HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. VOORGENOMEN BESLUIT

Op 24 december 2015 is van

UPL Europe Ltd.
The Centre, 1st Floor
Birchwood Park
WA3 6YN WARRINGTON, CHESHIRE
United Kingdom

een aanvraag tot toelating ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Xanadu

op basis van de werkzame stoffen bensulfuron-methyl en metsulfuron-methyl. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is het Verenigd Koninkrijk.

HET COLLEGE IS VOORNEMENS TE BESLUITEN tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.

- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 en artikel 36, derde lid, van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

Zienswijzenprocedure

Ingevolge artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 geldt dat dit ontwerpbesluit gedurende twee weken ter inzage wordt gelegd op het Ctgb; hiervan wordt mededeling gedaan in de Staatscourant. Het ontwerpbesluit wordt gedurende deze

periode tevens op de website van het Ctgb geplaatst. Belanghebbenden kunnen gedurende de ter inzagelegging schriftelijk bij het Ctgb aangeven dat zij een zienswijze zullen indienen; de zienswijze dient schriftelijk binnen twee weken na de inzageperiode te worden ingediend.

Ede, …..

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20131597 NLTG
Type aanvraag:	aanvraag tot nationale toelating gewasbeschermingsmiddel (NL=CMS)
Middelnaam:	Xanadu
Verzenddatum aanvraag:	3 december 2013
*Formele registratiedatum: **	24 december 2015
Datum in behandeling name:	14 juni 2018
Datum compliance check:	n.v.t.

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

Aangezien Xanadu een voor Nederland nieuwe werkzame stof bevat (bensulfuron-methyl, zie hieronder), is de zienswijzeprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 van toepassing.

2.2 Stofinformatie

Werkzame stof	Gehalte
bensulfuron-methyl	500 g/kg
metsulfuron-methyl	40 g/kg

- De stof bensulfuron-methyl is per 1 november 2009 geplaatst op Annex I van Richtlijn 91/414/EEG (2009/11/EC d.d. 18 februari 2009) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 oktober 2022.

- De stof metsulfuron-methyl is per 1 april 2016 goedgekeurd volgens Verordening (EU) 1107/2009 (Uitvoeringsverordening (EU) 2016/139 d.d. 2 februari 2016). De goedkeuring van deze werkzame stof expireert op 31 maart 2023.

2.3 Toelatingsinformatie

Toelatingsnummer:	15746 N
Expiratiedatum:	31 oktober 2023
Afgeleide parallel of origineel:	Origineel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
Water dispergeerbaar granulaat

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Xanadu

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
-

Pictogram	GHS07 GHS09
Signaalwoord	Waarschuwing
Gevarenaanduidingen	H319 Veroorzaakt ernstige oogirritatie. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P264 Na het werken met dit product ... grondig wassen. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P337 + P313 Bij aanhoudende oogirritatie: een arts raadplegen. P273 Voorkom lozing in het milieu. P391 Gelekte/gemorste stof opruimen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH208 Bevat bensulfuron-methyl. Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Product code: **HCJ03**

Product name: **Xanadu**

Active substance: **Metsulfuron-methyl 40 g/kg + Bensulfuron-methyl 500 g/kg WG**

Central Zone
Zonal Rapporteur Member State: United Kingdom

NATIONAL ASSESSMENT – The Netherlands

Applicant: **UPL Europe Ltd**

Date: **November 2018**

Evaluator: **Ctgb, NL**

Table of Contents

PART A – RISK MANAGEMENT

This document describes the acceptable use conditions required for the registration of HCJ03 containing the active substances metsulfuron-methyl and bensulfuron-methyl which were included on Annex I of Directive 91/414/EEC (Commission Directive 2000/49/EC of 26 July 2000 for metsulfuron-methyl and Commission Directive 2009/11/EC of 18 February 2009 for bensulfuron-methyl). Metsulfuron-methyl and bensulfuron-methyl have been transposed onto Annex I of Regulation (EC) No. 1107/2009 by Implementing Regulation (EU) No. 540/2011 of 25 May 2011. The approval of Metsulfuron-methyl has been renewed by Commission Implementing Regulation (EU) 2016/139 of 2 February 2016.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and where appropriate the addenda for the Netherlands. The information, data and assessments provided in Registration Report, Parts B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to HCJ03 where those data have not been considered in the EU review. Otherwise assessments for the safe use of HCJ03 have been made using endpoints agreed in the EU review of the active substances metsulfuron-methyl and bensulfuron-methyl. This document describes the specific conditions of use and labelling required for the Netherlands for the registration of HCJ03.

Appendix 1 of this document is a copy of the proposed product label for the Netherlands.

Appendix 2 of this document contains copies of the letters of access to the protected data/third party data that were needed for evaluation of the formulation.

Appendix 3 of this document contains the reference list.

1 DETAILS OF THE APPLICATION

1.1 Application Background

This application was submitted by UPL Europe Limited.

The application is for approval of Xanadu (product code HCJ03), a water dispersible granule containing 40 g/kg metsulfuron-methyl and 500 g/kg bensulfuron-methyl for use as an herbicide for the control of broad-leaved weeds in winter and spring cereals.

1.2 Annex I Inclusion

Metsulfuron-methyl

The Commission Implementing Regulation renewing the approval of metsulfuron-methyl ((EU) 2016/139) provides specific provisions which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metsulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

— the protection of consumers,

— the protection of groundwater,

— the protection of non-target terrestrial plants.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit to the Commission, the Member States and the Authority by 30 September 2016 confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (IN-A4098) to confirm that this metabolite is not genotoxic and not relevant for risk assessment.

These concerns have been addressed within the current submission.

Bensulfuron-methyl

The Annex I Inclusion Directive for bensulfuron-methyl (2009/11/EC of 18 February 2009) 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.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on bensulfuron-methyl and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 08 December 2008 shall be taken into account. In this overall assessment:

Member States must pay particular attention to the:

- protection of aquatic organisms in relation to these identified risks. Risk mitigation measures, such as buffer zones, shall be applied where appropriate.
- protection of groundwater where the active substance is applied in regions with vulnerable soil and/or climatic conditions.

These concerns have been addressed within the current submission.

Information on the detailed composition of HCJ03 can be found in the confidential dossier of this submission (Registration Report - Part C).

1.3 Regulatory Approach

To obtain approval the product HCJ03 must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Chemical Active and Chemical Product, with an assessment to Uniform Principles, using Annex I agreed endpoints.

This application was submitted in order to allow the first approval of this product in the Netherlands in accordance with the above.

1.4 Data Protection Claims

A list of data for which protection is claimed by UPL Europe Ltd., as appropriate is provided in the Part B and C reference lists.

1.5 Letter of Access

None.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name	Xanadu
Authorisation Number (for re-registration)	not applicable
Function	Herbicide
Applicant	UPL Europe Ltd.
Composition	40 g/kg metsulfuron-methyl and 500 g/kg bensulfuron-methyl
Formulation type	Water dispersible granule [Code: WG]
Packaging	100 g, 200g, 300g, 400g, 500g, 1000g HDPE packs packed with measuring cones in box (plastic or carton)

2.2 Classification and Labelling under Regulation (EC) No. 1272/2008

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS07 GHS09	Signal word:	warning
H-statements:	H319	Causes serious eye irritation.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P264	Wash … thoroughly after handling.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	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.	
	P273	Avoid release to the environment.	
	P391	Collect spillage.	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	EUH208	Contains bensulfuron-methyl. May produce an allergic reaction.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	-
H-statements:	Acceptable proposal applicant
P-statements:	Acceptable proposal applicant
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.3 Product Uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	**Pest or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / kind	Timing / growth stage of crop & season	Max. number (min interval between applications) a) per use b) per crop/season	g product/ha a) max. rate per appl. b) max. total rate per crop/season	g, a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	NL	Winter wheat [TRZAW]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
2	NL	Winter barley [HORVW]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
3	NL	Winter rye [SECCW]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
4	NL	Triticale [TTLSS]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
5	NL	Spring wheat [TRZAS]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	

1	2	3	4	5	6	7	8	10	11	12	13	14
Use No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F G or I	**Pest or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / kind	Timing / growth stage of crop & season	Max. number (min interval between applications) a) per use b) per crop/season	g product/ha a) max. rate per appl. b) max. total rate per crop/season	g, a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
6	NL	Spring barley [HORVS]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
7	NL	Spring rye [SECCS]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	
8	NL	Oats [AVESA]	F	Annual broadleaved weeds	Spray	Post-emergence application March-May BBCH 13-39	a) 1 b) 1	a) 100 b) 100	a) 4 (MSM) + 50 (BSM) b) 4 (MSM) + 50 (BSM)	200-400	-	

3 RISK MANAGEMENT

3.1 Reasoned Statement of the Overall Conclusions Taken in Accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The product Xanadu (development code HCJ03) is a water dispersible granule. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of light brown sprinkles, with a woody odour. It is not explosive and has no oxidising properties. It has no self-ignition temperature below 400°C. In aqueous solution (1%), it has a pH value around 8.8. The stability data indicate a shelf life of at least 2 years at ambient temperature in HDPE. Its technical characteristics are acceptable for a water dispersible granule formulation, taking into account that the spray fluid should be agitated.

Implications for labelling:

The label should include the following measures to ensure a homogeneous spray fluid:

- The spray fluid should be agitated during preparation of the spray fluid and during use (Dutch: *Continu roeren tijdens het bereiden en verspuiten van de spuitvloeistof)*

Compliance with FAO specifications:

The product HCJ03 complies with relevant FAO specifications.

Nature and characteristics of the packaging:

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

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Analytical methods for determination of metsulfuron-methyl and bensulfuron-methyl, impurities and relevance of CIPAC methods in HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl and bensulfuron-methyl. Therefore all relevant data are provided and are considered adequate.

For determination of the active substances in the formulation, an HPLC-UV method with phenyl sulfone as internal standard and detection at 226nm was validated to SANCO/3030/99 rev 4. The method is suitable for determining both active substances simultaneously.

CIPAC Method MT 441/WG/M/3 and CIPAC Method MT 502/WG/M /2.1 are available for the determination of metsulfuron-methyl and bensulfuron-methyl, respectively, in water dispersible granule (WG) formulations.

No methods for the determination of relevant impurities are necessary: no relevant impurities have been detected in the technical material of either metsulfuron-methyl and bensulfuron-methyl and no impurities are likely to form during the formulation process or storage period.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 - 5.8)

Additional data on methods/validation in high acid crops for metsulfuron-methyl have been provided, but as the EU dossier contained adequate methods, the methods are not relied on and therefore not evaluated by the zonal rapporteur. The analytical methods available are acceptable.

The Dutch national requirement for an LOQ of 0.1µg/L for analytical methods for surface water is met. For metsulfuron-methyl, the LOQ is 0.01µg/L. For bensulfuron-methyl, the LOQ is 0.05 µg/L.

3.1.3 Mammalian toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute toxicity (Part B, Section 3, Point 7.1)

According to the calculation method HCJ03 is not acutely toxic by the oral and dermal routes of exposure. HCJ03 is nearly dust free and does not require evaluation for acute inhalation toxicity. It is not irritating to the skin and considered to be irritant to the eyes (H319). In line with the UK assessment, HCJ03 is not considered a skin sensitiser by NL. However, the NL conclusion is only based on bridging with the other WG-formulations with comparable or greater concentrations of bensulfuron-methyl and comparable co-formulants, which did not trigger a sensitisation reaction (refer to the Core, CP 7.1.6 for further discussion). NL does not agree with the re-analysis of the study by Armondi (1991), as it might be questioned whether the concentration in the induction phase was too low according to OECD406 guideline. Based on bridging, HCJ03 is not considered a skin sensitiser.

3.1.3.2 Operator exposure (Part B, Section 3, Point 7.3)

Conclusion from the Core:

According to the model calculations (UK POEM and German BBA (geometric)), it can be concluded that with regard to metsulfuron-methyl the risk for the operator using **Fout! Verwijzingsbron niet gevonden.** for the proposed uses is acceptable without the use of personal protective equipment (PPE).

Using the German BBA (geometric) model it can be concluded that with regard to bensulfuron-methyl the risk for the operator using **Fout! Verwijzingsbron niet gevonden.** for the proposed uses is acceptable without the use of PPE. Using the UK POEM it can be concluded that the risk of the operator using **Fout! Verwijzingsbron niet gevonden.** on cereals is acceptable with the use of PPE worn in the form of gloves during mixing/loading and application.

The combined systemic operator exposure for application through a field crop boom sprayer is less than 100% of the AOEL for both bensulfuron-methyl (with the use of PPE worn in the form of gloves during mixing/loading and application) and metsulfuron-methyl (no PPE) for an operator. This is found to be within acceptable limits and no further risk assessment is required.

3.1.3.3 Bystander exposure (Part B, Section 3, Point 7.4)

Conclusion from the Core:

According to the UK model, it can be concluded that the risk for bystanders and residents exposed to HCJ03 containing the active ingredients metsulfuron-methyl and bensulfuron-methyl is acceptable following application to field (low) crops.

For NL also a risk assessment for bystanders and residents is needed with the DE model with a distance of 1 m. The results of this risk assessment are presented below.

Internal bystander and resident exposure to bensulfuron-methyl and risk assessment for the use of Xanadu

Route		Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day)[b]	% AEL [c]
Bystander exposure during application in representative uses according to the German model				
Child	Total	0.02	1.94	1
Adult	Total	0.10	7.20	1

	Route	Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day)[b]	% AEL [c]
Resident exposure during application in all representative uses according to the German model				
Child	Total	0.01	1.94	1
Adult	Total	0.02	7.20	<1

a External exposure was estimated according to the German guidance paper for exposure and risk assessment for bystanders and residents (Martin et al. 2008, J. Verbr. Lebensm. 3: 272-281):
- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 75%
- biological availability via the oral route: 100% (see List of Endpoints)

b From the systemic AOEL of 0.12 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 for children and of 60 kg for adults.

c The % AEL is calculated by dividing the internal exposure by the systemic AEL and multiplying this by 100%.

Internal bystander and resident exposure to metsulfuron-methyl and risk assessment for the use of Xanadu

	Route	Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day)[b]	% AEL [c]
Bystander exposure during application in representative uses according to the German model				
Child	Total	<0.01	4.04	<1%
Adult	Total	0.01	15.00	<1%
Resident exposure during application in all representative uses according to the German model				
Child	Total	0.01	4.04	<1%
Adult	Total	0.02	15.00	<1%

a External exposure was estimated according to the German guidance paper for exposure and risk assessment for bystanders and residents (Martin et al. 2008, J. Verbr. Lebensm. 3: 272-281):
- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 75%
- biological availability via the oral route: 100% (see List of Endpoints)

b From the systemic AOEL of 0.25 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 for children and of 60 kg for adults.

c The % AEL is calculated by dividing the internal exposure by the systemic AEL and multiplying this by 100%.

It is concluded that there is no undue risk to any bystander or resident after accidental short-term exposure to Xanadu.

3.1.3.4 Worker exposure (Part B, Section 3, Point 7.5)

Conclusion from the Core:

The combined systemic exposure to bensulfuron-methyl and metsulfuron-methyl resulting from contact with foliage treated with Xanadu during crop-inspection as the sum of the component exposures is 4% when expressed as percentages, for an unprotected worker inspecting treated crops. This is found to be within acceptable limits and no further risk assessment is required.

3.1.4 Residues and consumer exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

EU-MRLs for Metsulfuron-methyl and Bensulfuron-methyl are established in Reg. (EC) 396/2005 by implementing Reg. (EU) 617/2014 and Reg. (EU) 2018/78.

The stability of residues for the active substances Metsulfuron-methyl and Bensulfuron-methyl was reviewed during the Annex I inclusion process and considered sufficient for this product registration.

For Metsulfuron-methyl, the residue definition in plants for monitoring is Metsulfuron-methyl (parent) and for risk assessment is Metsulfuron-methyl (parent) pending submission of sufficient metabolism data in cereals and rotational crops. Concerns were raised in the EFSA conclusion regarding the absence of cereal and rotational crop metabolism data, as well as the residue definition for risk assessment considering that there is no final conclusion yet on the genotoxic potential of metabolite triazine amine (IN-A4098). Therefore, the consumer risk assessment for the representative uses was not finalised. Whilst a confirmatory data requirement was set in the Review Report (SANTE/10319/2015) in regards to the metabolite IN-A4098, the issues with the metabolism and rotational crop data are only listed as data gaps in the EFSA conclusion. As such the current evaluation has been conducted without prejudice of the final outcome of the confirmatory data assessment.

The residue definition in livestock is Metsulfuron-methyl for monitoring and for risk assessment is Metsulfuron-methyl (parent) and triazine amine (IN-A4098) (finalisation pending plant residue definition and respective livestock exposure estimates.

The assessment of the metabolite IN-A4098 was considered further in the confirmatory data. It is noted in the review report (SANTE/10319/2015 Rev 3) that:

'With regards the relevance of metabolite IN-A4098, […] genotoxicity tests indicate that the metabolite is not genotoxic, however, a number of equivocal results […] prevented a final conclusion on the genotoxic potential from being fully established.'

It was also noted that:

'From the information available it is apparent that parent metsulfuron-methyl is the major component in commodities and any metabolites that may be present will be at very low levels when metsulfuron-methyl is applied at the intended GAP, thus ensuring an acceptable risk to consumers.'

This evaluation has been conducted based on the information provided in the review report (SANTE/10319/2015 Rev 3) and without prejudice of the final outcome of the confirmatory data assessment. As the proposed use is within the GAP evaluated for the renewal of the active and is not expected to trigger the need for consideration of livestock feeding studies, further consideration of the livestock residue definition has not been made at this time.

For Bensulfuron-methyl the residue definition in plants for risk assessment and monitoring was set during the approval to Bensulfuron-methyl (for cereals only) based upon a water/soil surface application in rice. EFSA considered that this was not suitable to address the metabolism occurring following foliar application. The applicant submitted a new study in rice following foliar application. The study supports the provisional plant residue definition for Bensulfuron-methyl. It is considered that the metabolism study following foliar application on rice is sufficient for extrapolation to wheat (OECD Guideline 501).

No residue definition was proposed in livestock for Bensulfuron-methyl as the representative use did not exceed the trigger requiring such studies. Based on the proposed use of 'Xanadu' no significant residues are expected to occur in livestock diet, therefore no further consideration has been given to the residue definitions in livestock.

The applicant submitted 4 new residue trials on wheat in northern Europe and, in addition, 4 supporting residue trials in southern Europe. The latest application was done at BBCH 39. As no PHI is proposed, a restriction should be set that applications at later growth stages are not allowed. These trials are considered sufficient to demonstrate that the current EU-MRLs for Metsulfuron-methyl and Bensulfuron-methyl are not exceeded when the product is applied to the intended GAP.

Animal feeding studies as well as processing studies were not triggered and are therefore not required, neither for Metsulfuron-methyl, nor for Bensulfuron-methyl.

Studies in rotational crops were considered during the Annex I inclusion of Metsulfuron-methyl in a field based study on various crops with a 365 day plant back interval. This study was addressed in the Art. 12

MRL review (2013), as well. It was noted that the studies did not investigate a plant-back interval of 30 days, however, EFSA considered that this was not required as crop failure is not expected to occur when the product is applied at BBCH 39. Following discussion with efficacy specialists, they agreed that crop failure at BBCH 39 would be highly unlikely and they also noted that, if crop failure where to occur at this stage (typically mid-May to early June for BBCH 39), then the earliest crop that might succeed it would be oilseed rape which is typically sown in August i.e. still >30 days later.

Following the renewal of Metsulfuron-methyl, the information reported on rotational crops was considered insufficient by the peer review (2015). Therefore, a data gap was identified for sufficient rotational crop metabolism data with Metsulfuron-methyl. As this was only listed as a data gap in the EFSA conclusion, no further consideration of rotational crop metabolism for Metsulfuron-methyl has been made during the current product assessment.

For Bensulfuron-methyl, residues in rotational crops was considered for the approval of the active, as well as in a new study submitted by the applicant in the frame of this application. Residues in cereal grain are not expected to occur at levels ≥ 0.01 mg/kg based on the proposed use of Xanadu; however residues in straw could be expected to occur in rotated crops at levels ≥ 0.01 mg/kg. The highest TRR found in wheat straw in the rotational study was 0.0361 mg/kg, which is lower than the HR level found in the primary crop (0.05 mg/kg, wheat straw). Based on the estimated dietary burden calculation, residues at the level found in the rotated crop do not result in a need for the consideration of animal metabolism studies. As such no further consideration has been made.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

First-tiered TMDI calculations with the EFSA PRIMo rev. 2 were performed by the Netherlands by using all EU-MRLs as input values for the model. The highest TMDI estimation is 0.3 % of the ADI (FR toddler) for Metsulfuron-methyl and 0.4 % of the ADI (FR toddler) for Bensulfuron-methyl.

For the acute risk assessment, only HR values resulting from uses of the current product registration are used as input values. The highest IESTI calculation is 0.1 % of the ARfD for wheat for Metsulfuron-methyl. As no acute reference has been set for Bensulfuron-methyl, there is no need to evaluate the acute risk for this active substance.

Based on the different calculations made to estimate the risk for consumer though diet and other mean it can be concluded that the use of product HCJ03 does not lead to unacceptable risk for consumer when applied according to the GAP recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

For metsulfuron-methyl and its metabolites IN-F5438, IN-B5067, IN-A4098, IN-NC148, IN-D5803, IN-00581 and IN-V7160, no new studies are presented. All data were reviewed under the EU review of metsulfuron-methyl (2000/49/EC). Appropriate endpoints from the EFSA conclusion (EFSA Journal 2015, 13(1):3936) were used to calculate PECs for Xanadu, metsulfuron-methyl and its metabolites in soil, surface water, ground water and air for the intended use patterns.

For bensulfuron-methyl and its metabolites IN-R9419, IN-D1R84, IN-J0290, IN-F7880, IN-N5297 and IN-DAT97, no new studies are presented. All data were reviewed under the EU review of bensulfuron-methyl (2009/11/EC). Appropriate endpoints from the EFSA report (EFSA Scientific report (2008) 178, 1-102) were used to calculate PECs for XANADU, bensulfuron-methyl and its metabolites in soil, surface water, ground water and air for the intended use patterns. Two new studies are provided for bensulfuron-methyl photolysis metabolite IN-T5831, from which appropriate endpoints were used to calculate PECs in in soil, surface water, ground water and air for the intended use patterns.

3.1.5.1 Predicted environmental concentration in soil (PEC_{SOIL}) (Part B, Section 5, Points 9.4 and 9.5)

The PEC of XANADU, metsulfuron-methyl and its metabolites IN-00581, IN-A4098, IN-B5067, IN-D5803, IN-NC148, IN-F5438 and IN-V7160, and bensulfuron-methyl and its metabolites IN-R9419, IN-D1R84, IN-J0290, IN-F7880, IN-N5297 and IN-T5831 in soil have been assessed using the updated crop interception values as recommended by EFSA and the DT_{50} values established in the EU reviews or agreed in the assessment, or based on new data provided. Based on the recommended use rate of 1 x 100 g product/ha of Xanadu to winter and spring cereals at early growth stages (BBCH 13-39), and assuming foliar application with zero crop interception, the maximum initial predicted environmental concentrations in soil (PEC_{SOIL}) of metsulfuron-methyl and bensulfuron-methyl will be 0.005 and 0.067 mg/kg, respectively.

For metsulfuron-methyl metabolites IN-F5438, IN-B5067, IN-A4098, IN-NC148, IN-D5803, IN-00581 and IN-V7160 the proposed use pattern will lead to maximum initial PECs of 0.0008, 0.0008, 0.0008, 0.001, 0.0015, 0.0002 and 0.0003 mg/kg, respectively. For bensulfuron-methyl metabolites IN-R9419, IN-F7880, IN-J0290, IN-N5297, IN-D1R84 and IN-T5831 the proposed use pattern will lead to maximum initial PEC_{SOIL} of 0.018, 0.003, 0.012, 0.01, 0.006 and 0.004 mg/kg, respectively.

The worst case $DT_{90\ lab}$ exceeds 1 year for the bensulfuron-methyl metabolite IN-T5831. The predicted accumulation concentrations after 20 years will be 0.0045 mg/kg.

The results for PEC soil for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.1.5.2 Predicted environmental concentration in groundwater (PEC_{GW}) (Part B, Section 5, Point 9.6)

The PEC of metsulfuron-methyl and its soil metabolites IN-F5438, IN-B5067, IN-NC148, IN-D5803, IN-B5685, IN-D5119, IN-00581, IN-V7160 and IN-A4098 in groundwater have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL model using the DT_{50} and K_{OC} values established in the EU review. The PEC of bensulfuron-methyl and its soil metabolites IN-R9419, IN-F7880, IN-J0290, IN-N5297, IN-D1R84 and IN-T5831 in groundwater have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL model using the K_{OC} and DT_{50} values established in the EU review. The metsulfuron-methyl metabolites IN-B5685 and IN-D5119 are minor metabolites and were not identified at levels which trigger a requirement for groundwater exposure assessment. However, these metabolites were included in the groundwater modelling assessment as they are precursors of other major metabolites.

The PEC_{GW} at 1 m depth for metsulfuron-methyl, bensulfuron-methyl and their soil metabolites were calculated based on the recommended use rate of 1 x 100 g product/ha of Xanadu to winter and spring cereals at early growth stages (BBCH 13-39), and assuming foliar application with zero crop interception, in Kremsmünster scenario using FOCUS PEARL. For metabolite IN-DIR84, Tier 2 groundwater modelling using GeoPEARL is triggered since the normalised DT_{50} is shorter than 10 days and the mean K_{OM} is lower than 10 L/kg.

Based on the results obtained from the PEARL and GeoPEARL calculations, it was predicted that metsulfuron-methyl, bensulfuron-methyl and their metabolites will not be found in groundwater at concentrations greater than 0.1 µg/L. The use of Xanadu is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

However, the PEC_{GW} values exceeded 0.01 µg/L for metsulfuron-methyl and its metabolites IN-F5438, IN-B5067, IN-NC148, IN-00581 and IN-A4098 and for bensulfuron-methyl and its metabolites IN-F7880 and IN-N5297, a restriction on the use in groundwater protection areas should be placed on the label for all applications.

Om het grondwater te beschermen mag dit middel niet worden gebruikt in grondwaterbeschermingsgebieden.

3.1.5.3 Predicted environmental concentration in surface water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

The PEC of Xanadu, metsulfuron-methyl and its aquatic metabolites IN-A4098, IN-F5438 and IN-JX909, and bensulfuron-methyl and its aquatic metabolites IN-J0290 and IN-N5297 in surface water (PEC_{SW}) resulting from entry of metsulfuron-methyl or bensulfuron-methyl into surface water via spray drift have been assessed based on the national requirements for submission to The Netherlands using the TOXSWA model (version 1.2, GUI 1.0) and the DT_{50} water/sediment and K_{OC} (recalculated to give K_{OM}) values established in the EU reviews. All PEC calculations were performed in accordance with the critical GAP for The Netherlands. No ecotoxicological endpoints have been generated for sediment, therefore, PEC values in sediment are not required and thus have not been calculated.

The following restriction sentence has been proposed on the label (rephrased by Ctgb):

Om in het water levende organismen te beschermen is toepassing van dit middel op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT90.

This leads to a drift value of 0.2% used for PECsw calculations, based on the current assessment framework as laid down in the Evaluation Manual.

The maximum PEC values for surface water for metsulfuron-methyl and bensulfuron-methyl resulting from entry *via* spray drift were 0.004 and 0.048 µg/L, respectively.

The maximum PEC values for surface water for the metsulfuron-methyl metabolites IN-A4098, IN-F5438, and IN-JX909 were calculated as 0.001, 0.001 and <0.001 µg/L, respectively.

The maximum PEC values for surface water for the bensulfuron-methyl metabolites IN-J0290 and IN-N5297 were calculated as 0.002 and 0.008, respectively.

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

Groundwater monitoring data

There are no data available regarding the presence of the substance metsulfuron-methyl, bensulfuron-methyl or its metabolites in groundwater in the Netherlands.

Surface water monitoring data

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen).

Metsulfuron-methyl

The active substance metsulfuron-methyl was observed in the surface water (the most recent monitoring data is from 2016). One location shows an exceedance of the authorisation threshold/AA-EQS/MAC-EQS. Therefore it has been assessed whether there is a correlation between the observed exceedances and land use types. However the correlation cannot be established based on an exceedance in one location. Therefore, no consequences can be drawn from the observed exceedance.

Bensulfuron-methyl

Bensulfuron-methyl is not an existing active substance in The Netherlands and therefore surface water monitoring data are not available.

Drinking water criterion

Metsulfuron methyl

The active substance metsulfuron-methyl has been on the Dutch market for >3 years (authorised since 17-October-1991). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceedance of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

Bensulfuron-methyl

As bensulfuron-methyl is a new substance, there are no data available regarding its presence in surface water at drinking water abstraction points. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is used for the assessment.

DROPLET Results show that for all drinking water abstraction points the predicted concentrations are below 0.1 µg/L. Therefore, the application of Xanadu is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

3.1.5.4 Predicted environmental concentration in air (PEC_{AIR}) (Part B, Section 5, Point 9.9)

The low vapour pressure (3.3×10^{-10} Pa at 25°C) and Henry's law constant (2.87×10^{-6} Pa m^3 mol^{-1}at 20°C and pH 7) of metsulfuron-methyl indicate that the compound is unlikely to undergo significant volatilisation under practical conditions of use. Moreover, the atmospheric half-life of metsulfuron-methyl due to gas phase hydroxyl radical reaction was calculated to be 49.793 hours under environmental conditions with a diurnal cycle of 12 hours. Therefore, should metsulfuron-methyl reach air, residues in the atmosphere are expected to be readily degraded and would not be subject to significant concerns related to long range atmospheric transport and atmospheric accumulation.

The low vapour pressure (4.99×10^{-9} Pa at 25°C) and Henry's law constant (1.29×10^{-7} Pa m^3 mol^{-1}at 20°C and pH 7) of bensulfuron-methyl indicate that the compound is unlikely to undergo significant volatilisation under practical conditions of use. The atmospheric half-life of bensulfuron-methyl due to gas phase hydroxyl radical reaction was calculated to be 0.611 hours under environmental conditions with a diurnal cycle of 12 hours. Therefore, bensulfuron-methyl residues in the atmosphere are expected to be readily degraded and would not be subject to significant concerns related to long range atmospheric transport and atmospheric accumulation.

Implications for labelling resulting from environmental fate assessment: Based on the endpoints included in the EFSA conclusion (EFSA Journal 2015, 13(1):3936), metsulfuron-methyl cannot be classed as "rapidly degradable". Based on the endpoint included in the EFSA report (EFSA Scientific report (2008) 178, 1-102), bensulfuron-methyl cannot be classed as "rapidly degradable".

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

3.1.6.1 Effects on terrestrial vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Birds

Effects on birds for HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl and bensulfuron-methyl. However further data on HCJ03 is not relevant as active substance data on toxicity to birds is available showing low toxicity to birds and so additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. The risk assessments for HCJ03 with the proposed use pattern are provided here and are considered adequate.

The risk assessment for effects on birds is carried out according to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[1].**

For both metsulfuron-methyl and bensulfuron-methyl the screening step TER values exceed the trigger value of 10 for acute and 5 for long-term risk, indicating the risk to birds is acceptable following use of HCJ03 according to the proposed use pattern. The risk from uptake via drinking water and from secondary poisoning is also considered to be low as both active substances have log P_{OW} <3.0 and so further assessment was not required.

Terrestrial vertebrates (other than birds)

The effects on terrestrial vertebrates other than birds for HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl or bensulfuron-methyl. Further data on HCJ03 is not relevant as the toxicity to terrestrial vertebrates can be estimated from the toxicity of the active substances, in accordance with the EFSA guidance and so additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review.

The risk assessment for effects on mammals is carried out according to **EFSA Guidance Document on Risk Assessment for Birds and Mammals** 2009.

The acute and long-term risks for metsulfuron-methyl and bensulfuron-methyl to wild mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with the active substances and maximum predicted residues occurring on cereals calculated according to the intended use pattern. Acceptable acute risk from both substances was shown at the screening step with TER values exceeding the trigger value of 10 and for the chronic risk also at the screening step with TER values exceeding the trigger value of 5. The risk from update via drinking water and from secondary poisoning is also considered to be low as both active substances have log P_{OW} <3.0 and so further assessment was not required.

3.1.6.2 Effects on aquatic species (Part B, Section 6, Point 10.2)

Effects on aquatic organisms for HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl and bensulfuron-methyl. Data on HCJ03 is evaluated here and risk assessments for HCJ03 with the proposed use pattern are provided and are considered adequate.

In accordance with the national requirements for The Netherlands an assessment of the potential for metsulfuron-methyl and bensulfuron-methyl to reach surface water following application to field crops using TOXSAW GUI version 2.1 under typical conditions in The Netherlands.

[1] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009

Acceptable acute and chronic risk to fish, aquatic invertebrates and algae was shown for metsulfuron-methyl, bensulfuron-methyl and relevant metabolites based on the intended application of HCJ03 based on maximum initial PECsw values. For metsulfuron-methyl acceptable risk to aquatic plants was shown also based on maximum predicted exposure. For bensulfuron-methyl acceptable risk was shown with the inclusion of 90% drift reducing nozzles (0.2 % drift).

In accordance with the Ctgb requirements the combination toxicity of the product has also been assessed on the basis of the toxicity of the active substances. The resulting TER values for fish, aquatic invertebrates and algae each exceed the trigger values. For aquatic plants the calculated combined toxicity exceeds the trigger value of 10 with the addition of 90% drift reducing nozzles (0.2% drift). Assessment of the risk to aquatic plants, based on EyC50 of 0.000365 mg/L from the study with *Lemna gibba* as well as the formulation endpoint indicated acceptable risk with the addition of 90% drift reducing nozzles (0.2% drift) and so is consistent with the mitigation required for the risk assessment with bensulfuron-methyl.

3.1.6.3 Effects on bees and other arthropod species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees for HCJ03 formulation have not been evaluated as part of an EU review for either metsulfuron-methyl or bensulfuron-methyl. Therefore data on HCJ03 are provided here and the risk assessment with the proposed use pattern are considered acceptable.

The risk of HCJ03 to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with HCJ03, metsulfuron-methyl and bensulfuron-methyl, and the maximum single application rate of 100 g formulation/ha (equivalent to 4 g metsulfuron-methyl/ha and 50 g bensulfuron-methyl/ha). The calculated hazard quotients for the product and both active substances were below the trigger of 50 for acute oral and contact exposure, and so the risk to bees based on the intended use is considered to be acceptable.

Other non-target arthropods

Effects on arthropods other than bees of HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl or bensulfuron-methyl. Therefore all relevant data and assessments are provided here and are considered adequate.

Tier I in-field assessments indicated an acceptable risk to non-target arthropods based on maximum exposure. The resulting HQ values for in-field were below the relevant triggers indicating an acceptable risk.

The off-field risk to non-target arthropods was assessed based on drift rates specific to The Netherlands national requirements. The standard amount of drift for field crops in The Netherlands is set at 5.5%. For the intended application rate of 100 g HCJ03/ha the standard drift factor (% drift/100) is therefore 5.5/100 = 0.055. The off-field risk assessment resulted in HQ values lower than the relevant trigger indicating an acceptable risk.

3.1.6.4 Effects on earthworms and other soil macro-organisms (Part B, Section 6, Point 10.6)

Effects on earthworms and other soil non-target macro-organisms of HCJ03 were not evaluated as part of the EU review of bensulfuron-methyl and metsulfuron-methyl. Therefore all relevant data and assessments are provided here and are considered adequate. Based on the maximum predicted concentrations in soil following application of HCJ03, acceptable risk to earthworms and other soil macro-organisms was shown for both active substances and their metabolites. The risk to soil organisms from HCJ03 is therefore considered to be low.

Earthworms

Acute earthworm toxicity studies have been carried out with metsulfuron-methyl, bensulfuron-methyl and their metabolites. The acute toxicity of metsulfuron-methyl and bensulfuron-methyl to earthworms is

low, with an LC_{50} value of >1000 mg/kg reported for both substances. The risk to earthworms is therefore determined to be very low and no significant effects based on the intended application of HCJ03 are predicted.

Studies on the chronic effects of metsulfuron-methyl and bensulfuron-methyl to earthworms were not conducted as the acute toxicity was shown to be low (LC_{50} >1000 mg a.s./kg soil) and as the substances degrade relatively rapidly under field conditions with only one intended application made per season, chronic exposure is unlikely. Chronic effects on earthworms from the active substances is therefore predicted to be limited. The chronic toxicity of the product HCJ03 has been assessed to provide a protective assessment of potential risks from both active substances. Chronic earthworm toxicity studies have also been carried out with the metsulfuron-methyl metabolites IN-A4098, IN-00581, IN-NC148 and IN-F5438 and also showed toxicity to be low. The resulting TER values for HCJ03, metsulfuron-methyl and bensulfuron-methyl exceeded relevant triggers indicating an acceptable risk.

Effects on other soil non-target macro-organisms

The toxicity of the active substances to non-target soil macro-organisms is considered to be low as both active substances have field DT_{90} <100 days and only a single application of HCJ03 is recommended per year, indicating that there will be limited long-term exposure to soil macro-organisms. In the EFSA conclusion for bensulfuron-methyl it was noted that due to the low toxicity of the residues of the substance to earthworms and non-target arthropods, further studies with soil macroorganisms were not warranted. The toxicity of the product HCJ03 to *Folsomia candida* has been assessed. The risk of HCJ03 to other non-target soil macro-organisms, as represented by collembola, was assessed from toxicity exposure ratio (TER) between the toxicity endpoints and the maximum soil PECs. The resulting TER value exceeds the trigger value of 5 and so indicates acceptable risk.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

No tests are required considering the persistence trigger in accordance with the EU Guidance Document, since the field DT_{90} is <365 days for both metsulfuron-methyl and bensulfuron-methyl and only a single application is recommended per year, indicating that there will be no long-term exposure or accumulation of residues.

3.1.6.6 Effects on soil non-target micro-organisms (Part B, Section 6, Point 10.7)

Effects on soil micro-organisms for HCJ03 were not evaluated as part of the EU review of either metsulfuron-methyl or bensulfuron-methyl. Therefore all relevant data were assessed in the EU review. Risk assessments for HCJ03 with the proposed use pattern were provided and are considered adequate.

The risk of HCJ03, metsulfuron-methyl and bensulfuron-methyl and relevant metabolites to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with soil PECs.

All no effect levels exceed the relevant PEC values by a factor of at least 5, indicating that HCJ03 does not pose an unacceptable risk to soil micro-organisms.

3.1.6.7 Assessment of potential for effects on other non-target organisms (flora and fauna) (Part B, Section 6, Point 10.8)

Non-Target Plants

Effects on non-target plants for HCJ03 were not evaluated as part of the EU review of metsulfuron-methyl or bensulfuron-methyl. Therefore all relevant data were assessed in the EU review. During the commenting round, two member states expressed doubts on the risk assessment for non-target terrestrial plants because the most sensitive species for metsulfuron-was is not included (white mustard – 0.054 g a.s./ha according to EFSA Conclusion 2015) in the non-target plant tests of HCJ03. The Ctgb asked the applicant to address this issue for the Dutch addendum. The applicant tried to address the risk by using endpoints from another previously authorized formulation and proposing buffer zones.

The Ctgb did not agree with the applicant's risk assessment because the applicant has proposed to use endpoints from another formulation which contains only metsulfuron methyl, while the current formulation contains both metsulfuron methyl as well as bensulfuron methyl. Therefore, the effects of the current formulation on non-target plants could not be sufficiently addressed using data from the alternative formulation suggested by the applicant.

Therefore, the Ctgb proposed an alternative risk assessment. In order to achieve a conservative risk assessment and considering the fact that the most sensitive endpoint available is for metsulfuron methyl on white mustard (in the EFSA LoEP), all formulation endpoints from the current formulation were expressed as metsulfuron methyl. This dataset was then combined with the metsulfuron methyl endpoint of 0.054 g a.s./ha. A HC_5 value was calculated and compared with the exposure of metsulfuron methyl alone and a TER (trigger 2) was calculated. The endpoint for Bensulfuron methyl was taken from the list of endpoints in the RAR. This value was compared with the exposure for bensulfuron methyl alone and a TER (trigger 5) was calculated. Finally, combination toxicity was calculated. A TERcombi of 0.2 (trigger 0.2) was obtained indicating acceptable risk only if risk mitigation measures were used. These measures were based on the PRI report submitted by the applicant. The applicant responded to this assessment by requesting the Ctgb to consider all available data from the RAR for metsulfuron methyl for white mustard. This includes not only the endpoint of 0.054 g as/ha but also two other endpoints from separate studies. The applicant proposed to use a geomean of these three values in the HC5 calculation conducted by the Ctgb. Also, the applicant proposed to lower the trigger for metsulfuron methyl to 1 instead of 2 because the HC5 value was lower than the lowest geomean endpoint for white mustard. The Ctgb did agree with the applicant that all available information should be considered. However, it is important to bear in mind that the geomean calculation combines endpoints based on different factors i.e. biomass or shoot height and this introduces some form of uncertainty. Further uncertainty is introduced by the fact that the endpoints for white mustard from the RAR come from a formulation with only metsulfuron methyl. If bensulfuron methyl were also present in this formulation then the endpoint may be even lower. The Ctgb has made a comparison between the endpoints for Xanadu (expressed as g MSM/ha) and those for similar species exposed to the representative formulation from the RAR (also expressed as g MSM/ha). It was evident that most endpoints for Xanadu are lower (> factor 5) than the formulation in the RAR, except for sugar beet, soyabean and tomato. Therefore, the endpoints from the RAR do introduce some form of uncertainty into the assessment. Therefore, in a pragmatic approach, the Ctgb used the reconverted endpoints from Xanadu along with the geomean of the 3 endpoints of white mustard from the RAR, as proposed by the applicant to calculate an HC5. This was also presented in the applicant's response above and an HC5 value of 0.1069 g msm/ha will be used in the risk assessment. However, the Ctgb did not agree with the applicant's proposal of reducing the safety factor to 1 just because the HC5 value is lower than the lowest geomean endpoint. In fact, with all the uncertainties mentioned above, a safety factor of 2 was used in the risk assessment.

In order to compare like with like, all formulation endpoints for Xanadu were also expressed as g Bensulfuron methyl/ha. A HC5 value of 2.08 g BSM/ha was calculated for all these species. The HC5 values for both MSM and BSM were used in the risk assessment for individual as well as combination toxicity. The individual as well as combinations TER values were above the trigger of 2. Note that by converting the formulation endpoints to MSM and BSM, possible synergistic effects might be slightly magnified in the calculation, meaning that this could be considered conservative. Therefore, the risk is considered acceptable.

Therefore, the following restriction sentence must be placed on the label:

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing van dit middel uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT95.

Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

3.1.7 Efficacy (Part B, Section 7, Point 8)

This dossier concerns the registration of the new herbicide Xanadu (product code HCJ03) which is formulated is a Water-dispersible Granule (WG) and contains the active substances metsulfuron-methyl (40g/kg) and bensulfuron-methyl (500g/kg). The combination of the two active substances in the product Xanadu is the first association of both actives where authorisation is being sought for in NL. Moreover, up to the date of this evaluation, only herbicides including the active substance metsulfuron-methyl are authorized in NL and no products that contain the active bensulfuron-methyl.

Authorization is being sought for broadleaved weed control by means of a post-emergence spray application in (major) cereal crops; wheat (winter & spring), barley (winter & spring), rye (winter & spring), triticale and oats (for more detailed information regarding claimed uses reference is made to section 2.3 "Product uses (only national GAP)").

A total of 76 valid efficacy trials are submitted within this dossier, trials were carried out between 2012- and 2014 across all EPPO Climatic Zones in the Central Registration Zone (AT [5 trials], BE [1 trial], BG [4 trials], CZ [3 trials], DE [7 trials], DK [6 trials], FI [2 trials], FR [6 trials], HU [7 trials], LT [3 trials], LV [5 trials], NL [3 trials], PL [8 trials], RO [4 trials], SE [4 trials], SK [2 trials] & UK [6 trials]).

Trials were conducted in (major) cereal crops winter wheat, TRZAW (30 trials); winter barley, HORVW (13 trials); winter rye, SECCW (3 trials); spring wheat, TRZAS (7 trials); spring barley, HORVS (11 trials); winter & spring triticale, TTLWI & TTLSO (5 trial); winter & spring durum wheat, TRZDU (5 trials) and oats, AVESA (2 trials). Across all trials and EPPO Climatic Zones (multiple) data were generated on, for NL major, **annual** broadleaved weed species such as CHEAL, GALAP, MATCH, PAPRH, POLAV, POLCO, POLLA, POLPE, STEME,VERHE, VERPE and VIOAR. As efficacy was not determined on perennial broadleaved weed species but only on annual this will be specific mentioned in the table of uses on the Dutch label.

All trials were conducted according to general EPPO guidelines PP 1/135 (3), PP 1/152 (3/4), PP 1/181 (3/4) and specific EPPO guideline PP 1/93(3) 'Weeds in cereals'.

Therefore all the data regarding the efficacy of the product have been submitted. These data demonstrate that Xanadu (HCJ03) fulfils all criteria for the authorisation of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC)/Regulation (EC) No. 1107/2009.

EFFICACY

Preliminary trials

In 15 preliminary efficacy trials the inclusion of both the active substances metsulfuron-methyl and bensulfuron-methyl as well as the ratio of both actives was sufficiently justified in terms of improved efficacy on annual broadleaved weeds PAPRH, VERSS and GALAP.

Minimum Effective Dose

In all efficacy trials, Minimum Effective Dose was determined by comparing the efficacy on major (key) weed species GALAP, PAPRH, VERPE & VERHE of the intended dose rate of 100 g/ha Xanadu (delivering 4 g metsulfuron-methyl + 50 g bensulfuron-methyl) as well as lower dose rates 75 g/ha and 50 g/ha (respectively 75% and 50% of the intended dose rate). Based on the generated MED-data it is concluded that the intended dose rate of 100 g/ha Xanadu can be considered as the appropriate Minimum Effective Dose to deliver acceptable control on the tested (key) weed species.

Efficacy

Efficacy was demonstrated in comparison to a wide range of reference products, based on (a combination of) the following actives: amidosulfuron, diflufenican, iodosulfuron-methyl, ioxynil, mecoprop-P,

metsulfuron-methyl, pinoxaden, thifensulfuron-methyl and/or tribenuron-methyl which were, at the moment of trailing, authorized across the different CMS's of the Central Registration zone. For NL comparison, however not included in all trials, an authorized reference product based on 222 g/kg tribenuron-methyl + 111 g/kg metsulfuron-methyl applied a rate of 10 g a.s./ha + 5 g a.s./ha, respectively.

Based on the generated efficacy data on, in NL cereal cultivation, important annual broadleaved weeds species, it is concluded that an application of 100 g/ha Xanadu (HCJ03) achieves sufficient control on annual broadleaved weeds such as CHEAL, GALAP, MATCH, MATSS, PAPRH, POLAV, POLCO, POLLA, POLPE, STEME, VERHE, VERPE, VERSS and VIOAR which was at least comparable to the efficacy achieved by the reference product(s). Therefore, the claimed use of 100 g/ha Xanadu (HJC03) on **annual** broadleaved weeds in different cereal crops is found sufficiently justified and acceptable.

In the proposed GAP the recommended spray volume ranges from 200 to 400 liter water per hectare which is different to the for NL cereal cultivation commonly used 150 to 400 liter per hectare. Therefore the following instruction of use regarding spray volume will be imposed to the Dutch label.

In de teelt van wintertarwe, wintergerst, winterrogge, triticale, haver, zomertarwe, zomergerst en zomerrogge het middel toepassen in 200 - 400 liter water per hectare.

RESISTANCE MANAGEMENT

A full resistance risk analysis according to EPPO guideline PP 1/213(3) 'Resistance risk analysis' was provided within this dossier. Based on the risk analysis the following considerations are been made regarding resistance management.

Both metsulfuron-methyl and bensulfuron-methyl are ALS inhibitors, HRAC Group B. According to the information at www.weedscience.org as of October 2017 there are 53 reported cases of resistance to bensulfuron-methyl globally, 6 reported in Europe (Spain, Italy, and Portugal). These cases affect the following species *Cyperus difformis* (CYPDI), *Alisma plantago-aquatica* (ALSPA) and *Scirpus mucronatus* (SCPMU) all of which have occurred under rice cultivation. According to the same source there are 75 cases of reported resistance to metsulfuron-methyl, 15 of which are in Europe and predominantly affecting *Papaver rhoeas* (PAPRH), *Stellaria media* (STEME), *Senecio vulgaris* (SENVU) and *T. inodorum* (MATIN). Overall, therefore the inherent risk of resistance arising from the mode of action is high.

In terms of the target weed species a number of these would be categorised as a high risk of resistance development, particularly *Papaver rhoeas* (PAPRH) and *Stellaria media* (STEME). Species such as *M. inodorum* (HYPIN) & *T. inodorum* (MATIN) also represent a medium risk of resistance development.

The applicant has considered the use pattern of the product and as ALS inhibiting herbicides are increasingly authorised in crops across the rotation, including certain varieties of oilseed rape (imazamox), potatoes, maize as well as other cereal crops, where often there will be more than one application of a broad-leaved weed herbicide containing an ALS inhibitor. Therefore the unmodified risk is considered to be high.

Therefore the overall resistance risk, which includes the inherent risk of the compounds, the inherent risk of the weed species and agronomic risk, can be concluded as high for broadleaved weeds. Therefore a proper management strategy must be provided from the applicant in the instructions for use.

Key aspects of the Xanadu (HCJ03) weed resistance management strategy are:
- Development of resistance within a weed species can be avoided or delayed by sequencing or tank-mixing with suitable products having a different mode of action.
- Do not use Xanadu (HCJ03) or any other ALS inhibitor herbicide, as a sole means of broadleaved weed control in successive crops. Always use broadleaved weed herbicides with non-ALS mode of action throughout the crop rotation.
- Always monitor effectiveness of weed control and investigate any occurrences of poor effectiveness. If unexplained failure occurs, contact your agronomist who may consider a resistance test appropriate.

The applicant has proposed a strategy which is based on rotation of crops, cultural techniques and herbicide rotation. These are all useful tools to modify the risk of resistance development and the zRMS has concluded that label phrases or appropriate instructions for use are required on a national level. The applicant has made here for the following proposal:

The product contains bensulfuron-methyl and metsulfuron-methyl, which are ALS inhibitors, also classified by the Herbicide Resistance Action Committee as 'Group B'. When herbicides with the same mode of action are used repeatedly over several years in the same field strains of weeds resistant to herbicides may develop. Resistant species survive a correctly applied treatment at the recommended dose. It is recommended that Xanadu will be used as part of a cropping programme which includes the use of herbicides with different modes of action. Do not rely on one herbicide mode of action in the same field over several years.

The zRMS has considered the proposed management strategy as broadly acceptable and therefore resistance management will be implemented on the Dutch label by the placement of the following instruction of use:

Resistentiemanagement: Dit middel bevat de werkzame stoffen metsulfuron-methyl en bensulfuron-methyl. Deze werkzame stoffen behoren tot de sulfonylureum verbindingen. De HRAC code is B. In Nederland zijn onkruiden aangetroffen die resistent zijn tegen werkzame stoffen met HRAC code B. Omdat er binnen deze groep kruisresistentie bestaat, dit middel afwisselen met middelen met een ander werkingsmechanisme. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen op te volgen.

In addition, Dutch labels under WG format 2.1 offer the possibility to apply lower rates than the authorised rates (the label does indicate that efficacy under those circumstances is not tested). For this product, it should be stated on the label, that if the dose rate is lowered, resistance management should be taken into account, the sentence related to lowering of the dose rate should be changed to the following sentence:

* Verlaging van de dosis is toegestaan, hierbij dient rekening gehouden te worden met resistentiemanagement. Van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.

ADVERSE EFFECTS

Phytotoxicity to host crops

In addition to the phytotoxicity symptoms assessed in all efficacy trials, 65 specific crop safety trials were conducted in absence of weeds according to EPPO guidelines PP 1/93 (3) 'Weeds in cereals' and PP 1/135 (3) 'Phytotoxicity assessment'.

The trials were carried out between 2012 and 2014 in Maritime EPPO Climatic Zone (AT, BE, CZ, DE, DK, FR, NL, SE & UK; 36 trials), North-East EPPO Climatic Zone (FI, LT, LV & PL; 18 trials) and South-East EPPO Climatic Zone (HU & SK; 11 trials). Crop safety was determined across a range of commercial varieties in the following cereal crops: winter wheat, TRZAW (14 trials); winter barley, HORVW (10 trials); winter rye, SECCW (5 trials); spring wheat, TRZAS (6 trials); spring barley, HORVS (5 trials); Triticale, TTLWI & TTLSO (9 trials); oat, AVESW & AVESA (4 trials) & durum wheat, TRZDU (5 trials). In all trials crop safety was determined of the intended dose rate 100 g Xanadu (HCJ03) per hectare as well as twice the intended dose rate (200 g per hectare).

Based on the generated data it can be concluded that after an application of Xanadu some slight phytotoxicity symptoms may occur occasionally; however these adverse effects appeared to be transient. Therefore adverse effects to the host crop are considered unlikely as Xanadu is applied per the intended

GAP at a dose rate of 100 g product per hectare. In case Xanadu is overdosed, for example by overlapping spray swaths, there is a clear risk that more severe adverse effects will occur to the host crop. However, as avoiding overlapping spray swatch is considered to be part of Good Agricultural Practice in NL, zRMS recommendation to place an appropriate warning sentence on the national label is considered unnecessary for the Dutch label.

Yield & Quality

In all crop safety trials yield & quality, in absence of weeds, was determined. In a number of crop safety trials a split-plot approach with a single application at two different timings (crop stages) was used to generate twice the information out of an individual trial. Based on the generated data it was concluded that there was no evidence of negative impact on yield and quality from an application of Xanadu (HCJ03) if applied per the intended GAP.

In addition, effects on transformation processes were determined in two bread making studies and eight malting/brewing studies. In the studies the intended dose of 100 g/ha as well as twice the intended dose (200 g/ha) were tested. Based on the data generated, negative effects of an application of 100 g/ha Xanadu on bread-making or brewing can be considered negligible.

Finally, 30 trials were conducted to demonstrate the impact of an application of 100 g/ha Xanadu on treated plant and plant products to be used for propagation. Based on the results, it was concluded that it is highly unlikely that an application of 100 g/ha Xanadu has an impact on germination ability of seeds of treated cereal crops.

Impact on succeeding and adjacent crops

A step-wise assessment on the impact on succeeding crops was carried out following EPPO guideline PP 1/207 (2) 'Effects on succeeding crops'. Based on the results of a number of studies performed within the assessment the applicant concluded that there were risks regarding succeeding crops which were confirmed by the zRMS at evaluation of the dossier. Applicant and zRMS considers that the following instructions of use / warning sentences are relevant to address the risk to succeeding crops on the national label:

- In the autumn immediately following a normal harvest of spring treated cereal crops, either cereals (including wheat, durum wheat, barley, rye and triticale[1]) or oilseed rape may be planted without any restrictions.

- In the following spring, cereals (including wheat, durum wheat, barley, rye, triticale and oats) oilseed rape, sugar beet, peas, tomatoes, onions, soybean, maize or ryegrass can be sown, again without any restrictions.

- Finally, in case of crop failure, only cereals (including wheat, durum wheat, barley, rye and triticale[1]) and soybean may be sown immediately and without restriction.

To implement these instructions of use / warning sentences to the Dutch label the following information will be imposed to the Dutch label:

Volggewassen: In het jaar van toepassing kunnen na de oogst granen en winterkoolzaad veilig worden ingezaaid. In het volgende jaar kunnen ook maïs, bieten, uien, erwten, bonen en raaigras veilig worden ingezaaid. Met het inzaaien of telen van andere gewassen is geen ervaring opgedaan en wordt daarom niet aanbevolen.

Vervanggewassen: Bij het mislukken van een teelt kunnen alleen granen direct als vervangend gewas geteeld worden.

The impact an adjacent crops was assessed following EPPO guideline PP 1/256 (1) 'Effects on adjacent crops'. Based on the assessment, drift was considered to be the main risk for adjacent crops and zRMS recommended therefore to place an appropriate instruction of use to avoid drift on the national label.

However, since avoiding drift to adjacent crops, especially in case of herbicides, is considered common in NL within the principles of Good Agricultural Practice there is no need to implement the recommended warning sentences on the Dutch label.

Impact on beneficials and other non-target organisms

There were no adverse effects on beneficial or other non-target organisms observed in any of the efficacy and crop safety trials. Therefore, from an efficacy point of view, no impact on beneficials or other non-target organisms by an application of 100 g/ha Xanadu are expected. Nevertheless, reference is made to the Ecotoxicology section for further information regarding the impact on beneficials and other non-target organisms.

3.1.8 Substances of concern for national monitoring (Part B, Section 8)

No metabolites of metsulfuron-methyl or bensulfuron-methyl were detected that could be considered as potentially relevant metabolites with respect to groundwater contamination. Therefore there are no metabolites of which would be considered substances of concern for national monitoring.

3.2 Conclusions

The assessment conducted for Xanadu was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted.

3.3 Further Information to Permit a Decision to be Made or to Support a Review of the Conditions and Restrictions Associated with the Authorisation

None.

Appendix 1 Copy of the proposed product label for the Netherlands

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegelaten als onkruidbestrijdingsmiddel voor het professionele gebruik door middel van een na-opkomst toepassing in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Wintertarwe	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Wintergerst	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Winterrogge	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Triticale	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Haver	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Zomertarwe	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Zomergerst	Éénjarige breedbladige onkruiden	0,1 kg/ha	1
Zomerrogge	Éénjarige breedbladige onkruiden	0,1 kg/ha	1

* Verlaging van de dosis is toegestaan, hierbij dient rekening gehouden te worden met resistentiemanagement. Van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.

Overige toepassingsvoorwaarden
Continu roeren tijdens het bereiden en verspuiten van de spuitvloeistof.

In de teelt van wintertarwe, wintergerst, winterrogge, triticale, haver, zomertarwe, zomergerst en zomerrogge het middel toepassen in 200-400 liter water per ha.

Om het grondwater te beschermen mag dit middel niet worden gebruikt in grondwaterbeschermingsgebieden.

Om in het water levende organismen te beschermen is toepassing van dit middel op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT90.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing van dit middel uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT95.

<u>Volggewassen</u>

In het jaar van toepassing kunnen na de oogst granen en winterkoolzaad veilig worden ingezaaid. In het volgende jaar kunnen ook maïs, bieten, uien, erwten, bonen en raaigras veilig worden ingezaaid. Met het inzaaien of telen van andere gewassen is geen ervaring opgedaan en wordt daarom niet aanbevolen.

Vervanggewassen
Bij het mislukken van een teelt kunnen alleen granen direct als vervangend gewas geteeld worden.

Resistentiemanagement
Dit middel bevat de werkzame stoffen metsulfuron-methyl en bensulfuron-methyl. Deze werkzame stoffen behoren tot de sulfonylureum verbindingen. De HRAC code is B. In Nederland zijn onkruiden aangetroffen die resistent zijn tegen werkzame stoffen met HRAC code B. Omdat er binnen deze groep kruisresistentie bestaat, dit middel afwisselen met middelen met een ander werkingsmechanisme. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Appendix 2 Letter of Access

None.

Appendix 3 Reference list

Identity, physical and chemical properties and analytical methods

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Data protection granted Y/N	Justification if data protection is claimed	Owner
CP 2.1/01 2.2.1/01 2.2.2/01 2.3.2/01 2.3.3/01 2.4.2/01 2.6.2/01 2.7.1/01 2.8.1/01 2.8.2/01 2.8.8.1/01 2.8.3.1/01 2.8.3.2/01 2.8.5.2/01 2.8.6.1/01 2.8.6.3/01 2.8.6.5/01	2012	Physical, chemical and technical properties of bensulfuron-methyl/metsulfuron-methyl 50/4/WG (HCJ03), including accelerated storage stability UPL Europe Ltd. Report No. DL 12-130 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL
CP 2.7.5	2014	Shelf life of bensulfuron-methyl/metsulfuron-methyl 50/4/WG (HCJ03) for 2 years at ambient storage conditions in commercial packaging UPL Europe Ltd. Report No. DL 12-131 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL
CP 2.7.2	2015	Shelf life of bensulfuron-methyl/metsulfuron-methyl 50/4/WG (HCJ03) for 3 years at ambient storage conditions in commercial packaging UPL Europe Ltd. Report No. DL 14-116 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Data protection granted Y/N	Justification if data protection is claimed	Owner
CP 4.2.2/01	2014	Bensulfuron-methyl/Metsulfuron-Methyl 50/4 WG (HCJ03) Tank Cleaning UPL Europe Ltd. Report No. DL 14-176 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL
CP 5.2.2/01	2012	Revalidation of SOP DLA-272.4 'Bensulfuron-methyl/metsulfuron-methyl 50/2 and 50/4 formulations, determination of active ingredients by HPLC' and certification of bensulfuron-methyl/metsulfuron-methyl 50/4 WG (HCJ03) batch FL11-112-20F UPL Europe Ltd. Report No. DL 12-129 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL
CP 5.2.2/02	2012a	Validation of SOP DLA-272.4 'Bensulfuron-methyl/metsulfuron-methyl 50/2 and 50/4 formulations, determination of active ingredients by HPLC' and certification of Pull 52 DF (HCJ01) batch 281 DL 11-139 Cerexagri B.V. Rotterdam, The Netherlands GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL
CP 5.2.2/03	2012b	Bensulfuron-methyl/metsulfuron-methyl 50/2 and 50/4 formulations determination of active ingredients by HPLC SOP DLA-272.4 Not GLP, Unpublished	N	Y	N (non-GLP are not liable to receive data protection based on article 59,1(b))	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Data protection granted Y/N	Justification if data protection is claimed	Owner
CP 5.6/01	2015	Validation of an analytical method for the determination of bensulfuron-methyl and its metabolites in drinking water and surface water UPL Europe Ltd. Report S15-01100 Eurofins Agroscience Services Chem Ltd., UK GLP, Unpublished	N	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL

Mammalian toxicology

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection awarded Y/N	Data protection claimed Y/N	Data protection granted Y/N	Owner
CP 7.1.4/01	2015	HCJ03: *in vitro* skin irritation human skin model test Unpublished report no.: HSMI-PH-15/0283 GLP, Unpublished	Y	Y	Y	UPL
CP 7.1.5/03	2015	HCJ03: Isolated chicken eye test method for identifying ocular corrosives and severe irritants Unpublished report no.: ICE-PH-15/0283 GLP, Unpublished	Y	Y	Y	UPL

Residues

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

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Data protection granted Y/N	Owner
CP 8.2/01	2011a	[^{14}C]-Bensulfuron-methyl: Metabolism in Rice Following Foliar Application United Phosphorus Ltd. Report No. AU-2010-16 JRF America Not GLP Unpublished	N	Y	Y	UPL
CP 8.3.1/01	2014	Residues of metsulfuron-methyl and bensulfuron-methyl in wheat at harvest following a single application of HCJ03. northern and southern zone – 2013 United Phosphorus Ltd. Report No. 38SRFR13R01 GLP Unpublished	N	Y	Y	UPL
CP 8.6/01	2011b	[^{14}C]-Bensulfuron-methyl: Uptake of Soil Residues by Wheat United Phosphorus Ltd. Report No. AU-2010-17 JRF America GLP Unpublished	N	Y	Y	UPL

Environmental fate and behaviour

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on	Owner
CP 9.1.1/01	2015	IN-T5831 – Rate of degradation in three soils under aerobic conditions Company Report No. 20140160 ibacon GmbH, Germany GLP, Unpublished	Y	Y	Y	UPL
CP 9.3.1/01	2015	IN-T5831 – Adsorption/desorption behaviour Company Report No. 104121295 Innovative Environmental Services (IES) Ltd., Switzerland GLP, Unpublished	Y	Y	Y	UPL

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on	Owner
CP 9.7.1/01	2015a	A modelling assessment for metsulfuron-methyl and its metabolites in surface water using the TOXSWA model following application to cereal crops in The Netherlands Company Report No. UPL/12/05-SW8 JSC International Limited, UK Not GLP, Unpublished	N	N	Y	UPL
CP 9.7.1/02	2015b	A modelling assessment for bensulfuron-methyl and its metabolites in surface water using the TOXSWA model following application to cereal crops in The Netherlands Company Report No. UPL/12/05-SW7 JSC International Limited, UK Not GLP, Unpublished	N	N	Y	UPL

Ecotoxicology

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on Y/N	Owner
CP 10.4.2.1/01	2014	Effects of HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl*WG) (Acute contact and oral) on Honey bees (*Apis mellifera* L.) in the laboratory. Company report no. 85097035 Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.5.1/01	2014a	Effects of Code: HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl*WG) on the predatory mite *Typhlodromus pyri* in the laboratory-Dose response test. Company report no. 85096063 Ibacon GmbH, Germany GLP	Y	Y	Y	UPL

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on Y/N	Owner
		Unpublished				
CP 10.5.1/02	2014b	Effects of Code: HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl*WG) on the parasitoid *Aphidius rhapolosiphi* in the laboratory-Dose response test. Company report no. 85095001 Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.6.2/01	2014	HCJ03 (500 g/kg Bensulfuron-methyl + 40 g/kg Metsulfuron-methyl*WG): effects on reproduction and growth of earthworms *Eisenia fetida* in Artificial Soil with 10% Peat Company report no. 99681022. Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.6.6/01	2014	Effects of HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl *WG) on Reproduction of the Collembola *Folsomia candida* in artificial soil. Company report no. 85091016 Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.7.1/01	2015	HCJ03 (500 g/kg Bensulfuron-methyl + 40 g/kg Metsulfuronmethyl*WG): Effects on the activity of the soil microflora in the laboratory. Company report no. 99681080. Ibacon GmbH, Germany	Y	Y	Y	UPL

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on Y/N	Owner
		GLP Unpublished				
CP 10.8.1.2/01	2014a	Effects of HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl *WG) on terrestrial (non-target) plants: Vegetative vigour Company report no. 85090087 Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.8.1.3/01	2014b	Effects of HCJ03 (500 g/kg bensulfuron-methyl + 40 g/kg metsulfuron-methyl *WG) on terrestrial (non-target) plants: Seedling emergence and seedling growth test Company report no. 85090086 Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.8.2/01	2015	Toxicity of HCJ03 to the Aquatic Plant *Myriophyllum spicatum* in a static growth inhibition test with a prior rooting phase. Company report no. 85091215. Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.8.2.1/01*	2016a	Bensulfuron/Metsulfuron 50/4 WG (HCJ03): Toxicity to the Aquatic Plant *Lemna gibba* in a Static Growth Inhibition Test. Ibacon GmbH, Germany GLP Unpublished	Y	Y	Y	UPL
CP 10.8.1/01	2009	Spray drift and required buffer zones – An off-field evaluation of the	N	N	Y	n.a.

Data point	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Data protection granted Y/N	Study relied on Y/N	Owner
		AGRICHEM herbicide Fluroxypyr 200 g/L EC used in grassland, cereals and maize crops in the Netherlands – Confidential Report, Plant Research International B.V., Wageningen, The Netherlands Non-GLP Unpublished				
10.8.1.1/ 01	2009a	Metsulfuron-methyl 20% Wg: A toxicity test to determine the effects of the test substance on vegetative vigour of six species of plants Wildlife International, Ltd. 8598 Commerce Drive, Easton, Maryland 21601, USA Project no. 525-121 GLP, Unpublished	Y	Y	Y	AgriChem B.V.
10.8.1.2/02	2011a	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of four species of plants Wildlife International, Ltd. 8598 Commerce Drive Easton, Maryland 21601 USA Project no. 525-138 GLP, Not published	Y	Y	Y	AgriChem B.V.
10.8.1.2/03	2011b	Metsulfuron-methyl 20% WG: A toxicity test to determine the effects of the test substance on vegetative vigour of six species of plants Wildlife International, Ltd. 8598 Commerce Drive Easton, Maryland 21601 USA Project no. 525-141 GLP, Not published	Y	Y	Y	AgriChem B.V.

Efficacy

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.0	2015	Biological Assessment Dossier (BAD): Summary of the Efficacy Data and Information on the Plant Protection Product for HCJ03 - Core assessment. Syntech Research Trial / Protocol no.: n/a GEP: n.a., Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2010	Attività e selettività di diserbanti applicati in post-emergenza del frumento tenero. Universita Degli Studi di Bologna Trial / Protocol no.: 2010 - Bologna University GEP: N Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Attività e selettività di diserbanti applicati in post-emergenza del frumento duro. Universita Degli Studi di Bologna Trial / Protocol no.: 2011 - Bologna University GEP: N Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Efficacy and selectivity of HCJ01 applied in post-emergence on durum wheat. Consorzio Agrario de Ravenna Soc. Coop a r.l. Trial / Protocol no.: CSE37011 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Efficacy and selectivity evaluation of herbicides used in post-emergence application on durum wheat. Terremerse Soc. Coop. Trial / Protocol no.: CSD12011 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Efficacy and selectivity of HCJ01 applied in winter wheat in post-emergence. Agri 2000 Trial / Protocol no.: A11-115-09HE / 09A11HE1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Efficacy and selectivity of HCJ01 applied in winter wheat in post-emergence. Agri 2000 Trial / Protocol no.: A11-116-09HE / 09A11HE1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2011	Efficacia e selettivita di HCJ01 applicato su frumento in post-emergenza. Caip Consorzio Agrario Bologna e Modena Centro di Saggio Trial / Protocol no.: H-05-11 / n.a. GEP Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.1	2012	Verifica dell'attivita e selettivita di forumati dicotiledonicidi impiegati trattamenti di post-emergenza del frumento Universita degli Studi di Bologna Trial / Protocol no.: 2012 - Bologna University / n.a GEP: N Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2012	Efficacy and selectivity evaluation of herbicides used in post-emergence application on winter cereals. Caip Consorzio Agrario Bologna e Modena Centro di Saggio Trial / Protocol no.: H-01-12 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2012	Efficacy and selectivity of HCJ03 applied in post-emergence on winter wheat. Consorzio Agrario di Ravenna Soc. Coop a r.l. Trial / Protocol no.: CSE22012 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2012	Effects of HCJ03, HCG01 and HBS02 on succeeding crops. Consorzio Agrario di Ravenna Soc. Coop a r.l. Trial / Protocol no.: CSE23012 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2012	Efficacy and selectivity evaluation of herbicides used in post-emergence application on soft wheat. Terremerse Soc. Coop. Trial / Protocol no.: CSD10012 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2013	Efficacy and selectivity evaluation of herbicides used in post-emergence application on durum wheat. Terremerse Soc. Coop. Trial / Protocol no.: CSD15013 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2013	Efficacy and selectivity evaluation of herbicides applied in post-emergence application on soft wheat. Terremerse Soc. Coop. Trial / Protocol no.: CSD16013 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.1	2013	Efficacy and selectivity of HCG01, straight and tank-mixed, applied in post-emergence on wheat. Consorzio Agrario de Ravenna Soc. Coop a r.l. Trial / Protocol no.: CSE20013 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.1	2013	Efficacy and selectivity evaluation of herbicide applied in post-emergence application on winter cereals. Consorzio Agrario dell'Emilia. Trial / Protocol no.: H-01-13 / n.a. GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Bensulfuron-methyl / Metsulfuron-methyl WG (HCJ03): Efficacy against annual broadleaf weeds when applied post-emergence and crop selectivity in Winter Cereals. SynTech Research Austria – ATC Trial / Protocol no.: SRAT12-001-38HE / 38SRX12E3 GEP: Yes Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Bensulfuron-methyl / Metsulfuron-methyl WG (HCJ03): Efficacy against annual broadleaf weeds when applied post-emergence and crop selectivity in Winter Cereals. SynTech Research Austria - ATC Protocol no.: SRAT12-002-38HE / 38SRX12E3 Yes Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03: Efficacy and Crop selectivity in Winter Cereals. SynTech Research GmbH Trial / Protocol no.: SRDE12-001-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03: Efficacy and Crop selectivity in Winter Cereals. SynTech Research GmbH Trial / Protocol no.: SRDE12-002-38HE / 38SRX12E3 GEP :Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Efficacy test of Herbicide in Winter cereals. Agrolab A/S Trial / Protocol no.: SRDK12-001-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Efficacy test of Herbicide in Winter cereals. Agrolab A/S Trial / Protocol no.: SRDK12-002-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03 (500 + 40 g/kg bensulfuron + metsulfuron): efficacy and crop selectivity in winter barley. SynTech Research France S.A.S Trial / Protocol no.: SRFR12-108-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03 (500 + 40 g/kg bensulfuron + metsulfuron): efficacy and crop selectivity in winter cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR12-109-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Bensulfuron/metsulfuron: efficacy and crop selectivity in winter wheat. SynTech Research Hungary Kft Trial / Protocol no.: SRHU12-023-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Bensulfuron/metsulfuron: efficacy and crop selectivity in winter wheat. SynTech Research Hungary Kft Trial / Protocol no.: SRHU12-024-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	Bensulfuron-methyl/ Metsulfuron-methyl WG (HCJ03): Efficacy against annual broadleaf weeds when applied post-emergence and crop selectivity in Winter Cereals. SynTech Research Austria – ATC Trial / Protocol no.: SRAT12-003-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03: weed control efficacy and crop selectivity when applied in winter wheat. SynTech Research UK Trial / Protocol no.: SRUK12-032-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2012	HCJ03: weed control efficacy and crop selectivity when applied in winter wheat. SynTech Research UK Trial / Protocol no.: SRUK12-033-38HE / 38SRX12E3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria – ATC Trial / Protocol no.: SRAT13-013-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria – ATC Trial / Protocol no.: SRAT13-014-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria - ATC Trial / Protocol no.: SRAT13-015-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Determination of Efficacy and Crop safety of HCJ03 against broadleaved weeds in Cereals, 2 sites in Bulgaria 2013. Eurofins Agrosciences Services Trial / Protocol no.: S13-01902-01 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Determination of Efficacy and Crop safety of HCJ03 against broadleaved weeds in Cereals, 2 sites in Bulgaria 2013. Eurofins Agrosciences Services Trial / Protocol no.: S13-01902-02 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Czech Republic - ATC Trial / Protocol no.: SRCZ13-016-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research GmbH Trial / Protocol no.: SRDE13-001-206HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research GmbH Trial / Protocol no.: SRDE13-002-206HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research GmbH Trial / Protocol no.: SRDE13-003-206HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria - ATC Trial / Protocol no.: SRDE13-005-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-07 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-09 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-1038SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-01 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-02 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-126-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-127-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-128-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-013-38HE / 38SRX13E1- GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-014-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-015-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-016-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-03 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-04 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-05 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and crop selectivity in cereals with HCJ03 in the Netherlands in 2013. Agrichem B.V. Trial / Protocol no.: 201301028021302 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and crop selectivity in cereals with HCJ03 in the Netherlands in 2013. Agrichem B.V. Trial / Protocol no.: 201301028021303 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and crop selectivity in cereals with HCJ03 in the Netherlands in 2013. Agrichem B.V. Trial / Protocol no.: 201301028021304 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and selectivity of product HCJ03 in control of dicotyledonous weed plants in cereals: TRZAW/Triticum aestivum/winter wheat in Poland. Staphyt Trial / Protocol no.: MZA-1316146-PL01 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and selectivity of product HCJ03 in control of dicotyledonous weed plants in cereals: HORVW (Hordeum vulgare/winter) in Poland. Staphyt Trial / Protocol no.: MZA-1316146-PL02 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and selectivity of product HCJ03 in control of dicotyledonous weed plants in cereals: HORVW (Hordeum vulgare/winter) in Poland. Staphyt Trial / Protocol no.: MZA-1316146-PL03 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and selectivity of product HCJ03 in control of dicotyledonous weed plants in cereals: TRZAS (Triticum aestivum spring) in Poland. Staphyt Trial / Protocol no.: MZA-1316146-PL04 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	Efficacy and selectivity of product HCJ03 in control of dicotyledonous weed plants in cereals: HORVS (Hordeum vulgare spring) in Poland. Staphyt Trial / Protocol no.: MZA-1316146-PL05 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2013. Eurofins Agroscience Services GmbH Trial / Protocol no.: S13-02491-01 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2013. Eurofins Agroscience Services GmbH Trial / Protocol no.: S13-02491-02 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-06 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. Agrolab A/S Trial / Protocol no.: 38SRX13E1-1-08 / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria - ATC Trial / Protocol no.: SRAT13-017-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03 (500+40 g/L bensulfuron-methyl+metsulfuron-methyl): Efficacy and Crop selectivity in winter wheat. SynTech Research UK Trial / Protocol no.: SRUK13-014-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03: Efficacy and Crop selectivity in Winter Barley. SynTech Research UK Trial / Protocol no:. SRUK13-015-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2013	HCJ03 (500+40 g/L bensulfuron-methyl+metsulfuron-methyl): Efficacy and Crop selectivity in spring barley. SynTech Research UK Trial / Protocol no.: SRUK13-016-38HE / 38SRX13E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria - ATC Trial / Protocol no.: SRAT14-035-38HE / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Evaluation of the efficacy and crop selectivity of HCJ03 in winter wheat. Redebel Trial / Protocol no.: R089-14H / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Evaluation of the efficacy and crop selectivity of HCJ03 in winter wheat. Redebel Trial / Protocol no.: R090-14H / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Durum Wheat. SynTech Europe. Spring 2014. 1 site in Bulgaria Eurofins Agroscience Services Austria Trial / Protocol no.: S14-02144-01 / S14-02144 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Determination of efficacy and crop safety of HCJ03 against annual broad leaved weeds in winter wheat, 1 site in Bulgaria 2014 Eurofins Agroscience Services Austria Trial / Protocol no.: S14-02143-01 / S14-02143 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Research Austria - ATC Trial / Protocol no. SRCZ14-012-38HE / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Determination of Efficacy of HCJ03 when applied post-emergence against annual broadleaved weeds in Spring Triticale, 1 site in Germany 2014 Eurofins Agroscience Services Trial / Protocol no.: 38SRX14E1-1_01 / S14-02641 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Winter Rye . SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-08 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and crop selectivity in cereals. SynTech Europe. Spring 2014. SynTech Research France S.A.S Trial / Protocol no.: SRFR14-077-38HE / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: efficacy and crop selectivity in cereals. SynTech Europe. Spring 2014 SynTech Research Hungary Kft Trial / Protocol no.: SRHU14-236-38HE / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in cereals (Winter Wheat). SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-03 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Spring Barley. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-04 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Winter Rye. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-05 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. (winter wheat) SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-01 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in winter cereals (Winter Rye). SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-02 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2014 SynTech Research Poland Trial / Protocol no.: 38SRX14E1-1_PL01 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2014 SynTech Research Poland Trial / Protocol no.: 38SRX14E1-1_PL02 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2014 SynTech Research Poland Trial / Protocol no.: 38SRX14E1-1_PL / 0338SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Determination of Efficacy and Crop Safety of HCJ03 when applied post-emergence against annual broadleaved weeds in Winter Wheat, 2 Sites in Romania 2014 Eurofins Agroscience Services Austria Trial / Protocol no.: S14-01810-01 / S14-01810 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	Determination of Efficacy and Crop Safety of HCJ03 when applied post-emergence against annual broadleaved weeds in Winter Wheat, 2 Sites in Romania 2014 Eurofins Agroscience Services Austria Trial / Protocol no.: S14-01810-02 / S14-01810 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Spring Oats. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-06 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Spring Barley. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-1-07 / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.2.2 KCP 6.2.3 KCP 6.4.1	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2014 SynTech Research UK Trial / Protocol no.: SRUK14-045-38HE / 38SRX14E1-1 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.3	2012	HCJ03 (500+40 g/L bensulfuron-methyl + metsulfuron-methyl): Grassweed activity - Glasshouse herbicide screen. UK. SynTech Research UK Trial / Protocol no.: SRUK12-103-38HE / 38SRX12E13 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	Bensulfuron-methyl/ Metsulfuron-methyl WG (HCJ03): Crop selectivity when applied post-emergence in Durum Wheat. SynTech Research Austria - ATC Trial / Protocol no.: SRAT12-004-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	Bensulfuron-methyl/ Metsulfuron-methyl WG (HCJ03): Crop selectivity when applied post-emergence in Winter Barley. SynTech Research Austria - ATC Trial / Protocol no.: SRDE12-014-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	HCJ03 (500 + 40 g/kg bensulfuron + metsulfuron: crop selectivity in winter cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR12-111-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	Bensulfuron/metsulfuron: crop selectivity in winter wheat. SynTech Research Hungary Kft Trial / Protocol no.: SRHU12-025-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	HCJ03: crop selectivity when applied in winter wheat. SynTech Research UK Trial / Protocol no.: SRUK12-034-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2012	HCJ03: crop selectivity when applied in winter barley. SynTech Research UK Trial / Protocol no.: SRUK12-035-38HE / 38SRX12E4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research Austria - ATC Trial / Protocol no.: SRAT13-018-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research Austria - ATC Trial / Protocol no.: SRCZ13-019-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research Austria - ATC Trial / Protocol no.: SRCZ13-020-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research Austria - ATC Trial / Protocol no.: SRDE13-007-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research Austria - ATC Trial / Protocol no.: SRDE13-008-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. Agrolab A/S Trial / Protocol no.: 38SRX13E1-2-02 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-122-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Winter Wheat). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL01 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Winter Barley). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL02 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Spring Wheat). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL03 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Spring Oats). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL04 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Spring Barley). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL05 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Spring Triticale). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL06 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	Selectivity of HCJ03 in cereals (Winter Rye). Poland. 2013 Staphyt Trial / Protocol no.: MZA-13-16147-PL07 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Single Timing. Agrolab A/S Trial / Protocol no.: 38SRX13E1-2-03 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.4	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-123-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.4	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Europe. Spring 2013 SynTech Research France S.A.S Trial / Protocol no.: SRFR13-124-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.4	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SynTech Europe. Spring 2013 SynTech Research France S.A.S Trial / Protocol no.: SRFR13-125-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. Single Timing. Agrolab A/S Trial / Protocol no.: 38SRX13E1-2-05 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. Single Timing. Agrolab A/S Trial / Protocol no.: 38SRX13E1-2-01 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. Single Timing. Agrolab A/S Protocol no.: 38SRX13E1-2-04 / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Research Austria - ATC Protocol no.: SRAT13-082-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Research Austria - ATC Protocol no.: SRCZ13-022-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity, two timings, post-emergence application on winter cereals. SynTech Research France S.A.S Protocol no.: SRFR13-118-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research Hungary Kft Protocol no.: SRHU13-017-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Protocol no.: 38SRX13E1-3-02 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Research GmbH Protocol no.: SRSK13-023-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2013	HCJ03 (500+40 g/L bensulfuron-methyl+metsulfuron-methyl): crop selectivity in winter oat. SynTech Research UK Trial / Protocol no.: SRUK13-018-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Winter Rye. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-2-01 / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Winter Rye. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-2-02 / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	Determination of Crop safety of HCJ03 when applied post-emergence in Winter Triticale, 2 Sites in Germany 2014 Eurofins Agroscience Services Trial / Protocol no.: 38SRX14E1-2_02 / S14-02642 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Research Austria - ATC Trial / Protocol no.: SRAT14-013-38HE / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Research Austria - ATC Trial / Protocol no.: SRAT13-021-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research GmbH Trial / Protocol no.: SRDE13-004-206HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Trial / Protocol no.: 38SRX13E1-3-05 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Trial / Protocol no.: 38SRX13E1-3-0638SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity, two timings, post-emergence application on winter cereals. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-117-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-018-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-019-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-020-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SynTech Research Hungary Kft Trial / Protocol no.: SRHU13-021-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Trial / Protocol no.: 38SRX13E1-3-01 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Trial / Protocol no.: 38SRX13E1-3-03 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	Crop selectivity in cereals with HCJ03 in the Netherlands in 2013. Agrichem B.V. Trial / Protocol no.: 2013.01.028.02.1322 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	Crop selectivity in cereals with HCJ03 in the Netherlands in 2013. Agrichem B.V. Trial / Protocol no.: 2013.01.028.02.1323 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. Agrolab A/S Trial / Protocol no.: 38SRX13E1-3-04 / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2013	HCJ03 (500+40 g/L bensulfuron-methyl+metsulfuron-methyl): crop selectivity in winter barley. SynTech Research UK Trial / Protocol no.: SRUK13-017-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	HCJ03: Efficacy and Crop selectivity in Cereals. SynTech Europe. Spring 2014 SynTech Research Poland Trial / Protocol no.: 38SRX14E1-2_PL01 / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	Evaluation of the selectivity of HCJ03 in winter barley. Redebel Trial / Protocol no.: R091-14H / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	Determination of Crop safety of HCJ03 when applied post-emergence in Winter Triticale, 2 Sites in Germany 2014 Eurofins Agroscience Services Trial / Protocol no.: 38SRX14E1-2_01 / S14-02642 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	HCJ03: Crop selectivity in Cereals. Two Timings. SynTech Europe. Spring 2014 SynTech Research Hungary Kft Trial / Protocol no.: SRHU14-237-38HS / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	HCJ03: Crop selectivity in Winter Wheat and Crop Carryover Effect in Field Peas. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-3-01 / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	HCJ03: Crop selectivity in Spring Wheat and Crop Carryover Effect in Rotation crops. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-3-04 / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3 KCP 6.4.5	2014	HCJ03: Crop selectivity in Cereals and Crop carryover in rotation crops. Two Timings. SynTech Europe. Spring 2014. SynTech Research Hungary Kft Trial / Protocol no.: SRHU14-283-38HS / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Winter Wheat and Crop Carryover Effect in Sugar Beet. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-3-02 / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Spring Barley and Crop Carryover Effect in Rotation crops. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-3-03 /38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Winter Rye and Crop Carryover Effect in Winter Oilseed Rape. 2 Timings. SynTech Europe. Spring 2014 Agrolab A/S Trial / Protocol no.: 38SRX14E1-3-05 / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Cereals and Crop carryover in rotation crops. Two Timings. SynTech Europe. Spring 2014. SynTech Research Hungary Kft Trial / Protocol no.: SRHU14-238-38HS / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.1 KCP 6.4.2 KCP 6.4.3	2014	HCJ03: Crop selectivity in Cereals and Crop carryover in rotation crops. Two Timings. SynTech Research Austria - ATC Trial / Protocol no.: SRSK14-014-38HE / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-106-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Effects of HCJ03 on the Malting/Brewing process. SynTech Europe. In France, spring 2013. SGS Agri Min Trial / Protocol no.: SRFR13-107-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Effects of HCJ03 on the Malting/Brewing process. SynTech Europe. In France, spring 2013. SGS Agri Min Trial / Protocol no.: SRFR13-108-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-110-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Effects of HCJ03 on the Malting/Brewing process. SynTech Europe. In France, spring 2013. SGS Agri Min Trial / Protocol no.: SRFR13-111-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-112-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-114-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Effects of HCJ03 on the Malting/Brewing process. SynTech Europe. In France, spring 2013. SGS Agri Min Trial / Protocol no.: SRFR13-115-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Effects of HCJ03 on the Malting/Brewing process. SynTech Europe. In France, spring 2013. SGS Agri Min Trial / Protocol no.: SRFR13-116-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-082-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-083-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-085-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-086-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-087-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-088-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-089-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of beer obtained by Malting and Brewing processes - 11 sites in France (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-090-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of bread obtained by bread making process - 3 sites in France and 1 site in Italy (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-073-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.4.4	2013	Evaluation of Unintentional side effects of HCJ03 on organoleptic parameters of bread obtained by bread making process - 3 sites in France and 1 site in Italy (2013). SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-074-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Crop selectivity in Cereals. Single Timing. SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-071-38HE / 38SRX13E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-075-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-076-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.5	2013	HCJ03: Crop selectivity in Cereals. 2 Timings. SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT13-077-38HE / 38SRX13E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.5	2014	HCJ03: Crop selectivity in Cereals 2 Timings - Spring 2014 SynTech Research Spain S.L Trial / Protocol no.: SRES14-143-38HE / 38SRX14E1-2 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.5	2014	HCJ03: Crop selectivity in Cereals and Crop Carryover Effect in Rotation crops. 2 Timings. SynTech Europe. Spring 2014 SAGEA SynTech Research s.r.l Trial / Protocol no.: SRIT14-251-38HE / 38SRX14E1-3 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no.: SRFR13-105-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.4.4	2013	HCJ03: Effects on the Malting/Brewing process. SynTech Europe. Spring 2013. SynTech Research France S.A.S Trial / Protocol no. SRFR13-109-38HE / 38SRX13E1-4 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.5.1	2012	HJC03 (500+40 g/L bensulfuron-methyl+metsulfuron-methyl): Selectivity to following replacement cereal crops - Glasshouse herbicide screen. UK. SynTech Research UK Trial / Protocol no.: SRUK12-104-38HE / 38SRX12E14 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.5.1	2012	HJC03: Selectivity to Following Crops (herbicide carryover effect). UK. 2012 SynTech Research UK Trial / Protocol no.: SRUK12-036-38HE / 38SRX12E5 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.5.1	2012	HCJ03: Carryover trials - Austria - 2012-2013. SynTech Research Austria - ATC Trial / Protocol no.: SRAT12-006-38HE / 38SRX12E5 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.5.1	2012	HCJ03: Selectivity to Following Crops. SynTech Europe. 2012. SynTech Research France S.A.S Trial / Protocol no.: SRFR12-113-38HE / 38SRX12E5 GEP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.6	2014	Bensulfuron-methyl/Metsulfuron-methyl 50/4 WG (HCJ03), Tank cleaning. Cerexagri B.V. Trial / Protocol no.: DL14-176 / n.a. GEP:N / GLP: Y Unpublished	Y	Y	Y	UPL Europe Ltd.
KCP 6.0	2012	The actual distribution of crops in Europe. Centre Wallon de Recherches Agronomiques Trial / Protocol no.: n.a. GEP: N Published	N	N	Y	Public Domain
KCP 6.0	1990	Bensulfuron-methyl, metsulfuron-methyl and their combination for weed control in rice. E.I. Du Pont de Nemours & Company Trial / Protocol no.: n.a. GEP: N Published	N	N	Y	Public Domain
KCP 6.3	2015	The International Survey of Herbicide Resistant Weeds. WeedScience.org Trial / Protocol no.: n.a. GEP: N Published	N	N	Y	Public Domain

Annex point	Year	Title, Source Company, Trial / Protocol no. GEP status, Published or Unpublished	Data Protection Claimed Y/N	Data Protection Granted Y/N	Study Relied on Y/N	Owner
KCP 6.3	2005	Criteria for Confirmation of Herbicide-Resistant Weeds - with specific emphasis on confirming low level resistance. International Survey of Herbicide-Resistant Weeds Trial / Protocol no.: n.a. GEP: N Published	N	N	Y	Public Domain
KCP 6.5.2	2001	New basic drift values in the authorization procedure for plant protection products. Workshop on Risk Assessment and Risk Mitigation Measures Trial / Protocol no.: n.a. GEP: N Published	N	N	Y	Public Domain