File No A8587F_10144	N	N	-	Trinexapac Task Force
CA 6.3.1	Brown D.	2016a	Trinexapac-ethyl - Residue Study on Barley in Belgium in 2015	N	N	-	Trinexapac

			Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37124 GLP not published Syngenta File No A8587F_10525				Task Force
CA 6.3.1	Brown D.	2016c	Trinexapac-ethyl - Residue Study on Wheat in Northern France and the UK in 2014 Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36094 GLP not published Syngenta File No A8587F_10145	N	N	-	Trinexapac Task Force
CA 6.3.1	Brown D.	2016d	Trinexapac-ethyl - Residue Study on Wheat in Poland, Germany, Austria and Germany in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37231 GLP not published Syngenta File No A8587F_10527	N	N	-	Trinexapac Task Force
CA 6.4.2	xxxxxxxxx	2000	Residues of CGA 179500 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of CGA 179500 (metabolite of trinexapac-ethyl, CGA 163935) at three dose levels xxxxxxxxxxxxxx 330/99 GLP not published Syngenta File No CGA179500/0030	Y	N	-	Trinexapac Task Force
CA 6.5.1	Cadalbert R., Buckel T.	2001	Hydrolysis of [1,2,6- ^{14}C]-Cyclohexanedione Labelled CGA 163935 under Processing Conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 01RC02 GLP not published Syngenta File No CGA163935/0733	N	N	-	Trinexapac Task Force
CA 6.5.1	Mound E. L.	2004	[^{14}C]Cyclohexyl Trinexapac Acid (CGA179500): Aqueous Hydrolysis at 90, 100 & 120 degrees C Syngenta Crop Protection AG, Basel, Switzerland	N	N	-	Trinexapac Task Force

			Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3480B GLP not published Syngenta File No CGA179500/0036				
CA 6.5.1	Scullion P.	2012	[^{14}C]Trinexapac acid: Simulated Processing - Aqueous Hydrolysis at 90, 100 and 120 °C ADAMA Celsius Property B.V., Amsterdam, Netherlands Harlan Laboratories Ltd., Itingen, Switzerland, C93481 GLP not published Syngenta File No CGA179500_11002	N	N	-	Adama Celsius
CA 6.5.1	Florchinger M.	2008	Abiotic Degradation (Hydrolysis) of ^{14}C-Trinexapac under Typical Conditions (pH, Temperature and Time) of Processing CHEMINOVA A/S, Lemvig, Denmark Eurofins - GAB, Niefern Öschelbronn, Germany, S08-03106 GLP not published Syngenta File No CGA179500_11004	N	N	-	Trinexapac Task Force
CA 6.5.3	Gasser A.	2001	Residue Study with Trinexapac-Ethyl (CGA 163935) in or on Winter Wheat in France (North) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 3011/00 GLP not published Syngenta File No CGA163935/0734	N	N	-	Trinexapac Task Force
CA 6.5.3	Mayer T.	2010	Trinexapac-ethyl – Magnitude of the Residues in or on Barley Syngenta Crop Protection, Inc., Greensboro, USA Syngenta Crop Protection, Inc., Greensboro, USA, T003422-07, ML08-1507-SYN GLP not published Syngenta File No CGA163935_50026	N	N	-	Trinexapac Task Force
CA 6.5.3	Mayer T.	2010a	Trinexapac-ethyl - Magnitude of the Residues in or on Wheat Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, T003605-07, ML08-1504-SYN GLP not published Syngenta File No CGA163935_50036	N	N	-	Trinexapac Task Force

CA 6.5.3	Ediger K.	2006	Trinexapac-ethyl - Magnitude of the Residues in or on Wheat Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T002695-03 GLP not published Syngenta File No CGA163935/1053	N	N	-	Trinexapac Task Force
CA 6.5.3	Mac Dougall J.	2016	Trinexapac-ethyl - Residue Processing Study on Barley in Spain and Italy in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37194 GLP Not published Syngenta File No A8587F_10526	N	N	-	Trinexapac Task Force
CA 6.5.3	Watson G.	2016	Analysis of Barley Processing Phase Specimens for CPCA from Study 699779 Trinexapac-ethyl - Residue Processing Study on Barley in Spain and Italy in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland ResChem Analytical Limited, Derby, UK, RES-00027 GLP not published Syngenta File No CA876_10004	N	N	-	Trinexapac Task Force
CA 6.5.3	Langridge G.	2016	Trinexapac-ethyl - Determination of Trinexapac-ethyl Metabolites CGA313458 and CGA113745 in Barley Process Fractions Syngenta, ADAMA Agriculture B.V., Schaffhausen, Switzerland, CHEMINOVA A/S, Lemvig, Denmark CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7354 GLP not published Syngenta File No CGA313458_10010	N	N	-	Trinexapac Task Force
CA 6.5.3	Langridge G.	2016	Trinexapac-ethyl - Determination of Trinexapac-ethyl Metabolites CGA313458 and CGA113745 in Wheat Process Fractions Syngenta CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7355 GLP not published Syngenta File No CGA313458_10011	N	N	-	Trinexapac Task Force
CA 6.5.3	Mac Dougall J.	2016	Trinexapac-ethyl – Residue Processing Study on Wheat in France	N	N	-	Trinexapac

			and Spain in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland Charles River Laboratories, Edinburgh, United Kingdom, 37278 GLP not published Syngenta File No A8587F_10524				Task Force
CA 6.5.3	Watson G.	2016	Analysis of Wheat Processing Phase Specimens for CPCA from Study 699784 Trinexapac-ethyl - Residue Processing Study on Wheat in France and Spain in 2015 Syngenta, CHEMINOVA A/S, Lemvig, Denmark, ADAMA Agriculture B.V., Schaffhausen, Switzerland ResChem Analytical Limited, Derby, UK, RES-00028 GLP not published Syngenta File No CA876_10003	N	N	-	Trinexapac Task Force
CA 6.6.1	Krauss J. H.	1992	Outdoor confined accumulation study on rotational crops after bareground soil application of (^{14}C-cyclohexyl)- CGA 163935 Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 23/92 GLP not published Syngenta File No CGA163935/0265	N	N	-	Trinexapac Task Force
CA 6.6.1	Quistad G., Kovatchev A.	2010	^{14}C-Trinexapac-ethyl - Uptake and Metabolism in Confined Rotational Crops Syngenta Crop Protection, Inc., Greensboro, USA PTRL West, Inc., Hercules, USA, 1802W GLP not published Syngenta File No CGA163935_50024	N	N	-	Trinexapac Task Force

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

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