

Product name: Spandis 54 WG

Product code: A18385B

Active Substances: Dicamba 400 g/kg, Nicosulfuron 100 g/kg,
Prosulfuron, 40 g/kg

REGISTRATION REPORT – POLAND

Part B, Sec. 1 to 9

Reference List

Application for authorisation (Article 33)

Applicant: Syngenta

Date: 11/07/2022

Section 1,2,4

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 2.1 / 01 & KCP 2.8.1 / 01 & KCP 2.8.2 / 01 & KCP 2.8.3 / 01 & KCP 2.8.5.1 / 02 & KCP 2.8.5.2 / 02 & KCP 2.8.7 / 01	Fumeaux J.	2013	A18385B - Technical Properties of Batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125738 Not GLP not published Syngenta File No A18385B_10062; VV-406869	N	Y	Syngenta
KCP 2.2 / 01 & KCP 2.3 / 01	Jackson W.	2013	A18385B - Safety Study Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT12/584 GLP not published Syngenta File No A18385B_10059; VV-406760	Y	Y	Syngenta
KCP 2.4 / 01 & KCP 2.6 / 01 & KCP 2.8.5.1 / 01 & KCP 2.8.5.2 / 01	Fumeaux J.	2013a	A18385B - Physical properties of batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10526086 GLP not published Syngenta File No A18385B_10067; VV-406871	Y	Y	Syngenta
KCP 2.7 / 01	Fumeaux J.	2013b	A18385B - Storage Stability and Shelf Life Statement (2 Weeks 54-C) in Packaging Made of HDPE according to CIPAC MT 46.3 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 300009718 Not GLP not published Syngenta File No A18385B_10061; VV-	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			406868			
KCP 2.7 / 02	Wochner F.	2015	A18385B - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 300046482 Not GLP not published Syngenta File No A18385B_10383; VV-413978	N	Y	Syngenta
KCP 2.11 / 01	Fumeaux J.	2013c	A18385B - The Effectiveness of the Spray Tank Cleaning Procedure Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 126304 Not GLP not published Syngenta File No A18385B_10060; VV-406761	N	Y	Syngenta
KCP 2.11 / 02	Dos Santos A-M.	2012	A18385B - Chemical Characterization of Batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10498610 GLP not published Syngenta File No A18385B_10064; VV-406870	Y	Y	Syngenta

Section 3

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.1	Hilton, H.	31/12/2012	Field study to evaluate the efficacy of CHA7980 in tank mixture with different adjuvants, when applied post-emergence to maize for weed control Report No. 343 NIS (7980+ADJ-UK-EFF-13-POST-MA-01) Document No. VV-879597 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.1	Pardi, J.	31/12/2012	Field study to evaluate the efficacy of CHA7980 with different adjuvants when applied post-emergence to maize, 1 site in Hungary Report No. 369 NIS (S13-02909-01) Document No. VV-879600 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.1	Sentanes, J.	31/12/2013	Field study to evaluate the efficacy of CHA7980 in tank mixture with different adjuvants, when applied post-emergence to maize for weed control Report No. 340 NIS (CHE0913) Document No. VV-879596 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.1	Hayden R.	2012	Field study to evaluate the efficacy of CHA7980 + ADIGOR and CHA7950 + ACTIROB B, when applied post-emergence to maize for the control of weeds SGS United Kingdom Ltd., Banbury, United Kingdom 12-000136-1 GEP unpublished Syngenta File No. A18385B_10170	Y	Y	SYN
KCP 6.2	Hayden R.	2012	Field study to evaluate the efficacy of CHA7980 + ADIGOR and CHA7950 + ACTIROB B, when applied post-emergence to maize for the control of weeds	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			SGS United Kingdom Ltd., Banbury, United Kingdom 12-000136-2 GEP unpublished Syngenta File No. A18385B_10170			
KCP 6.2	Dupeuble F.	2012	HERBICIDE - MAIZE - POST-EMERGENCE EFFICACY Anadiag France, Ruy, France 12CH6034LG603 GEP unpublished Syngenta File No. A18385B_10162	Y	Y	SYN
KCP 6.2	Allen A.R.	2013	To evaluate the crop safety and efficacy of CHA7980 + ADIGOR for the control of Elymus repens, Alopecurus myosuroides and broad-leaf weeds when applied post-emergence to maize Oxford Agricultural Trials Ltd., Bicester, United Kingdom 727B GEP unpublished Syngenta File No. A18385B_10202	Y	Y	SYN
KCP 6.2	Motais F.	2013	Evaluation of the efficacy of CHA 7980 + ADIGOR when applied post-emergence to maize for weed control, 1 Site in France, 2013 Eurofins Agroscience Services, France S13-02102-02 GEP unpublished Syngenta File No. A18385B_10204	Y	Y	SYN
KCP 6.2	Motais F.	2013	Evaluation of the efficacy of CHA 7980 + ADIGOR when applied post-emergence to maize for weed control, 1 Site in France, 2013 Eurofins Agroscience Services, France S13-02102-01 GEP unpublished Syngenta File No. A18385B_10203	Y	Y	SYN
KCP 6.2	Motais F.	2013	Evaluation of the efficacy of CHA 7980 + ADIGOR when applied post-emergence to maize for weed control, 1 Site in France, 2013 Eurofins Agroscience Services, France	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			S13-02102-04 GEP unpublished Syngenta File No. A18385B_10205			
KCP 6.2	Kranz D.	2012	Field study to evaluate the efficacy of CHA7980 + ADIGOR and CHA7950 + ACTIROB B, when applied post-emergence to maize for the control of weeds Staehler Austria GmbH & Co KG, Graz, Austria 12MH01-A1 GEP unpublished Syngenta File No. A18385B_10159	Y	Y	SYN
KCP 6.2 6.4.1	Carstens, H.	17/12/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DENOZH1602013 Document No. VV-861650 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4.1	Gelay-Turtaut L.	2013	Evaluation selectivity of CHA 7980 when applied after post-emergence on different maize varieties Heliantis Experimentations - Saint Paul les Romans - France 7980-FR-13-SEL-POST-MA GEP unpublished Syngenta File No. A18385B_10134 Syngenta File No. A18385B_10137	Y	Y	SYN
KCP 6.4.1	Estelle Perrin	2013	Evaluation selectivity of CHA 7980 when applied after post-emergence on different maize varieties Heliantis Experimentations - Saint Paul les Romans - France 7980-FR-13-SEL-POST-MA GEP unpublished Syngenta File No. A18385B_10137	Y	Y	SYN
KCP 6.2 6.4 6.4.2 6.4.3	Kokoskova, D.	01/10/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1042012	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Document No. VV-861624 Test Facility Syngenta GEP Unpublished			
KCP 6.2 6.4 6.4.2 6.4.3	Siebert, E.	09/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. DEESZH3212012 Document No. VV-861626 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.2 6.4 6.4.2 6.4.3	Stanclova, L.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1012012 Document No. VV-861625 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Broz, M.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZKJZH1052013 Document No. VV-861648 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Brunckhorst, G.	17/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. DEWEZH2352012 Document No. VV-861620 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Drzewiecki, S.	02/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture -	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			2d year Efficacy Report No. PLSOZH1272013 Document No. VV-861646 Test Facility Syngenta GEP Unpublished			
KCP 6.3	Drzewiecki, S.	14/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLSOZH1052015 Document No. VV-861662 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Ehrenschwender, G.	30/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. DESEZH4412012 Document No. VV-861622 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Ehrenschwender, G.	22/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DESEZH4432013 Document No. VV-861649 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Griehl, T.	14/09/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. DEOSZH3662012 Document No. VV-861621 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Griehl, T.	21/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Report No. DEOSZH3442013 Document No. VV-861652 Test Facility Syngenta GEP Unpublished			
KCP 6.3	Griehl, T.	22/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DEOSZH3662013 Document No. VV-861639 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Kokoskova, D.	13/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1052012 Document No. VV-861618 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Kokoskova, D.	08/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZVPZH1042013 Document No. VV-861644 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Kroehnke, J.	31/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLNWZH1012015 Document No. VV-861666 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Krueger, D.	25/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DEMVZH9112013 Document No. VV-861651	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Test Facility Syngenta GEP Unpublished			
KCP 6.3	Maass, P.	31/12/2012	Field study to evaluate the efficacy of CHA7980 + Adigor and CHA7950 + Actirob B when applied post-emergence to maize for the control of weeds Report No. 271 NIS (S12-00993-03) Document No. VV-879605 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.3	Nitzsche, H.	31/12/2013	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 327 NIS (7980-DE-13-EFF-Post_MA_tr3) Document No. VV-879594 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.3	Schmitt, B.	31/12/2013	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 328 NIS (7980-DE-13-EFF-Post_MA_tr4) Document No. VV-879595 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.3	Skrzypczak, W.	27/07/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLUPZH1392013 Document No. VV-861647 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Skrzypczak, W.	27/07/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLUPZH1402013 Document No. VV-861641	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Test Facility Syngenta GEP Unpublished			
KCP 6.3	Skrzypczak, W.	28/07/2014	A18385 B (WG54%-DIC/NSU/PSU) - Post-emergent broad-spectrum weed control by new premixture - 3d year Efficacy Report No. PLUP0H1122014 Document No. VV-861653 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Slowiak, K.	08/09/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLWEZH0032015 Document No. VV-861665 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Sobiech, L.	04/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLUPZH1052015 Document No. VV-861663 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Soukup, J.	09/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. CZCPZH1032012 Document No. VV-861619 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Soukup, J.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZCPZH1032013 Document No. VV-861640 Test Facility Syngenta GEP Unpublished	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Mecklenburg-Vorpommern (Deutschland) Report No. N/A Document No. VV-877787 Test Facility N/A Not GLP Published	Y	Y	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Sachsen-Anhalt (Deutschland) Report No. N/A Document No. VV-877788 Test Facility N/A Not GLP Published	Y	Y	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Unterfranken (Deutschland) Report No. N/A Document No. VV-877789 Test Facility N/A Not GLP Published	Y	Y	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Hannover (Deutschland) Report No. N/A Document No. VV-877784 Test Facility N/A Not GLP Published	Y	Y	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Lüneburg (Deutschland) Report No. N/A Document No. VV-877785 Test Facility N/A Not GLP Published	Y	Y	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Warminsko-Mazurskie (Polska) Report No. N/A Document No. VV-877786 Test Facility N/A Not GLP Published	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 6.3	Stanclova, L.	31/07/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1022012 Document No. VV-861617 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Stanclova, L.	16/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZNEZH1052013 Document No. VV-861643 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Uminski, P.	02/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLFPZH1122013 Document No. VV-861645 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3 6.4.1	Uminski, P.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLFPZH1132013 Document No. VV-861642 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Uminski, P.	29/07/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLFPZH1042015 Document No. VV-861664 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.3	Weiss, E.	31/12/2012	Field study to evaluate the efficacy of CHA7980 + Adigor, when	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			applied post-emergence to maize for the control of weeds Report No. 326 NIS (7980-DE-13-EFF-Post_MA_tr2) Document No. VV-879593 Test Facility Syngenta, Ltd. GEP Unpublished			
KCP 6.4 6.4.2 6.4.3	Broz, M.	15/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZKJZH1062013 Document No. VV-861630 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Drzewiecki, S.	19/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLSOZH1282013 Document No. VV-861635 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2	Hohnschild, J.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 302 NIS (7980-12-DE...SEL-POST-MA TR2) Document No. VV-879591 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2	Kolditz, M.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 347 NIS (7980-DE-13-SEL-MA_tr1) Document No. VV-879598 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2	Kroehnke, J.	18/10/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
6.4.3			Report No. PLBCZH1512015 Document No. VV-861659 Test Facility Syngenta GEP Unpublished			
KCP 6.4 6.4.2 6.4.3	Merz, D.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG-DIC/NSU/PSU) - 1st y registration trials Report No. DESWZH5222012 Document No. VV-861627 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2	Scharf, H.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 348 NIS (7980-DE-13-SEL-MA_tr2) Document No. VV-879599 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Sobieszczanski, R.	30/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLUPZH1412013 Document No. VV-861634 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Solarska, E.	04/12/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLULZH1012015 Document No. VV-861661 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Soukup, J.	29/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZCPZH1042013	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Document No. VV-861633 Test Facility Syngenta GEP Unpublished			
KCP 6.4 6.4.2 6.4.3	Stanclova, L.	10/02/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZNEZH1062013 Document No. VV-861631 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3892013 Document No. VV-861637 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3902013 Document No. VV-861636 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2	Thiel, M.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 301 NIS (7980-12-DE...SEL-POST-MA TR1) Document No. VV-879590 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4 6.4.2 6.4.3	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			year Crop tolerance Report No. PLFPZH1142013 Document No. VV-861628 Test Facility Syngenta GEP Unpublished			
KCP 6.4 6.4.2 6.4.3	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1152013 Document No. VV-861632 Test Facility Syngenta GEP Unpublished	Y	Y	SYN
KCP 6.4.1	Hintz, C.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post- emergence on different maize varieties Report No. 261 NIS (7950 + 7980 VAR trial 2) Document No. VV-879602 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4.1	Thiel, M.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post- emergence on different maize varieties Report No. 262 NIS (7950 + 7980 VAR trial 3) Document No. VV-879603 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN
KCP 6.4.1	Wetzig, I.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post- emergence on different maize varieties Report No. 260 NIS (7950 + 7980 VAR trial 1) Document No. VV-879601 Test Facility Syngenta, Ltd. GEP Unpublished	Y	Y	SYN

Section 5

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 5.1.1/01	Dos Santos A.	2012	A18385B - Analytical Method SF-570/1 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10494732 Not GLP not published Syngenta File No A18385B_10044 ; VV-128246	N	Y	SYN
KCP 5.1.1/02	De Benedictis S.	2014	A18385B - Validation of Analytical Method SF-570/1 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 126609 GLP not published Syngenta File No A18385B_10045; VV-406938	Y	Y	SYN
KCP 5.1.1/03	De Benedictis S.	2013	A18385B - Analytical Method SD-1693/1 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10543871 Not GLP not published Syngenta File No A18385B_10031; VV-128236	N	Y	SYN
KCP 5.1.1/04	De Benedictis S.	2013a	A18385B - Validation of Analytical Method SD-1693/1 for Determination of CGA159902 in Formulations Containing Prosulfuron Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 126361 GLP not published Syngenta File No A18385B_10030; VV-406129	Y	Y	SYN
KCP 5.1.2./01 (used in KCP 10.2.1 / 01)	Liedtke A.	2013	Prosulfuron/dicamba/nicosulfuron WG (A18385B) plus adigor (A12127R) - Toxicity to Pseudokirchneriella subcapitata in a 96-hour algal growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D75032 GLP not published Syngenta File No A18385B_10020; VV-405587	Y	Y	Syngenta
KCP	Liedtke A.	2013a	Prosulfuron/dicamba/nicosulfuron WG	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
5.1.2./02 (used in KCP 10.2.1 / 02)			(A18385B) plus adigor (A12127R) - Toxicity to the aquatic higher plant Lemna gibba in a 7-day growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D75010 GLP not published Syngenta File No A18385B_10021; VV-405419			
KCP 5.2/01	Richardson M.	2008	Dicamba - Analytical Method for the Determination of Residues of Dicamba (SAN837) and its metabolite NOA414746 in Animal Matrices. Final Determination by GC-MSD Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.03A Not GLP not published Syngenta File No SAN837_11276; VV-127750	N	Y	Cheminova A/S
KCP 5.2/02	Heillaut C	2008	Dicamba - Validation of Residue Method GRM022.03A for Dicamba (SAN837) and NOA414746 Metabolite in Animal Matrices (milk, eggs, muscle, fat, liver and kidney) SynTech Research France SAS, La Chapelle de Guinchay, France ADME - Bioanalyses, Vergeze, France, T010322-04-REG GLP not published Syngenta File No SAN837_10997; VV-382384	Y	Y	Cheminova A/S
KCP 5.2/03	Morriss A	2009	Independent Laboratory Validation of a Method (GRM022.03A) for the Determination of Residues of Dicamba and its metabolite NOA414746 in Animal Matrices Syngenta - Jealott's Hill, Bracknell, United Kingdom CEMAS, North Ascot, United Kingdom, CEMR-3620 GLP not published Syngenta File No SAN837_11279; VV-383427	Y	Y	SYN
KCP 5.2/04	Class T, Kuhn T	2010	Dicamba - Independent Laboratory Validation of Analytical Method GRM022.03A for the Determination of	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Residues of Dicamba and its Metabolite NOA414746 in Animal Materials by GC/MS (NCI) Syngenta - Jealott's Hill, Bracknell, United Kingdom PTRL Europe, Ulm, Germany, B 1836 G GLP not published Syngenta File No SAN837_11330; VV-386364			
KCP 5.2/05	Hargreaves S. L.	2007	Dicamba - Residue Method for the Determination of Residues in Air Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.01A GLP not published Syngenta File No SAN837/6677; VV-124517	Y	Y	SYN
KCP 5.2/06	Emburey S.	2007	Dicamba - Validation of an Analytical Method for the Determination of Residues of Dicamba Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, T010135-04-REG GLP not published Syngenta File No SAN837/6678; VV-334321	Y	Y	SYN

Section 6

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 7.1.1 / 01	xxxxxxxxxx	2013a	Prosulfuron/dicamba/nicosulfuron WG (A18385B) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXX GLP not published Syngenta File No A18385B_10008; VV-405072	Y	Y	SYN
KCP 7.1.2 / 01	xxxxxxxxxxxxxx	2013b	Prosulfuron/dicamba/nicosulfuron WG (A18385B) - Acute Dermal Toxicity Study in Rats Syngenta XXXXXXXXXXXXXXXXXXXX XXXXXXXXXXXX GLP not published Syngenta File No A18385B_10007; VV-405071	Y	Y	SYN
KCP 7.1.4 / 01	xxxxxxxxxx	2013c	Prosulfuron/dicamba/nicosulfuron WG (A18385B) - Primary Skin Irritation Study in Rabbits Syngenta XXXXXXXXXXXXXXXXXXXX, XXXXXXXXXXXXXXX not published Syngenta File No A18385B_10009; VV-405073	Y	Y	SYN
KCP 7.1.5 / 01	xxxxxxxxxx	2013d	Prosulfuron/dicamba/nicosulfuron WG (A18385B) - Acute Eye Irritation Study in Rabbits Syngenta XXXXXXXXXXXXXXXXXXXX GLP not published Syngenta File No A18385B_10022; VV-405644	Y	Y	SYN
KCP 7.1.6 / 01	xxxxxxxxxx	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) - Local Lymph Node Assay in the Mouse Syngenta XXXXXXXXXXXX GLP not published Syngenta File No A18385B_10018; VV-405478	Y	Y	SYN

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 7.1.1 / 02	xxxxxxxxxxxxxx	1994	CGA 152005 WG 75, (A-8714 C) - Acute oral toxicity in the rat Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0420	N	Y	Syngenta
KCP 7.1.1 / 03	xxxxxxxxxxxxxx	1996	Acute oral toxicity in the rat Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0606	N	Y	Syngenta
KCP 7.1.1 / 04	xxxxxxxxxxxxxx	1996a	Acute oral toxicity in the mouse Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0605	N	Y	Syngenta
KCP 7.1.2 / 02	xxxxxxxxxxxxxx	1994	CGA 152005 WG 75, (A-8714 C) - Acute dermal toxicity in the rat Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0403	N	Y	Syngenta
KCP 7.1.4 / 02	xxxxxxxxxxxxxx	1994	CGA 152005 WG 75, (A-8714 C) - Acute dermal irritation/corrosion study in the rabbit Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0404	N	Y	Syngenta
KCP 7.1.5 / 02	xxxxxxxxxxxxxx	1994a	CGA 152005 WG 75, (A-8714 C) - Acute eye irritation/corrosion study in the rabbit Novartis Crop Protection AG, Basel, Switzerland xxxxxxxbsxxxxxxxxxx GLP	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			not published Syngenta File No CGA152005/0406			
KCP 7.1.6 / 02	xxxxxxxxxxxxxxxx	1994b	CGA 152005 WG 75, (A-8714 C) - Skin sensitization test in the Guinea Pig - Buehler Test Novartis Crop Protection AG, Basel, Switzerland xxxxxxxxxxxxxxxx GLP not published Syngenta File No CGA152005/0405	N	Y	Syngenta
KCP 7.3 / 01	Johnson I.	2012	Prosulfuron (A8714C) - In Vitro Absorption through Human Epidermis using [14C]-Prosulfuron Syngenta Dermal Technology Laboratory Ltd., Staffordshire, UK, JV2170- REG GLP not published Syngenta File No A8714C_11430	N	Y	Syngenta
KCA3 5.8 / 01	Callander R.	2005	CA349707: Bacterial Mutation Assay In S. Typhimurium And E.Coli Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, YV6941 GLP not published Syngenta File No CGA349707/0011	N	Y	Syngenta
KCA3 5.8 / 02	Clay P.	2005a	CGA 349707: L5178Y TK+/- Mouse Lymphoma Mutation Assay Syngenta Crop Protection AG, Basel, Switzerland Syngenta Limited, Cheshire, United Kingdom, VV0323 GLP not published Syngenta File No CGA349707/0012	N	Y	Syngenta
KCA3 5.8 / 03	Fox V.	2005a	CGA 349707: In Vitro Cytogenetic Assay In Human Lymphocytes Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom,	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			SV1296 GLP not published Syngenta File No CGA349707/0013			
KCA3 5.8 / 04	Hertner Th.	1993	CA 1118 A - Salmonella and escherichia/liver-microsome test Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 931097 GLP not published Syngenta File No CGA159902/0009	N	Y	Syngenta
KCA3 5.8 / 05	Clay P.	2005b	CGA 159902: L5178Y + / - Mouse Lymphoma Mutation Assay Syngenta Crop Protection AG, Basel, Switzerland Syngenta Limited, Cheshire, United Kingdom, VV0322 GLP not published Syngenta File No CGA159902/0014	N	Y	Syngenta
KCA3 5.8 / 06	Fox V.	2005b	CGA 159902: In Vitro Cytogenetic Assay In Human Lymphocytes Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, SV1295 GLP not published Syngenta File No CGA159902/0015	N	Y	Syngenta
KCA3 5.8 / 07	Clay P.	2005c	CGA 159902: In Vivo Rat Liver Unscheduled DNA Synthesis Assay Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, SR1326 GLP not published Syngenta File No CGA159902/0016	N	Y	Syngenta
KCA3 5.8 / 08	Clay P.	2005d	CGA 159902: Mouse bone marrow micronucleus test Syngenta Crop Protection AG, Basel, Switzerland	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, SM1319-REG GLP not published Syngenta File No CGA159902/0017			
KCA3 5.8 / 09	Wagner Valentine, VanDyke Melissa	2009	IN-A4098: Bacterial Reverse Mutation Assay DuPont Crop Protection, Newark, USA, Syngenta BioReliance, 9630 Medical Center Drive, Rockville, Maryland 20850, USA , DuPont-28277, BioRel: AC26XC.503.BTL, WRN: 18355, SCN: 500 GLP not published Syngenta File No CGA150829_10016	N	Y	Syngenta
KCA3 5.8 / 10	Stammberger I., Braun K.	1998	AE F059411: Bacterial Reverse Mutation Test Syngenta , 98.0717, C000993, M-181601-01-1 GLP not published Syngenta File No CGA150829_10024	N	Y	Syngenta
KCA3 5.8 / 11	Geleick D.	1991	CGA 150'829 tech. - Salmonella and escherichia/liver-microsome test. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland, 901510 GLP not published Syngenta File No CGA150829/0002	N	Y	Syngenta
KCA3 5.8 / 12	Gudi R.	2009	IN-A4098: In Vitro Mammalian Chromosome Aberration Test E.I. Dupont Nemours & Co., Inc., Wilmington, USA BioReliance, 9630 Medical Center Drive, Rockville, Maryland 20850, USA , DuPont-28082 GLP not published Syngenta File No	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			CGA150829_10014			
KCA3 5.8 / 13	Lloyd M.	2015	IN-A4098: In Vitro L5178Y Gene Mutation Assay at the tk locus E.I. Dupont Nemours & Co., Inc., Wilmington, USA, Cheminova A/S, Harboore, Denmark, Rotam Agrochem International Co. Ltd., Chai Wan, Hong Kong Covance Laboratories Limited, Harrogate, UK, DuPont-42500 GLP not published Syngenta File No CGA150829_10077	N	Y	Syngenta
KCA3 5.8 / 14	Meyer A.	1991	CGA 150`829 tech. - Cytogenetic test on Chinese hamster cells in vitro (EC-Conform). Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland, 901511 GLP not published Syngenta File No CGA150829/0009	N	Y	Syngenta
KCA3 5.8 / 15	Dollenmeier P.	1987	CGA 150`829 tech. - Chromosome studies on human lymphocytes in vitro. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 860159 GLP not published Syngenta File No CGA150829/0012	N	Y	Syngenta
KCA3 5.8 / 16	Clarke Jane	2009	IN-A4098: In Vitro Mammalian Cell Gene Mutation Test (CHO/HGPRT Assay) DuPont Crop Protection, Newark, USA, Syngenta BioReliance, 9630 Medical Center Drive, Rockville, Maryland 20850, USA , DuPont-28083, BioRel: AC26XC.782.BTL, WRN: 18355, SCN: 515 GLP not published Syngenta File No CGA150829_10015	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA3 5.8 / 17	Hertner Th.	1988	CGA 150`829 tech. - Autoradiographic DNA repair test on rat hepatocytes. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland, 871186 GLP not published Syngenta File No CGA150829/0011	N	Y	Syngenta
KCA3 5.8 / 18	Meyer A.	1988	CGA 150`829 tech. - Autoradiographic DNA repair test on human fibroblasts. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland, 871188 GLP not published Syngenta File No CGA150829/0010	N	Y	Syngenta
KCA3 5.8 / 19	Strasser F.	1988	CGA 150`829 tech. - Chromosome studies on somatic cells of Chinese hamster. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Basel, Genetische Toxikologie, Basel, Switzerland, 871187 GLP not published Syngenta File No CGA150829/0013	N	Y	Syngenta
KCA3 5.8 / 20	Sokolowski A	2010	SYN542604 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta - Jealott's Hill, Bracknell, United Kingdom Harlan, Cytotest Cell Research GmbH (Harlan CCR), 64380 Rossdorf, Germany, 1276501 GLP not published Syngenta File No SYN542604_10001	N	Y	Syngenta
KCA3 5.8 / 21	Bohnenberger S	2010	SYN542604 - Chromosome Aberration Test in Human Lymphocytes In Vitro	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Syngenta - Jealott's Hill, Bracknell, United Kingdom Harlan, Cytotest Cell Research GmbH (Harlan CCR), 64380 Rossdorf, Germany, 1276503 GLP not published Syngenta File No SYN542604_10000			
KCA3 5.8 / 22	Wollny H	2010	SYN542604 - Cell Mutation Assay at the Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y Cells Syngenta - Jealott's Hill, Bracknell, United Kingdom Harlan, Cytotest Cell Research GmbH (Harlan CCR), 64380 Rossdorf, Germany, 1276502 GLP not published Syngenta File No SYN542604_10002	N	Y	Syngenta
KCA3 5.8 / 23	Sokolowski A.	2013	CGA325025 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1527201 GLP not published Syngenta File No CGA325025_10007	N	Y	Syngenta
KCA3 5.8 / 24	Wollny H.	2013	CGA325025 - Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1527203 GLP not published Syngenta File No CGA325025_10008	N	Y	Syngenta
KCA3 5.8 / 25	Bohnenberger S.	2013	CGA325025 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany,	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			1527202 GLP not published Syngenta File No CGA325025_10009			
KCA3 5.8 / 26	Sokolowski A.	2014	SYN547308 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1577801 GLP not published Syngenta File No SYN547308_10002	N	Y	Syngenta
KCA3 5.8 / 27	Wollny H.	2014	SYN547308 - Cell Mutation Assay at the Thymidine Kinase Locus (TK+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1577803 GLP not published Syngenta File No SYN547308_10000	N	Y	Syngenta
KCA3 5.8 / 28	Bohnenberger S.	2014	SYN547308 - In Vitro Chromosome Aberration Test in Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1577802 GLP not published Syngenta File No SYN547308_10004	N	Y	Syngenta
KCA3 5.8 / 29	xxxxxxxxxxxxxxxxxxxx	2014	SYN547308 - Oral (Gavage) Mouse Micronucleus Test Final Report Syngenta xxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No SYN547308_10006	N	Y	Syngenta
KCA3 5.8 / 30	Sokolowski A.	2015a	CGA300406 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			GmbH (Harlan CCR), Germany, 1660401 GLP not published Syngenta File No CGA300406_10009			
KCA3 5.8 / 31	Wollny H.	2015	CGA300406 - Cell Mutation Assay at the Thymidine Kinase Locus (TKP+/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1660403 GLP not published Syngenta File No CGA300406_10011	N	Y	Syngenta
KCA3 5.8 / 32	Sokolowski A.	2015b	CGA300406 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1660402 GLP not published Syngenta File No CGA300406_10013	N	Y	Syngenta
KCA3 5.8 / 33	xxxxxxxxxxxxxxxx	2015	CGA300406 - Oral (Gavage) Mouse Micronucleus Test Syngenta xxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No CGA300406_10015	N	Y	Syngenta

Section 7

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA1 6.3.1 / 01	Kaethner M.	1995	Determination of Residues of Dicamba and 5-OH Dicamba in Corn (whole plant , cobs and grain) after Application of SAN 845 H 70 WG under Field Conditions in Italy, 1994 (DC). Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Ltd., Huningue, France, R10305 GLP not published Syngenta File No SAN837/5588; VV-381298	Y	Y	SYN
KCA1 6.3.1 / 02	Gasser A.	1998	Determination of Residues of Dicamba and 5-OH Dicamba in Corn (Zea mays) matrices after application of Cadence or Mondak 21 S under field conditions in Italy, 1996 Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, R96-032 GLP not published Syngenta File No SAN837/0416; VV-381309	Y	Y	SYN
KCA1 6.5.3 / 01	Richards S., MacKenzie R.	2004	Residue Study with Dicamba (SAN837) in or on Winter Barley and Brewing Fractions in the United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7017 GLP not published Syngenta File No SAN837/6359; VV-331997	Y	Y	SYN
KCA1 6.5.3 / 02	Richards S.	2004	Residue Study with Dicamba (SAN837) in or on Winter Barley and Brewing Fractions in The United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7018 GLP not published Syngenta File No SAN837/6360; VV-332134	Y	Y	SYN
KCA1 6.5.3 / 03	Stolze K.	2000	Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H Novartis Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, gr 05298 GLP not published Syngenta File No CGA131036/1037; VV-	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			312430			
KCA1 6.5.3 / 04	Stolze K.	2000a	Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H Syngenta Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, gr 06498 GLP not published Syngenta File No CGA131036/1070; VV-324009	Y	Y	SYN
KCA1 6.5.3 / 05	Stolze K.	2000b	Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H Syngenta Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, gr 04398 GLP not published Syngenta File No CGA131036/1069; VV-323997	Y	Y	SYN
KCA1 6.5.3 / 06	Stolze K.	2000c	Determination of SAN 837, 5-OH-Dicamba and CGA 131036 in Oats and Determination of SAN 837 and 5-OH-Dicamba in Processing Products after Application of NAD 11010 H Syngenta Crop Protection AG, Basel, Switzerland Novartis Agro GmbH, Frankfurt, Germany, gr 07598 GLP not published Syngenta File No CGA131036/1068; VV-323902	Y	Y	SYN
KCA1 6.5.3 / 07	Wesche H.	1998	Determination of Dicamba residues in spring wheat after application of NAD 11000 H under field conditions in Germany 1997 Syngenta Agrostat GmbH, Herrentierbach, Germany, G/01/SW/1/97 GLP not published Syngenta File No SAN837/0297; VV-365805	Y	Y	SYN
KCA1 6.5.3 / 08	Wesche H.	1998a	Determination of Dicamba residues in spring wheat after application of NAD 11000 H under field conditions in Germany 1997 Syngenta Agrostat GmbH, Herrentierbach, Germany, G/01/SW/2/97	Y	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			GLP not published Syngenta File No SAN837/0298; VV-365807			

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Prosulfuron

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.1	Eudy L.W.	1994a	Title: Stability of CGA-152005 fortified into corn substrates under freezer storage conditions. Company Report No.: ABR-93051 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.1	Eudy L.W.	1994b	Title: Stability of CGA 152005 fortified into meat, milk, and eggs under freezer storage conditions. Company Report No.: ABR-93055 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.1	Eudy L.W.	1997	Title: Stability of CGA-152005 fortified into meat, milk and eggs under freezer storage conditions. Company Report No.: ABR-97044 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.1	Hayworth C.	1994	Title: Storage stability of in field-incurred residues of CGA-152005 in corn (whole plant) under freezer storage conditions. Company Report No.: ABR-94046 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.2.1	Rezaaiyan R.	1994a	Title: Uptake and metabolism of CGA 152005 in field grown corn after spray treatment with [phenyl- ¹⁴ C]-CGA-152005 and [triazine- ¹⁴ C]-CGA-152005. Company Report No.: ABR-93047 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.2.1	Rezaaiyan R.	1994b	Title: Uptake and metabolism of CGA 152005 in greenhouse grown corn after spray treatment or stem injection with [phenyl- ¹⁴ C]-CGA-152005 and [triazine- ¹⁴ C]-CGA-152005. Company Report No.: ABR-93048 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.2.1	Rezaaiyan R.	1994c	Title: Stability of CGA-152005 metabolites in greenhouse grown corn after spray treatment with [phenyl- ¹⁴ C]-CGA-152005 and [triazine- ¹⁴ C]-CGA-152005. Company Report No.: ABR-93050 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxx	1994	Title: Metabolism of [triazine- ¹⁴ C]-CGA 152005 in the chicken – Addendum 1. Company Report No.: F-00115 xxxxxxxxxxxxx GLP Unpublished	N	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxx	1993a	Title: Metabolism of [triazine- ¹⁴ C]-CGA 152005 in the chicken. Company Report No.: F-00115 xxxxxxxxxxxxx Farmington, USA GLP Unpublished	N	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxxxxxxxxxx	1993b	Title: Metabolism of [phenyl- ¹⁴ C]-CGA 152005 in the chicken. Company Report No.: F-00116 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.2.3	xxxxxxxxxxxx	1994a	Title: Metabolism of [triazine- ¹⁴ C]-CGA-152005 in lactating goats after multiple oral administrations. Company Report No.: ABR-93041 xxxxxxxxxxxx GLP Unpublished	N	Y	SYN
KCA 6.2.3	xxxxxxxxxxxx	1994b	Title: Metabolism of [phenyl- ¹⁴ C]-CGA-152005 after multiple oral administrations to lactating goat. Company Report No.: ABR-93042 xxxxxxx GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999a	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North). Company Report No.: 3096/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999b	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North). Company Report No.: 3097/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999c	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (North). Company Report No.: 3098/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999d	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South). Company Report No.: 3099/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Gasser A.	1999e	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South). Company Report No.: 3100/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999f	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South). Company Report No.: 3101/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Gasser A.	1999g	Title: Residue Study with Prosulfuron (CGA 152005) and Pyridate (SAN 319) in or on Maize in France (South). Company Report No.: 3102/98 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Hofherr W.	1997a	Title: Magnitude of Residues after Application of Prosulfuron (CGA 152005) and Primisulfuron-Methyl (CGA 136872) as Formulation WG 80 (A-8988 A) in Maize. Company Report No.: 3024/96 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Hofherr W.	1997b	Title: Magnitude of Residues after Application of Prosulfuron (CGA 152005) and Primisulfuron-Methyl (CGA 136872) as Formulation WG 80 (A-8988 A) in Maize. Company Report No.: 3025/96 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Kwiatkowski A., Mound L.	2006	Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue study on Maize in Italy. Company Report No.: 04-7015 Source: Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom GLP Unpublished	N	Y	SYN
KCA 6.3	Maffezzoni M.	1994	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France. Company Report No.: OH93209 Source: Ciba-Geigy SA, France GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994a	Title: CGA 152005, PEAK 75 WG, Maize, Germany. Company Report No.: 3134/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994b	Title: CGA 152005, PEAK 75 WG, Maize, Germany. Company Report No.: 3133/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994c	Title: CGA 152005, PEAK 75 WG, Maize, Germany. Company Report No.: 3132/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994d	Title: CGA 152005, PEAK 75 WG, Maize, Greece. Company Report No.: 3089/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Mostert I.	1994e	Title: CGA 152005, PEAK 75 WG, Maize, Greece. Company Report No.: 3088/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994f	Title: CGA 152005, PEAK 75 WG, Maize, Greece. Company Report No.: 3087/93 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993a	Title: CGA 152005 and Bromoxynil-Phenol, WG 63, Residue, Maize, Switzerland. Company Report No.: 3003-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993b	Title: CGA 152005 and Bromoxynil-Phenol, WG 63, Residue, Maize, Switzerland. Company Report No.: 3004-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994g	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, Switzerland. Company Report No.: 3018/94 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1994h	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, Switzerland. Company Report No.: 3019/94 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Mostert I.	1993c	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France. Company Report No.: 3046-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993d	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France. Company Report No.: 3045-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993e	Title: CGA 152005 and Bromoxynil-Phenol (C 9217), WG 63, Maize, France. Company Report No.: 3044-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993f	Title: CGA 152005 + CGA 136872, WG 80, Residue, Maize, Switzerland. Company Report No.: 3006-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mostert I.	1993g	Title: CGA 152005 + CGA 136872, WG 80, Residue, Maize, Switzerland. Company Report No.: 3005-92 Source: Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Mound L., Gardinal P., Kwiatkowski A.	2006	Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue Study in or on Maize In Switzerland. Company Report No.: 04-7016 Source: Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Mound L., Kwiatkowski A.	2007	Title: Prosulfuron (CGA152005) and Dicamba (SAN837): Residue study on Maize in Italy. Company Report No.: 05-7010 Source: Syngenta – Jealott’s Hill International, Bracknell, Berkshire, United Kingdom GLP Unpublished	N	Y	SYN
KCA 6.3	Oppillart S.	2009a	Title: Dicamba (CGA57706) and Prosulfuron (CGA152005) – Residue study on Corn in France (north) in 2007. Company Report No.: T001033-07-REG Source: Eurofins – ADME Bioanalyses, Vergeze, France GLP Unpublished	N	Y	SYN
KCA 6.3	Oppillart S.	2009b	Title: Dicamba (CGA57706) and Prosulfuron (CGA152005) – Residue study on Corn in France (north) in 2007. Company Report No.: T001034-07-REG Source: Eurofins – ADME Bioanalyses, Vergeze, France GLP Unpublished	N	Y	SYN
KCA 6.3	Pointurier R.	1998a	Title: Magnitude of Residues of CGA 152005 and Bromoxynil in Maize after Application of Formulations A 8714 C WG 75 and F 70568 WP 20. Company Report No.: 9720401 Source: Novartis Agro S.A., Aigues-Vives, France GLP Unpublished	N	Y	SYN
KCA 6.3	Pointurier R.	1992	Title: CGA 152005, WG 63, Maize (Grains, Cobs and Fodder), France. Company Report No.: OH92007 Source: Ciba-Geigy SA, France GLP Unpublished	N	Y	SYN
KCA 6.3	Pointurier R.	1998b	Title: Magnitude of Residues of CGA 152005 and Bromoxynil in Maize after Application of Formulations A 8714 C WG 75 and F 70568 WP 20. Company Report No.: 9720402 Source: Novartis Agro S.A., Aigues-Vives, France GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Salvi M.	2002a	Title: Residue Study with Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in or on Maize in Switzerland. Company Report No.: 3005/00 Source: ADME – Bioanalyses, Vergeze, France GLP Unpublished	N	Y	SYN
KCA 6.3	Salvi M.	2002b	Title: Residue Study with Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in or on Maize in Switzerland. Company Report No.: 3004/00 Source: ADME – Bioanalyses, Vergeze, France GLP Unpublished	N	Y	SYN
KCA 6.3	Schulz H.	2011a	Title: Dicamba and Prosulfuron – Residue Study on Maize in France (North) in 2008. Company Report No.: T009437-07-REG Source: SGS Institut Fresenius GmbH, Taunusstein, Germany GLP Unpublished	N	Y	SYN
KCA 6.3	Schulz H.	2011b	Title: Dicamba and Prosulfuron – Residue Study on Maize in France (South) in 2008. Company Report No.: T009438-07-REG Source: SGS Institut Fresenius GmbH, Taunusstein, Germany GLP Unpublished	N	Y	SYN
KCA 6.3	Simon P.	2002a	Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000. Company Report No.: gr03200 Source: Syngenta Agro GmbH, Maintal, Germany GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Simon P.	2002b	Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000. Company Report No.: gr02100 Source: Syngenta Agro GmbH, Maintal, Germany GLP Unpublished	N	Y	SYN
KCA 6.3	Simon P.	2002c	Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000. Company Report No.: gr04300 Source: Syngenta Agro GmbH, Maintal, Germany GLP Unpublished	N	Y	SYN
KCA 6.3	Simon P.	2002d	Title: Residues of Primisulfuron-Methyl (CGA 136872) and Prosulfuron (CGA 152005) in Maize after Post-emergence Application of A8988A, Germany 2000. Company Report No.: gr05400 Source: Syngenta Agro GmbH, Maintal, Germany GLP Unpublished	N	Y	SYN
KCA 6.3	Simon P.	2006	Title: Prosulfuron and Dicamba: Residue Study in or on Maize in Germany 2004 (Test Product: A14031B). Company Report No.: gmz043004 Source: Syngenta Agro GmbH, Maintal, Germany GLP Unpublished	N	Y	SYN
KCA 6.5.3	Oakes T.L.	1994a	Title: Analytical determination of CGA 152005 in samples of whole corn and the corresponding processed fractions, USA. Company Report No.: MW-HR-103-92, no. 2 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.5.3	Oakes T.L.	1994b	Title: Analytical determination of CGA 152005 in samples of whole corn and the corresponding processed fractions, USA. Company Report No.: MW-HR-702-92, no. 2 Source: Ciba-Geigy Corp., Greensboro, NC, USA GLP Unpublished	N	Y	SYN
KCA 6.6.1	Daun R.J.	1994	Title: Uptake and metabolism of CGA 152005 in field rotational crops following a 1X bare ground treatment with [phenyl- ¹⁴ C]-CGA 152005 and triazine- ¹⁴ C-CGA-152005. Company Report No.: HWI 6117-219 Source: Hazelton Wisconsin Inc., Madison WI, USA GLP Unpublished	N	Y	SYN

Nicosulfuron

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.1	Schulz M., Ullrich-Mitzel A.	1995	Title: Storage stability of SL-950 and its metabolites ASDM and ADMP in corn plants and ears Company Report No.: 304762 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.2.1	Mamouni A.	1995	Title: ¹⁴ C-SL-950 (P) Plant metabolism study with corn in the greenhouse Company Report No.: 272158 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.2.1	Schanné C.	1991	Title: ¹⁴ C-SL-950 (Pm): Plant metabolism study with corn in the greenhouse Company Report No.: 274173 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.2.3	Burri R.	1995a	Title: ¹⁴ C-SL-950 (P): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat	N	Y	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Company Report No.: 358323 Source: ISK GLP Unpublished			
KCA 6.2.3	Burri R.	1995b	Title: ¹⁴ C-SL-950 (Pm): Distribution, degradation, metabolism and excretion after repeated oral administration to a lactating goat Company Report No.: 358312 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.2.3	xxxxxxxxxx.	1995c	Title: ¹⁴ C-SL-950 (Pm): Absorption, distribution and excretion after repeated oral administration to a lactating goat, based on an assumed daily intake of 0.15 mg/kg diet Company Report No.: 367356 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Bonfanti F.	1995	Title: SL-950: Determination of residues in maize. Italy 1992 Company Report No.: F-005-H Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz H.	1993	Title: Determination of the residues of SL-950 and its metabolites in corn (Germany, 1991) Company Report No.: 310656 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz H.	1994a	Title: Determination of the residues of SL-950 and its metabolites in corn (Exp.No. S009KP, France 1991); Field part attached Company Report No.: 313964 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz H.	1994b	Title: Determination of the residues of SL-950 and its metabolites in corn (Exp.No. 30536, France 1991); Field part attached Company Report No.: 313975 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz H., Ullrich A.	1991a	Title: Determination of the residues of SL-950 and its metabolites in corn. Report to: Determination of residues of SL-950 in corn; Field part attached Company Report No.: 272114	N	Y	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Source: ISK GLP Unpublished			
KCA 6.3	Schulz H., Ullrich A.	1991b	Title: Determination of the residues of SL-950 and its metabolites in corn. Report to: Determination of residues of SL-950 in corn (dissipation study); Field part attached Company Report No.: 272125 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz M.	1994	Title: Re-analysis of SL-950 in corn samples (France, 1991) by GC/MS Company Report No.: F-005-H Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz M.	1994b	Title: SL-950 4% SC: Residue analysis in corn – Greece 1993; Field part attached Company Report No.: 363666 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz M.	1995a	Title: Determination of the residues of SL-950 and its metabolites in fresh corn samples (Germany, 1992) Company Report No.: 343528 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Schulz M.	1995b	Title: SL-950: Residue in maize-Italy 1992 Company Report No.: 330693 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Ulrich C.	1994a	Title: Nicosulfuron (4% w/v) – water miscible suspension. Field trials to generate samples for residue analysis following one application in maize Company Report No.: ER 91 DEU 501 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.3	Ulrich C.	1994b	Title: Nicosulfuron (4% w/v) – water miscible suspension. Field trials to generate samples for residue analysis following one application in maize Company Report No.: ER 92 DEU 501 Source: ISK GLP	N	Y	ISK

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Unpublished			
KCA 6.3	Wyss-Benz M.	1994	Title: SL-950 4% SC: Residue analysis in corn – Spain 1992; Field part attached Company Report No.: 330715 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.6.1	Becker F.A., Raunft E.	1996	Title: Phytotoxicity test of nicosulfuron on rotational crops under field conditions in Germany (trial period 1993/94) Company Report No.: DE/HN/035/93 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.6.1	Schulz M.	1995	Title: Analysis of soil residue samples; Analytical report to: evaluation of the phytotoxicity of nicosulfuron on subsequent crops under field conditions in Germany Company Report No.: 350267 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.6.1	Hesse B., Becker F.A.	1995	Title: Investigation into the dissipation behaviour of nicosulfuron and its influence on rotation crops under field conditions in the Federal Republic of Germany Company Report No.: DE/HN/01/91 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.6.1	Wyss-Benz M.	1993a	Title: Determination of the residues of SL-950 and its metabolites in soil (field study II, Germany) Company Report No.: 310678 Source: ISK GLP Unpublished	N	Y	ISK
KCA 6.6.1	Wyss-Benz M.	1993b	Title: Analysis of soil residue samples; Analytical report to: evaluation of the phytotoxicity of nicosulfuron on subsequent crops under field conditions in Germany Company Report No.: 310680 Source: ISK GLP Unpublished	N	Y	ISK

Dicamba

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.1	xxxxxxxxx	1996	Title: Stability of dicamba and 3,6-dichlorosalicylic acid in stored frozen beef tissues and milk Company Report No.: 151 Source: xxxxxxxxxxxxxxxx USA GLP Unpublished	N	Y	SYN
KCA 6.1	Jimenez N.C.	1995	Title: Stability of Dicamba and 5-Hydroxy Dicamba in Stored Frozen Field Corn Company Report No.: 127 Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA GLP Unpublished	N	Y	SYN
KCA 6.2.1	Butz R., Atallah Y.	1981a	Title: Metabolic Fate of Dicamba in Sugarcane Plants Company Report No.: 24 Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA Non-GLP Unpublished	N	Y	SYN
KCA 6.2.1	Butz R., Atallah Y.	1981b	Title: Extractability of Dicamba Residues from Sugarcane Leaves Company Report No.: 13 Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA Non-GLP Unpublished	N	Y	SYN
KCA 6.2.1	Butz R., Atallah Y.	1982	Title: Foliar Absorption, Metabolism and Translocation of Dicamba by Soybeans at Early Pod fill and Late Senescent Stages Company Report No.: 39 Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA Non-GLP Unpublished	N	Y	SYN
KCA 6.2.1	Butz R.	1982	Title: Foliar Absorption, Metabolism and Translocation of Dicamba by Cotton Plants Company Report No.: 44 Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.2.1	Butz R.	1984	Title: Characterization of Radiocarbon from Seeds of 14C-Dicamba Treated Cotton Plants after Acid Hydrolysis Company Report No.: 70 Source: Novartis Crop Protection AG, Basel, Switzerland; Velsicol Environmental Science, Chicago, USA GLP Unpublished	N	Y	SYN
KCA 6.2.1	Völlmin S.	1999	Title: Metabolism and Behaviour of Dicamba in Field grown Spring Wheat after Application of [Phenyl-(U)-14C] Material Company Report No.: 97SV01 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxxx	1983	Title: Pharmacokinetics and Metabolism of 14C-dicamba in Hens Company Report No.: 65 Source: Novartis Crop Protection AGxxxxxxxxxx Non-GLP Unpublished	N	Y	SYN
KCA 6.2.2	xxxxxxxxxxxxxxxxxx	1994	Title: Dicamba: Metabolism in Laying Hens Company Report No.: 25 Source: Novartis Crop Protection AG, xxxxxxxxxxxxxx GLP Unpublished	N	Y	SYN
KCA 6.2.3	xxxxxxxxxxx	1994	Title: Metabolism of Dicambain Lactating Goats Company Report No.: 28 Source: xxxxxxxxxxxxxx USA GLP Unpublished	N	Y	SYN
KCA 6.2.3	xxxxxxxxxxx	1980	Title: Metabolic Fate of the Herbicide Dicamba in a Lactating Cow J.Agric.Food Chem. Vol. 28, No. 4, 1980 Published	N	Y	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Gasser A.	1998	Title: SAN 837 H, Cadence 70 WG, A-9781 A (SAN 845 H 70 WG) or Banvel D, 480 SL, A-7254 B (SAN 1214 H 480 SL), Corn (zea mays), Spain, 1996 Company Report No.: R96-008 Source: Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished	N	Y	SYN
KCA 6.3	Hertl P.	1995	Title: Determination of residues of DICAMBA in Corn (Zea mais) after application of BANVEL 4S or SAN 845 H 70 WG under field conditions in the Federal Republic of Germany, 1993. Company Report No.: R10280 Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France GLP Unpublished	N	Y	SYN
KCA 6.3	Kaethner M.	1993	Title: Determination of residues of Dicamba and 5-OH Dicamba on corn after application of two different formulations, SAN 845 H 70 WG 001 SP and BANVEL 4S, and one mixture of SAN 845 H + SAN 1287 H at 6 leaf stage under field conditions in France Company Report No.: BS3941 Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France GLP Unpublished	N	Y	SYN
KCA 6.3	Kaethner M.	1996a	Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of BANVEL D under Field conditions in Spain, 1993 (RAH) Company Report No.: R93041E Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.3	Kaethner M.	1996b	Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of SAN 845 H under Field conditions in Spain, 1993 (RAH) Company Report No.: R93042E Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France GLP Unpublished	N	Y	SYN
KCA 6.3	Kaethner M.	1996c	Title: Determination of Residues of Dicamba and 5-OH Dicamba in Corn after Application of SAN 845 H 70 WG under Field Conditions in France (N/S), 1993 (RAH) Company Report No.: R93041F Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Ltd., Huningue, France GLP Unpublished	N	Y	SYN
KCA 6.3	Taylor D.T. et al.	1984	Title: Determination of Dicamba and 5-Hydroxy Dicamba, A-7254 B, in Autrian Maize Grain and Straw Company Report No.: 206/4 Source: Novartis Crop Protection AG, Basel, Switzerland; Hazleton Europe Ltd., Harrogate, North Yorkshire, United Kingdom GLP Unpublished	N	Y	SYN
KCA 6.4.1	xxxxxxxxxxxx	1984	Title: Determination of Dicamba Residues in Laying Hen Tissues and Eggs After a 28 Day Feeding Study Company Report No.: 74 Source: xxxxxxxxxxxx Non-GLP Unpublished	N	Y	SYN
KCA 6.4.1	xxxxxxxxxxxxxxxx	1984	Title: Transfer of dicamba residues to tissues and eggs of laying hens Company Report No.: 107-203 Source: xxxxxxxxxxxx Non-GLP Unpublished	N	Y	SYN
KCA 6.4.2	xxxxxxxxxxxxxxxxxx	1979	Title: Effect of feeding Dicamba to dairy cattle (Residues in Liver, Kidney, Muscle, and Fat) Company Report No.: 379 Source: xxxxxxxxxxxxxxxx GLP Unpublished	N	Y	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCA 6.4.2	xxxxxxxxx	1979	Title: EFFECT OF FEEDING DICAMBA TO DAIRY CATTLE (Residues in Milk) Company Report No.: 379 Source: xxxxxxxxxxxx GLP Unpublished	N	Y	SYN
KCA 6.5.1	Grout S.J.	2003	Title: Aqueous Hydrolysis at 90°, 100 & 120 °C Company Report No.: RJ3333B Source: GLP Unpublished	N	Y	SYN
KCA 6.6.1	Moore P.	1989	Title: Confined Accumulation Studies of Dicamba on Rotational Crops After Spring Application Company Report No.: 16 Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA Non-GLP Unpublished	N	Y	SYN
KCA 6.6.1	Pierotti M.V.	1995	Title: Confined Accumulation Studies of Dicamba on Rotational Crops Company Report No.: 22 Source: Novartis Crop Protection AG, Basel, Switzerland; Sandoz Agro Inc., Des Plaines, USA GLP Unpublished	N	Y	SYN

Section 8

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
Prosulfuron						
KCP 9.1.1.1 / 01	Patel, M.	2014	Prosulfuron – Laboratory Degradation Kinetics for Modelling Endpoints for the soil metabolite SYN547308. Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY, United Kingdom. Report No RAJ1065B. Non GLP Unpublished, Syngenta File No SYN547308_10009; VV-628381	N	Y	Syngenta
KCP 9.1.1.2.1 / 01	Hardy, I.A.J. and Jastrzebski, N.D.	2016	Prosulfuron - Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies for Trigger Endpoints. Batelle UK Ltd., Essex, UK. Report No: NC/15/041B. Non GLP Unpublished, Syngenta File No CGA152005_10793; VV-629450	N	Y	Syngenta
KCP 9.1.1.2.1 / 02	Hardy, I.A.J. and Jastrzebski, N.D.	2016a	Prosulfuron - Kinetic Modelling Evaluation of Data from Field Soil Dissipation Studies Normalised to 20°C (Q ₁₀ 2.58). Batelle UK Ltd., Essex, UK. Report Number: NC/15/041A. Non GLP Unpublished, Syngenta File No CGA152005_10792; VV-629449	N	Y	Syngenta
KCP 9.1.2 / 01	Crabtree, G.	2014	SYN547308 - Adsorption and Desorption Properties of 14C-SYN547308, a Metabolite of Prosulfuron. Smithers Viscient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1PY, UK. Report No 3200461. Non GLP Unpublished, Syngenta File No SYN547308_10010; VV-409563	Y	Y	Syngenta
KCP 9.2.4 / 01	De Vries, K.	2016	Prosulfuron - A Leaching Assessment for Parent and Soil Metabolites CGA150829, CGA159902, CGA300406, SYN542604, CGA349707, CGA325025 and SYN547308 Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Dr. Knoell Consult GmbH, Mannheim, Germany, Report Number 103276-2. Non GLP Unpublished, Syngenta File No CGA152005_10795; VV-629994	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 9.2.5 / 01	De Vries, K.	2016a	Prosulfuron - A European Environmental Fate Assessment for Parent Using the FOCUS Surface Water Models at Steps 3 to 4 Following Spray Application to Maize and Cereals in the EU. Dr. Knoell Consult GmbH, Mannheim, Germany, Report No 103276-1. Non GLP Unpublished, Syngenta File No CGA152005_10806; VV-630378	N	Y	Syngenta
Nicosulfuron						
KCP 9.2.4	González Camarero, P.	2020	Nicosulfuron - A Leaching Assessment for Parent and Metabolites HMUD, AUSN, UCSN, ASDM, ADMP and MU-466 Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Maize knoell Germany GmbH, Mannheim, Germany, Report No 113644-2 Non GLP Unpublished, Syngenta File No VV-877107	N	Y	Syngenta
KCP 9.2.5	González Camarero, P.	2020a	Nicosulfuron - A European Environmental Fate Assessment for Nicosulfuron Using the FOCUS Surface Water Models at Steps 3 to 4 Following Spray Application to Maize knoell Germany GmbH, Mannheim, Germany, Report No 113644-3 Non GLP Unpublished, Syngenta File No VV-877111	N	Y	Syngenta
Dicamba						
KCP 9.2.4	González Camarero, P.	2020b	Dicamba - A Leaching Assessment for Parent and Metabolite DSCA. Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Maize, knoell Germany GmbH, Mannheim, Germany, Report No 113644-1 Non GLP Unpublished, Syngenta File No VV-877105	N	Y	Syngenta

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
Prosulfuron						

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 9.1.1	Atkins, R.H.	1993	Aerobic Metabolism of Phenyl-14C-CGA-152005 in Sandy Loam Soil Novartis Crop Protection AG, Basel, Switzerland Not Known, PTRL 583 GLP, not published Syngenta File No CGA152005/0189	N	Y	Syngenta
KCP 9.1.1	Atkins, R.H.	1993a	Aerobic Metabolism of Triazine 14C-CGA-152005 in Sandy Loam Soil Novartis Crop Protection AG, Basel, Switzerland Not Known, PTRL NO 585 GLP, not published Syngenta File No CGA152005/0183	N	Y	Syngenta
KCP 9.1.1	Atkins, R.H.	1994	Aerobic Metabolism of Triazine-14C-CGA-152005 in Soil at Approximately pH 6 Novartis Crop Protection AG, Basel, Switzerland Not Known, 636 GLP, not published Syngenta File No CGA152005/0399	N	Y	Syngenta
KCP 9.1.1	Atkins, R.H.	1994a	Aerobic Metabolism of Phenyl-14C-CGA-152005 in Soil at Approximately pH 6 Novartis Crop Protection AG, Basel, Switzerland PTRL East, Inc., Richmond, USA, 635 GLP, not published Syngenta File No CGA152005/0471	N	Y	Syngenta
KCP 9.1.1	Fahrbach, M.	2011	[14C]-Prosulfuron - Aerobic Soil Metabolism Study (Rate) in Four Soils Incubated at 20 °C Harlan Laboratories Ltd., Itingen, Switzerland, C95314 GLP, not published Syngenta File No CGA152005_10603	N	Y	Syngenta
KCP 9.1.1	Hurt, A., Mason, G., Hamlet, J.	2011	PROSULFURON - Rate of Degradation of Soil Metabolites CGA325025 and SYN524604 in Three Soils, under Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, T001216-06-REG GLP, not published Syngenta File No CGA325025/0004	N	Y	Syngenta
KCP 9.1.1	Jungmann, V., Nicollier, G.	2006	Rate of Degradation of [triazinyl-6-14C]-labelled CGA150829 (Metabolite of CGA152005) in Various Soils under Aerobic Laboratory Conditions at 20 °C	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, T001214-06 GLP, not published Syngenta File No CGA150829/0027			
KCP 9.1.1	Kuet, S.	2006	Prosulfuron - Rate of Degradation of Soil Metabolite CGA349707 in Three Soils, under Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, T001218-06-REG GLP, not published Syngenta File No CGA349707/0014	N	Y	Syngenta
KCP 9.1.1	Nicollier, G., Berdat, T.	2006	Rate of Degradation of [phenyl-U-14C]-labelled CGA159902 (Metabolite of CGA152005) in Various Soils under Aerobic Laboratory Conditions at 20°C Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, T001215-06 GLP, not published Syngenta File No CGA159902/0020	N	Y	Syngenta
KCP 9.1.1	Reischmann, F.J.	1994	Degradation of CGA 152005 in Four Soils under Aerobic Laboratory Conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PR 21/93 (92RF05-1 AND 92RF05-2) GLP, not published Syngenta File No CGA152005/0200	N	Y	Syngenta
KCP 9.1.1	Reischmann, F.J.	1994a	Influence of Soil Biomass on the Degradation Half-Life of CGA 152005 Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PR 19/94 GLP, not published Syngenta File No CGA152005/0400	N	Y	Syngenta
KCP 9.1.2	Reischmann, F.J.	1993	Leaching model study with CGA 152005 in four soils under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 92RF10 6/93 GLP, not published Syngenta File No CGA152005/0212	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 9.1.1	Reischmann, F.J.	1994	Degradation of CGA 152005 in Four Soils under Aerobic Laboratory Conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PR 21/93 (92RF05-1 AND 92RF05-2) GLP, not published Syngenta File No CGA152005/0200	N	Y	Syngenta
KCP 9.1.2.1	Kesterson, A.	1992	Column Leaching of [14C] triazine CGA 152005 in four soil types Novartis Crop Protection AG, Basel, Switzerland PTRL West Inc., Richmond CA, USA, 533 GLP, not published Syngenta File No CGA152005/0111	N	Y	Syngenta
KCP 9.1.2.2	Burgener, A.	1996	Mobility and degradation in soil in outdoor lysimeters Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, RCC 321570 GLP, not published Syngenta File No CGA152005/0806	N	Y	Syngenta
KCP 9.2.2	Eatherall, A.	2004	Prosulfuron (CGA 152005): Summary of Whole-System Half-life Data in Water-Sediment Studies Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ0273B GLP, not published Syngenta File No CGA152005/0797	N	Y	Syngenta
KCP 9.2.4.1	Comoretto, L.	2007	Prosulfuron (CGA152005) - Leaching Behaviour of Prosulfuron and Six Metabolites (CGA150829, CGA159902, CGA300406, CGA325025, SYN542604 and CGA349707) using the FOCUS-PELMO Groundwater Scenarios Following Application to Maize at 20 g ha ⁻¹ Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RAJ0568B Not GLP, not published Syngenta File No CGA152005/0904	N	Y	Syngenta
KCP 9.2.4.1	Patterson, D.	2013	Use of prosulfuron soil degradation DegT50 of 18.1d in a leaching assessment using the FOCUS PEARL 4.4.4	N	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			groundwater scenarios following use on maize crops. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY, UK. Unpublished statement, Syngenta File No CGA152005_10669			
KCP 9.3.1	Reischmann, F.J.	1992	Volatilization of CGA 152005 from soil surface under controlled laboratory conditions Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 18-92 GLP, not published Syngenta File No CGA152005/0092	N	Y	Syngenta
Nicosulfuron						
	Derz, K.	2013	[¹⁴ C]-Nicosulfuron: Uptake and Translocation in Wheat and Tomato from Hydroponic System Fraunhofer IME Germany, Report No SYN-013/7-63. GLP, not published Syngenta File No ASF628_11206	N	Y	Syngenta
KCP 9.1.2	Graham R., Strachan K.	2008	[¹⁴ C] Nicosulfuron: Adsorption/Desorption in Soil Covance Laboratories Ltd, Harrogate North Yorkshire, UK., Report No 79 NIS Cheminova A/S GLP, not published Syngenta File No ASF628_11275	N	Y	Cheminova A/S

Section 9

List of data submitted by the applicant and relied on

Most of the studies have been evaluated in fRR of A18385B (zRMS – SK) dated 16/08/2016. Only four studies have been assessed in this report (KCP 10.4.1.1/01, 10.4.2/05, 10.6.4/01 and 10.6.4/02).

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 10.2.1 / 01	Liedtke A.	2013	Prosulfuron/dicamba/nicosulfuron WG (A18385B) plus adigor (A12127R) - Toxicity to <i>Pseudokirchneriella subcapitata</i> in a 96-hour algal growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D75032 GLP not published Syngenta File No A18385B_10020; VV-405587	Y	Y	Syngenta
KCP 10.2.1 / 02	Liedtke A.	2013a	Prosulfuron/dicamba/nicosulfuron WG (A18385B) plus adigor (A12127R) - Toxicity to the aquatic higher plant <i>Lemna gibba</i> in a 7-day growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D75010 GLP not published Syngenta File No A18385B_10021; VV-405419	Y	Y	Syngenta
KCP 10.3.1.1 / 01	Kling A.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Acute Oral and Contact Toxicity to the Honeybee, <i>Apis mellifera</i> L. under Laboratory Conditions Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S13-00901 GLP not published Syngenta File No A18385B_10014; VV-404782	Y	Y	Syngenta
KCP 10.3.2.1 / 01	Fallowfield L.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-19 GLP not published Syngenta File No A18385B_10017; VV-404789	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
KCP 10.3.2.1 / 02	Stevens J.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-18 GLP not published Syngenta File No A18385B_10013; VV-405152	Y	Y	Syngenta
KCP 10.3.2.2 / 01	Fallowfield L.	2014	Prosulfuron/Dicamba/Nicosulfuron WG (A1835B) plus Adigor (A12127R) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite <i>Typhlodromus pyri</i> Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-53 GLP not published Syngenta File No A18385B_10070; VV-406997	Y	Y	Syngenta
KCP 10.3.2.2 / 02	Stevens J.	2013a	Prosulfuron/Dicamba/Nicosulfuron WG (A1835B) plus Adigor (A12127R) - A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-52 GLP not published Syngenta File No A18385B_10034; VV-406310	Y	Y	Syngenta
KCP 10.3.2.2 / 03	Tew G.	2014	Prosulfuron/Dicamba/Nicosulfuron WG (A1835B) plus Adigor (A12127R) - A rate-response extended laboratory bioassay of the effects of fresh residues on the rove beetle <i>Aleochara bilineata</i> Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-54 GLP not published Syngenta File No A18385B_10072; VV-407006	Y	Y	Syngenta
KCP 10.3.2.2	Vaughan R.	2014	Prosulfuron / dicamba / nicosulfuron WG (A18385B) plus Adigor (A12127R) - a rate-	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
/ 04			response extended laboratory test to evaluate the effects of fresh residues on the green lacewing <i>Chrysoperla carnea</i> (Neuroptera, Chrysopidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-55 GLP not published Syngenta File No A18385B_10081; VV-407544			
KCP 10.4.1.1 / 01	Friedrich S.	2015	CGA300406 - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil with 5 % peat Syngenta BioChem Agrar, Gerichshain, Germany, 15 10 48 138 S GLP not published Syngenta File No CGA300406_10018; VV-414538	Y	Y	Syngenta
KCP 10.4.1.1 / 02	Friedrich S.	2012	CGA349707 - Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil with 5 % peat Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 068 S GLP not published Syngenta File No CGA349707_10001; VV-402755	Y	Y	Syngenta
KCP 10.4.1.1 / 03	Friedrich S.	2012a	CGA159902 - Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil with 5 % peat Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 066 S GLP not published Syngenta File No CGA159902_10003; VV-402932	Y	Y	Syngenta
KCP 10.4.1.1 / 04	Friedrich S.	2012b	SYN542604 - Sublethal toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil with 5 % peat Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 070 S GLP not published Syngenta File No SYN542604_10007; VV-402929	Y	Y	Syngenta
KCP	Friedrich	2012c	CGA325025 - Sublethal toxicity to the	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
10.4.1.1 / 05	S.		earthworm <i>Eisenia fetida</i> in artificial soil with 5 % peat Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 064 S GLP not published Syngenta File No CGA325025_10003; VV-402933			
KCP 10.4.1.1 / 06	Friedrich S.	2012d	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 115 S GLP not published Syngenta File No A18385B_10000; VV-403301	Y	Y	Syngenta
KCP 10.4.2 / 01	Friedrich S.	2012e	CGA349707 - Effects on the reproduction of the collembolans <i>Folsomia candida</i> Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 067 S GLP not published Syngenta File No CGA349707_10002; VV-402756	Y	Y	Syngenta
KCP 10.4.2 / 02	Friedrich S.	2012f	CGA159902 - Effects on the reproduction of the collembolans <i>Folsomia candida</i> Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 065 S GLP not published Syngenta File No CGA159902_10002; VV-402759	Y	Y	Syngenta
KCP 10.4.2 / 03	Friedrich S.	2012g	SYN542604 - Effects on the reproduction of the collembolans <i>Folsomia candida</i> Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 069 S GLP not published Syngenta File No SYN542604_10006; VV-402926	Y	Y	Syngenta
KCP 10.4.2 / 04	Friedrich S.	2012h	CGA325025 - Effects on the reproduction of the collembolans <i>Folsomia candida</i> Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 063 S	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			GLP not published Syngenta File No CGA325025_10002; VV-402757			
KCP 10.4.2 / 05	Friedrich S.	2015a	CGA300406 - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta BioChem Agrar, Gerichshain, Germany, 15 10 48 139 S GLP not published Syngenta File No CGA300406_10017; VV-414529	Y	Y	Syngenta
KCP 10.4.2 / 06	Friedrich S.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 084 S GLP not published Syngenta File No A18385B_10011; VV-404932	Y	Y	Syngenta
KCP 10.4.2 / 07	Schulz L.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Syngenta BioChem Agrar, Gerichshain, Germany, 13 10 48 085 S GLP not published Syngenta File No A18385B_10012; VV-404934	Y	Y	Syngenta
KCP 10.5 / 01	Hutcheson K.	2015	CGA349707 - Effect on soil microbial activity, carbon and nitrogen transformations Syngenta CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-6587 GLP not published Syngenta File No CGA349707_10012; VV-411802	Y	Y	Syngenta
KCP 10.5 / 02	Schulz L.	2013a	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta BioChem Agrar, Gerichshain, Germany, 13	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			10 48 061 C/N GLP not published Syngenta File No A18385B_10010; VV-405078			
KCP 10.6.2 / 01	Bramby- Gunary J.	2013	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, ACE-12-183 GLP not published Syngenta File No A18385B_10004; VV-403949	Y	Y	Syngenta
KCP 10.6.4 / 01	Dickinson R.	2015	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test in a higher tier field study Syngenta Agrochemex International Ltd., Aldhams Farm Research Station, Lawford, United Kingdom, ACE-14-062 GLP not published Syngenta File No A18385B_10378; VV-413377	Y	Y	Syngenta
KCP 10.6.2 / 02	Bramby- Gunary J.	2013a	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, ACE-12-182 GLP not published Syngenta File No A18385B_10003; VV-403948	Y	Y	Syngenta
KCP 10.6.4 / 02	Dickinson R.	2015a	Prosulfuron/Dicamba/Nicosulfuron WG (A18385B) plus Adigor (A12127R) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth in a higher tier field study Syngenta Agrochemex International Ltd., Aldhams Farm Research Station, Lawford, United Kingdom, ACE-14-061	Y	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data Protection Claimed Y/N	Used for evaluation Y/N	Owner
			GLP not published Syngenta File No A18385B_10377; VV-413376			