

References for the plant protection product: NIKITA_ADM.4651.H.1.A_ADAMA PL 2021-12
(List with references (PPP) at national level according SANCO/12580/2012 – rev. 4, 22 March 2019)

Identity, Physical and chemical properties, Further information

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 2 / 01	Adolph S.	2012	A18032E - Chemical characterization of batch SMU2BP001 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 124460 GLP not published Syngenta File No A18032E_10026	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
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 2.8.5.3 / 01 KCP 2.9.1/01	Fumeaux J.	2013	A18032E - Technical properties of batch SMU2BP001 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125711 Not GLP not published Syngenta File No A18032E_10034	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 2.2 / 01 & KCP 2.3 / 01	Blessington K.	2012	A18032E - Safety Study Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT12/564 GLP not published Syngenta File No A18032E_10029	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 2.4 / 01 & KCP 2.6 / 01 & KCP 2.8.5.1 / 01 & KCP 2.8.5.2 / 01 KCP 2.9.1/02	Fumeaux J.	2013a	A18032E - Physical properties of batch SMU2BP001 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125030 GLP not published Syngenta File No A18032E_10028	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 2.7 / 01	Kundel P.	2013	A18032E - Storage stability and shelf life statement (2 weeks 54 -C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Munchwilen,	N	N	Not relevant	SYN (ADAMA has LOA)	N

			Switzerland, 10531055 Not GLP not published Syngenta File No A18032E_10033					
KCP 2.7 / 02	Kundel P.	2015	A18032E - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 300045056 Not GLP not published Syngenta File No A18032E_10317	N	N	Not relevant	SYN (ADAMA has LOA)	N
KCP 2.9.1/03	Hartmut T.	2021	Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of Nikita Adama BioChem project No.: 21 35 CRX 0016 Extranet code 218167-21 ADAMA trial code UK21HONOPLA044A GLP not published Report 21 35 CRX 0016	N	Y	Not relevant	ADAMA	N
KCP 2.11 / 01	Kundel P.	2013a	A18032E - The Effectiveness of the Spray Tank Cleaning Procedure Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125696 Not GLP not published Syngenta File No A18032E_10031	N	N	Not relevant	SYN (ADAMA has LOA)	N

Efficacy

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 6	Ing. Markéta Hambálková	2018	Efficacy of NIKITA applied in early post emergence for controlling of weeds on corn/Czech republic/2018 Trial ID : CZ18HEZEAMX102A GEP	N			ADAMA	
KCP 6	prof. Ing. Josef Soukup, CSc.	2018	Efficacy of NIKITA applied in early post emergence for controlling of weeds on corn/Czech Republic/2018 Trial Code: CZ18HEZEAMX102B GEP	N			ADAMA	
KCP 6	Ing. Petr Horník	2018	Efficacy of NIKITA applied in early post emergence for controlling of weeds on corn/Czech republic/2018 Trial Code: CZ18HEZEAMX102C GEP	N			ADAMA	
KCP 6	prof. Ing. Josef Soukup, CSc.	2018	Efficacy of NIKITA with adjuvants applied in post emergence for controlling of weeds on corn/Czech Republic/2018 Trial Code: CZ18HEZEAMX205B GEP	N			ADAMA	
KCP 6	Ing. Petr Horník	2018	Efficacy of NIKITA with adjuvants applied in post emergence for controlling of weeds on corn/Czech republic/2018 Trial Code: CZ18HEZEAMX205C GEP	N			ADAMA	
KCP 6	Dr inż Łukasz Sobiech	2018	Badanie skuteczności i fitotoksyczności preparatu Nikita 562,5 WG w zabiegu powschodowym w zwalczaniu chwastów w uprawie kukurydzy Efficacy and phytotoxicity of Nikita 562,5 WG in post-emergence treatment of weed control in corn Trial ID: PL18HEZEAMX099A GEP	N			ADAMA	
KCP 6	Dr inż katarzyna Furman-Frątczak	2018	Ocena skuteczności i selektywności preparatu stosowanego samodzielnie oraz z adiuwantami w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy and selectivity of Nikita used alone and in tank-mix with adjuvants for the control of weeds in corn. Report nr: 098/1 PL18HEZEAMX99B GEP	N			ADAMA	

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 6	Dr inż katarzyna Furman- Frątczak	2018	Ocena skuteczności i selektywności preparatu stosowanego samodzielnie oraz z adiuwantami w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy and selectivity of Nikita used alone and in tank-mix with adjuvants for the control of weeds in corn. Report nr: 098/1 PL18HEZEAMX99C GEP	N			ADAMA	
KCP 6	Dr inż Łukasz Sobiech	2018	Badanie skuteczności i fitotoksyczności preparatu Nikita 562,5 WG w zabiegu powstochodowym w zwalczaniu chwastów w uprawie kukurydzy Efficacy and phytotoxicity of Nikita 562,5 WG in post-emergence treatment of weed control in corn Trial ID: PL18HEZEAMX100B GEP	N			ADAMA	
KCP 6	Dr inż Łukasz Sobiech	2018	Badanie skuteczności i fitotoksyczności preparatu Nikita 562,5 WG w zabiegu powstochodowym w zwalczaniu chwastów w uprawie kukurydzy Efficacy and phytotoxicity of Nikita 562,5 WG in post-emergence treatment of weed control in corn Trial ID: PL18HEZEAMX100C GEP	N			ADAMA	
KCP 6	Dr inż Agnieszka Kukuła	2019	Ocena skuteczności preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy of NIKITA (ADM.4651.H.1.A) for the control of weeds on corn /Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds on corn in Poland 2019) Trial code: PL19HEZEAMX044A GEP	N			ADAMA	
KCP 6	Dr inż Agnieszka Kukuła	2019	Ocena skuteczności preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy of NIKITA (ADM.4651.H.1.A) for the control of weeds on corn /Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds on corn in Poland 2019) Trial code: PL19HEZEAMX044B GEP	N			ADAMA	
KCP 6	Adam Pawlak	2019	Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds on corn in	N			ADAMA	

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Poland 2019. Trial code:PL19HEZEAMX044C GEP					
KCP 6	Łukasz Sobiech	2019	Badanie skuteczności produktu ADM.4651.H1A w zwalczaniu chwastów w uprawie kukurydzy Efficacy of ADM.4651.H1A in weed control in corn cultivation Trial code:PL19HEZEAMX044D GEP	N			ADAMA	
KCP 6	Łukasz Sobiech	2019	Badanie skuteczności produktu ADM.4651.H1A w zwalczaniu chwastów w uprawie kukurydzy Efficacy of ADM.4651.H1A in weed control in corn cultivation Trial code:PL19HEZEAMX044E GEP	N			ADAMA	
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu ADM.4651.H.1.A stosowanego w zwalczaniu chwastów w uprawie kukurydzy, Polska 2019 Selectivity of ADM.4651.H.1.A applied in control of weeds in corn, Poland 2019 Report number: 3_01_F19_05 Client's number: PL19HSZEAMX051A GEP	N			ADAMA	
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu ADM.4651.H.1.A stosowanego w zwalczaniu chwastów w uprawie kukurydzy, Polska 2019 Selectivity of ADM.4651.H.1.A applied in control of weeds in corn, Poland 2019 Report number: 3_02_F19_06 Client's number: PL19HSZEAMX051B GEP	N			ADAMA	
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu ADM.4651.H.1.A stosowanego w zwalczaniu chwastów w uprawie kukurydzy, Polska 2019 Selectivity of ADM.4651.H.1.A applied in control of weeds in corn, Poland 2019 Report number: 3_03_F19_07 Client's number: PL19HSZEAMX051C GEP	N			ADAMA	
KCP 6.4	Dr Dariusz Gajek	2019	Selectivity of ADM.4651.F.1.A in corn /Poland/ 2019 FINAL REPORT nr: PL19HSZEAMX051D	N			ADAMA	

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			(ARC19_ZEAMX_ADAM_01a) GEP					
KCP 6.4	Dr Dariusz Gajek	2019	Selectivity of ADM.4651.F.1.A in corn /Poland/ 2019 FINAL REPORT nr: PL19HSZEAMX051E (ARC19_ZEAMX_ADAM_01b) GEP	N			ADAMA	
KCP 6	Dr inż Agnieszka Kukuła	2020	Ocena skuteczności preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy of NIKITA (ADM.4651.H.1.A) for the control of weeds on corn / Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds on corn in Poland 2019) Final report nr : 20ADA762-1 Client's code: PL20HEZEAMX005A GEP	N			ADAMA	
KCP 6	Łukasz Sobiech	2020	Ocena skuteczności preparatu ADM.4651.H.1.A stosowanego w terminie powstępowym w zwalczaniu chwastów w uprawie kukurydzy Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds in maize cultivation Research number: 24rej/19/20/Br Trial code: AH/20/K/19/Br/005B Client's trial number: PL20HEZEAMX005B GEP	N			ADAMA	
KCP 6	Łukasz Sobiech	2020	Ocena skuteczności preparatu ADM.4651.H.1.A stosowanego w terminie powstępowym w zwalczaniu chwastów w uprawie kukurydzy Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds in maize cul- tivation Research number: 24rej/19/20/Zł Trial code: AH/20/K/19/Zł/005C Client's trial number : PL20HEZEAMX005C GEP	N			ADAMA	
KCP 6	Adama Szemendera	2020	Skuteczność preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w kukurydzy Efficacy of NIKITA (ADM.4651.H.1.A) in control of weeds in maize Report number: 16 01_F20_25 Client's number: PL20HEZEAMX005D	N			ADAMA	

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			GEP					
KCP 6	Dr inż Agnieszka Kukuła	2020	Ocena skuteczności preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w uprawie kukurydzy The evaluation of efficacy of NIKITA (ADM.4651.H.1.A) for the control of weeds on corn / Efficacy of ADM.4651.F.1.A applied in post emergence for controlling of weeds on corn in Poland 2019) Final report nr : 20ADA764-1 Client's code: PL20HEZEAMX005E GEP	N			ADAMA	
KCP 6	Adama Szemendera	2020	Skuteczność preparatu NIKITA (ADM.4651.H.1.A) w zwalczaniu chwastów w kukurydzy Efficacy of NIKITA (ADM.4651.H.1.A) in control of weeds in maize Report number: 271 01 720 463 Client's number: PL20HEZEAMX005F GEP	N			ADAMA	
KCP 6.4	Mgr inż. Adam Szemendera	2020	Selektywność preparatu ADM.4651.H.1.A stosowanego w zwalczaniu chwastów w uprawie kukurydzy, Polska 2020 Selectivity of ADM.4651.H.1.A applied in control of weeds in corn, Poland 2020 Report number: 17_01_F20_26 Client's number: PL20HSZEAMX006A GEP	N			ADAMA	
KCP 6.4	Dr inż Dariusz Gajek	2020	Selectivity of ADM.4651.F.1.A in maize /Poland/ 2020 Final report nr: PL20HSZEAMX006B (ARC20_ZEAMX_ADAM_37A) Trial number: PL20HSZEAMX006B GEP	N			ADAMA	
KCP 6.4	Dr inż Dariusz Gajek	2020	Selectivity of ADM.4651.F.1.A in maize /Poland/ 2020 Final report nr: PL20HSZEAMX006C (ARC20_ZEAMX_ADAM_37B) Trial number: PL20HSZEAMX006C GEP	N			ADAMA	
KCP 6.4	Mgr inż. Adam Szemendera	2020	Selektywność preparatu ADM.4651.H.1.A stosowanego w zwalczaniu chwastów w uprawie kukurydzy, Polska 2020 Selectivity of ADM.4651.H.1.A applied in control of weeds in corn, Poland 2020	N			ADAMA	

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Report number: 17_01_F20_27 Client's number: PL20HSZEAMX006D GEP					
KCP 6.4	Adam Pawlak	2020	Selectivity of ADM.4651.F.1.A in maize /Poland/ 2020. STAPHYT Ref.: APK-20-44685-PL01 Sponsor Ref. :PL20HSZEAMX006E GEP	N			ADAMA	

Analytical Methods

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 5.1.1 / 01	Adolph S.	2012	Analytical Method SF-568/1 - mesotrione/dicamba/nicosulfuron WG (15731.25/10) in formulation, by HPLC Syngenta Syngenta Crop Protection, MÃ¼nchwilen, Switzerland, 10493506 Not GLP not published Syngenta File No A18032E_10062	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 02	De Benedictis S.	2013	A18032E - Validation of Analytical Method SF-568/1 Syngenta Syngenta Crop Protection, MÃ¼nchwilen, Switzerland, 10528232 GLP not published Syngenta File No A18032E_10063	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 03	Hager M.	2011	R287431 - Analytical Method SD-977/2 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 10427012 Not GLP not published Syngenta File No R287431_10003	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 04	Hager M.	2011a	Validation of method SD-977/2 - R287431 in A14203B, A13789C, A14351BX, A12909Q, A15189G, A12738A, A15901A and A18219B Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, 10427878 GLP not published Syngenta File No R287431_10001	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 05	Hager M.	2013	Mesotrione - Relevant Impurity in A18032E Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 10538107	N	N	Not relevant	SYN (ADAMA has LoA)	N

			Not GLP not published Syngenta File No A18032E_10061					
KCP 5.1.1 / 06	Hager M.	2017	A18032E- Statement on Validation of Analytical Method SD-977 /2 for the Determination of R287431 (Xan-1) in Formulation A18032E Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300074792 Not GLP not published Syngenta File No A18032E_10366	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 07	Hager M., <i>et al</i>	2017	A18032E - Response to the Greek Regulatory Authority Concerning Relevant Impurity R287431, Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA Not GLP not published Syngenta File N.o. A18032E_10452	N	SYN (ADAMA has LOA)	KCP 5.1.1 / 07	Hager M., <i>et al</i>	N
KCP 5.1.1 / 08	Huang S.	2016	ZA1296 - SD-1990/1 - Determination of R287432 in Mesotrione Related Formulations by Liquid Chromatography/Mass Spectrometry (LC/MS) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300068727 Not GLP not published Syngenta File No A13789C_50005	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 09	Huang S.	2016a	A13789C - Validation of Analytical Method SD-1990/1 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160250 GLP not published Syngenta File No A13789C_50004	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 10	Huang S.	2016b	A18032E - Statement on Validation of Analytical Method SD-1990/1 for Determination of R287432 in Formulation A18032E (SAN837/ZA1296/nicosulfuron WG (31.25/15/10)) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072567	N	N	Not relevant	SYN (ADAMA has LoA)	N

			Not GLP not published Syngenta File No A18032E_10347					
KCP 5.1.1 / 11	Meyerhoffer W., Zhang Y., Patterson J.	2016	ZA1296 - SD-1973/1 - Determination of Impurity DCE (1,2-dichloroethane) in Mesotrione Related Formulations by Headspace Gas Chromatography Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300066025 Not GLP not published Syngenta File No A13789C_50002	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 12	Meyerhoffer W.	2016	A13789C - Validation of Analytical Method SD-1973/1 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160249 GLP not published Syngenta File No A13789C_50001	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.1 / 13	Meyerhoffer W.	2016a	A18032E - Statement on Validation of Analytical Method SD-1973/1 for Determination of 1,2-Dichloroethane (DCE) in Formulation A18032E (SAN837/ZA1296/Nicosulfuron WG (31.25/15/10)) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072403 Not GLP not published Syngenta File No A18032E_10346	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.2.1 / 01 & KCP 5.2.4 / 01	Braid S., Garcia-Alix M.	2013	Dicamba - Analytical Method GRM022.06A for the Determination of Dicamba and its Metabolite NOA414746 in Soil Syngenta CEMAS, North Ascot, United Kingdom, GRM022.06A Not GLP not published Syngenta File No SAN837_11434	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.1 / 02 & KCP 5.2.4 / 02	Garcia-Alix M.	2013	Dicamba - Analytical Method GRM022.06A for the Determination of Dicamba and its Metabolite NOA414746 in Soil Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5791-REG	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N

			GLP not published Syngenta File No SAN837_11433					
KCP 5.1.2.1 / 03 & KCP 5.2.5 / 01	Hargreaves S.	2007	Dicamba - Residue Method for the Determination of Residues in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.02A Not GLP not published Syngenta File No SAN837/6654	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.1 / 04 & KCP 5.2.5 / 02	Emburey S.	2007	Dicamba - Validation of an Analytical Method for the Determination of Residues of Dicamba in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, T002102-06-REG GLP not published Syngenta File No SAN837/6653	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.1 / 05 & KCP 5.2.5 / 03	Kotthoff M.	2016	Dicamba - Independent Laboratory Validation of Analytical Method GRM022.02A for the Determination of Residues of Dicamba (SAN837) in Water Syngenta Fraunhofer Institute, Schmallenberg, Germany, SYN-037/6-22 GLP not published Syngenta File No SAN837_11602	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.1 / 06 & KCP 5.2.6 / 01	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	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.1 / 07 & KCP 5.2.6 / 02	Emburey S.	2007a	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	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N

			not published Syngenta File No SAN837/6678					
KCP 5.1.2.1/08 KCP 5.2.5 / 04	Allen, L. & Brooks S.	2017	Dicamba - Residue Method GRM022.09A for the Determination of the Metabolite NOA414746 (DCSA) in Water. Syngenta Analytical Method GRM022.09A. CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD UK. GLP Not published Syngenta File No. NOA414746_10010	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.1/09 & KCP 5.2.5 / 05	Allen, L.	2017	Dicamba - Validation of Draft Residue Method GRM022.09A for the Determination of Dicamba Metabolite NOA414746 (DCSA) in Water. CEMAS Report Number CEMR-7878. CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD UK. GLP Not published Syngenta File No. NOA414746_10011	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.1 / 08 & KCP 5.2.4 / 03	Williams R.	2004	Analytical Method 1200-03 for the Determination of Mesotrione and its Metabolites AMBA and MNBA, in Soil, Using Liquid Chromatography - Electrospray Ionization Tandem Mass Spectrometry (Including Validation Data) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001200-03 GLP not published Syngenta File No ZA1296/1567	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.1 (report available from data owner)	Schneider M. Holzer S.	2016	Groundwater Monitoring for Nicosulfuron and Six Metabolites in Four Representative Regions in Germany SGS INSTITUT FRESENIUS GmbH Report: DuPont-28685 GLP Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	DuPont (ADAMA is co-owner)	N

KCP 5.1.2.1 (report available from data owner)	Ferrari F	2016	Groundwater Monitoring for nicosulfuron and 6 Metabolites in Maize Growing Regions of Italy LABCAM s.r.l. Report: DuPont-40798 (Interim Report) GLP Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	E.I. du Pont de Nemours and Company, Cheminova, (ADAMA has LoA from Dupont (1 LoA))	N
KCP 5.1.2.4 / 01	Bachelor B.	2014	Analytical Method Transfer and Partial Validation for the Determination of CA3511 in Dosing Formulations Syngenta Xenometrics, LLC, Stilwell, KS, USA, 11070 GLP not published Syngenta File No CA3511_50013	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.4 / 02	Faulkner L., Heap C.	2013	CA3511 - Feasibility of the Assay for the Determination of CA3511 in 1 % w/v Aqueous Carboxymethylcellulose Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0147 Not GLP not published Syngenta File No CA3511_10006	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.2.4 / 03	Faulkner L., Heap C.	2013a	CA3511 - Validation of the Assay for the Determination of CA3511 in 1 % w/v Aqueous Carboxymethylcellulose Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0148 GLP not published Syngenta File No CA3511_10007	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.4 / 04	Faulkner L., Heap C.	2013b	CA3511 - Validation of the Formulation Procedure for CA3511 in 1 % w/v Aqueous Carboxymethylcellulose and Assessment of Formulation Stability Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0149 GLP not published Syngenta File No CA3511_10009	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.4 / 05	xxxxxxxxxx	2016	AMBA - Single Dose Oral (Gavage) Proof of Exposure Study in the Rat Syngenta xxxxxxxxxxxxxxxxxx GLP not published	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

			Syngenta File No R044276_10012					
KCP 5.1.2.5 / 01	Richards S., Mackenzie R.	2006	Residue analytical method for the determination of residues of dicamba (SAN837) and 5-hydroxy dicamba (NOA405873) in barley (grain, straw, whole plant) and barley processed fractions (malt, wort, spent hops and spent yeast) Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, REM 193.05 Not GLP not published Syngenta File No SAN837/6535	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 02	Richards SJ., Mackenzie R., Crook SJ.	2008	Residue analytical method for the determination of Dicamba (SAN837) and 5-Hydroxy Dicamba (NOA405873) in barley (grain, straw, whole plant) and barley processed fractions (malt, wort, spent hops and spent yeast) Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, REM193.05B Not GLP not published Syngenta File No SAN837/6686	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 03	Richards S., Mackenzie R.	2004	Residue Study with Dicamba (SAN837) in or on Winter Barley in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7009 GLP not published Syngenta File No SAN837/6191	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 04	Richards S.	2004	Residue Study with Triasulfuron (CGA131036) and Dicamba (SAN837) in or on Winter Barley in The United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7013 GLP not published Syngenta File No CGA131036/1358	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N

KCP 5.1.2.5 / 05	Richards S., Mackenzie R.	2004a	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	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 06	Braid S., Kennedy S.	2017	Dicamba - Analytical Method GRM022.07A for the Determination of Dicamba and its Metabolite NOA405873 in Crops Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.07A Not GLP not published Syngenta File No SAN837_11703	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 07	Kennedy S.	2016	Dicamba - Validation of Analytical Method GRM022.07A for the Determination of Dicamba and its metabolite NOA405873 in Plant Matrices by LC-MS/MS Syngenta CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7414 GLP not published Syngenta File No SAN837_11691	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.1.2.5 / 08	Crook S., Andrews G.	2016	Nicosulfuron - Analytical Method GRM074.01A for the Determination of Nicosulfuron in Plant Matrices Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM074.01A Not GLP not published Syngenta File No ASF628_11278	N	N	Not relevant	SYN (ADAMA has LoA)	N
KCP 5.1.2.5 / 09	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

KCP 5.1.2.6 / 01	Weber K.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Assessment of Toxic Effects on Daphnia magna using the 48 h Acute Immobilisation Test Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S12-02294 GLP not published Syngenta File No A18032E_10008	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 02	Falk S.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Testing of Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata Syngenta Eurofins Agrosience Services GmbH, Niefern-Äschel., Germany, S12-02296 GLP not published Syngenta File No A18032E_10002	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 03	xxxxxxxxxxxxx	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Acute Toxicity Testing in Rainbow Trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) Syngenta xxxxxxxxxxxxx S12-02295 GLP not published Syngenta File No A18032E_10001	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 04	xxxxxxxxxxxxx	2012a	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor(A12127R) - Assessment of Toxic Effects on the duckweed Lemna gibba in a Semi-Static Test Syngenta xxxxxxxxxxxxxxxxxxxxx S12-02297 GLP not published Syngenta File No A18032E_10009	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 05	Bramby-Gunary J.	2013	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

			Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-149 GLP not published Syngenta File No A18032E_10025					
KCP 5.1.2.6 / 06	Bramby-Gunary J.	2013a	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-148 GLP not published Syngenta File No A18032E_10024	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 07	Hengsberger A., Wydra V.	2015	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a reciprocal growth inhibition test Syngenta IBACON GmbH, Rossdorf, Germany, 105731240 GLP not published Syngenta File No ZA1296_10436	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 08	Kosak L., Wydra V.	2016	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta IBACON GmbH, Rossdorf, Germany, 105732240 GLP not published Syngenta File No ZA1296_10438	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 09	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spicatum in a water/sediment system Syngenta Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP not published Syngenta File No ZA1296_10504	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 5.1.2.6 / 10	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize in Northern France	N	Y	Data/study never submitted before to	SYN (ADAMA has LoA)	N

			and the United Kingdom in 2015 Syngenta Eurofins Agroscience Services Ltd, Wilson, UK, S15-02057 GLP not published Syngenta File No A12739A_11065			Poland		
KCP 5.1.2.6 (report available from data owner)	Obert-Rauser P.	2016	MU-466: Toxicity to the Duckweed Lemna gibba under Laboratory Conditions Eurofins Agroscience Services Report: S15-05478 GLP: yes Published: No	N	Y	Data protection is claimed for this study starting with this submission in Poland. Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA.	Nicosulfuron Task Force (ADAMA is member)	N
KCP 5.1.2.6 (report available from data owner)	Dengler D.	2009	Assessment of Toxic Effects of HMUD on the Duckweed Lemna gibba in a Semi Static Test Eurofins-GAB GmbH Report: GAB S08-00827 GLP: yes Published: No	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Nufarm S.A.S (ADAMA has LoA from Nufarm (2 LoA))	N
KCP 5.2.1 / 01	Swales S.	2016	SAN837 - Uptake and Metabolism of [14C]-SAN837 in Confined Rotational Crops Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, AgroChemex Ltd, Manningtree, United Kingdom, 3200368 GLP not published Syngenta File No SAN837_11645	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.2.1 (report available from data owner)	Steinhilper D	2008	Validation of a Multiresidue method for the determination of Nicosulfuron in maize, Cheminova A/S. Report No.: 107 NIS GLP Unpublished	N	Y	Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA	Cheminova	N
KCP 5.2.1 (report available from data owner)	Schwarz T.	2008	Independent Laboratory Validation (ILV) of a residue analytical method for the determination of residue of nicosulfuron in maize plant, straw and grain, using LC/MS/MS, Cheminova A/S. Report No.: 119 NIS	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Cheminova	N

			GLP Unpublished					
KCP 5.2.1 (report available from data owner)	Cabusas, M.E. Pentz, A.	2012	Analytical Method for the Determination of Nicosulfuron and Rimsulfuron in Corn, Cherry, Lemon and Soybean Matrices using HPLC/ESI-MS/MS, Non GLP Unpublished	N	N	Not relevant	E.I. du Pont de Nemours and Company (Study not protected, non-GLP)	N
KCP 5.2.1 (report available from data owner))	McInerney K.	2016	Validation report DuPont-11776 RV2: Extension of the Linearity Range for Nicosulfuron in Oily and Acidic Crop Report No.: 100077587-03 Non GLP Unpublished	N	N	Not relevant	Nicosulfuron Task Force (ADAMA is member)	N
KCP 5.2.1 (report available from data owner)	Ducat, N., Pigeon O.	2004	Independent Laboratory validation of DuPont-11776, "Analytical Enforcement Method for the Determination of Nicosulfuron in Corn Matrices using HPLC/ESI-MS/MS Report No.: DuPont-12347 GLP Unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (Study should not attract data protection)	N
KCP 5.2.2 / 01	Richardson M., Braid S.	2012	Dicamba - Analytical Method for the Determination of Residues of Dicamba (SAN837) in Animal Matrices Final Determination by GC-MSD Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.05A Not GLP not published Syngenta File No SAN837_11414	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)	N
KCP 5.2.2 / 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	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)	N
KCP 5.2.2 / 03	Class T, Kuhn T	2010	Dicamba - Independent Laboratory Validation of Analytical Method GRM022.03A for the Determination of Residues of Dicamba and its Metabolite NOA414746 in Animal Materials by	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on	SYN/ BASF(ADAMA has LoA)	N

			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			data protection if required.		
KCP 5.2.2 (report available from data owner)	Wolf, S.	2009	Development and Validation of a Residue Analytical Method for Nicosulfuron in Animal Tissues (Milk, Egg, Muscle and Liver) Report No.: 90011604 Non GLP Unpublished	N	N	Not relevant	Agan Chemical Manufacturerers Ltd	N
KCP 5.2.3 (report available from data owner)	xxxxxxxxxxxxxxxx	2016a	Method Validation for the Determination of Nicosulfuron in Mouse Plasma Report No.: 100077587-04 GLP Unpublished	Y	Y	Data protection is claimed for this study starting with this application in Poland. Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA.	Nicosulfuron Task Force (ADAMA is member)	N

Mammalian Toxicology

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 7.1.1 / 01	xxxxxxxxxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10018	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.1.2 / 01	xxxxxxxxxxxxxx	2012	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Dermal Toxicity Study in Rats Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10006	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.1.3 / 01	xxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Inhalation Toxicity Study (Nose-Only) in the Rat Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10019	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.1.4 / 01	xxxxxxxxxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Primary Skin Irritation Study in Rabbits Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10016	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.1.5 / 01	xxxxxxxxxxxxxx	2012	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Eye Irritation Study in Rabbits Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10013	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.1.6 / 01	xxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Local Lymph Node Assay in the Mouse Syngenta	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

			xxxxxxxxxxxxxxxx GLP; not published Syngenta File No A18032E_10023					
KCP 7.3 / 01	Blackstock C., Vinall J.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Dicamba in Concentrate Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 34224 GLP; not published Syngenta File No A18032E_10281	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.3 / 02	Blackstock C., Haldane C.	2015	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Mesotrione in Concentrate Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36743 GLP; not published Syngenta File No A18032E_10320	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 7.3 / 03	Kerin T., Wilinska I.	2017	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Mesotrione in Two In Use Dilutions Through Human Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 38101 GLP not published Syngenta File No A18032E_10373	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

Mesotrione

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCA2 5.8.1 / 01	xxxxxxxxxxxxxxxxxx	2016	CA3511 - Oral (Gavage) Prenatal Developmental Toxicity Study in the Rat Syngenta xxxxxxxxxxxxxx GLP; not published Syngenta File No CA3511_10024	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA2 5.8.1 / 02	xxxxxxxxxxxxxxxxxxxx.	2016	CA3511 - Oral (Gavage) Two- Generation Reproduction Toxicity Study in the Rat Syngenta xxxxxxxxxxxxxxxxxxxx GLP; not published Syngenta File No CA3511_10030	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA2 5.8.1 / 03	xxxxxxxxxxxxxx	2016	AMBA - Oral (Gavage) Rat Micronucleus Test Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP; not published Syngenta File No R044276_10010	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

Metabolism and Residues

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCA1 6.3.1 / 02	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.3.1 / 03	Mound L., Gardinal P., Kwiatkowski A.	2006	Prosulfuron (CGA152005) and Dicamba (SAN837): Residue Study in or on Maize In Switzerland Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, 04-7016 GLP not published Syngenta File No SAN837/6543	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.3.1 / 04	Simon P.	2006	Prosulfuron and Dicamba: Residue study in or on maize in Germany 2004 (Test product: A14031B) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, gmz043004 GLP not published Syngenta File No SAN837/6545	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.3.1 / 05	Oppiliart S	2009	Dicamba (CGA57706) and Prosulfuron (CGA152005) - Residue Study on Corn in France (North) in 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - ADME Bioanalyses, Vergeze, France, T001033-07-REG GLP not published Syngenta File No A14031E_10809	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.5.1	Yeomans P.	2015	NOA405873 - Simulated Processing Practices:	N	Y	Data/study never	SYN	N

/01			Aqueous Hydrolysis of [14C] 5-Hydroxy-Dicamba at 90, 100 and 120 -C Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, 3200933 GLP not published Syngenta File No NOA405873_10000			submitted before to Poland	(ADAMA has LoA)	
KCA1 6.6.1 /01	Swales S.	2016	SAN837 - Uptake and Metabolism of [14C]-SAN837 in Confined Rotational Crops Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, AgroChemex Ltd, Manningtree, United Kingdom, 3200368 GLP not published Syngenta File No SAN837_11645	N	Y	D Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.6.2 /01	Andrews G.	2016a	Dicamba- Residue Study on Rotational Crops in Southern France and Spain in 2014 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0223573-REG GLP not published Syngenta File No A7254B_10456	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA1 6.6.2 /02	Austin R., Andrews G.	2016	Dicamba - Residue Study on Rotational Crops in the United Kingdom and Northern France in 2014 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, NC14032 GLP not published Syngenta File No A7254B_10460	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA3 6.1 (report available from data owner)	Peatman M. H.	2007	Nicosulfuron: Storage Stability of Residues in Corn Matrices Stored Deep Frozen Report No. 0676/032-D2149 (NIS-42) GLP, unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Cheminova A/S (ADAMA has access (3 LoA))	N
KCA3 6.2.1 (report available from data owner)	Scott M.T.	1989	Plant metabolism study of ¹⁴ C-DPX-V9360 in corn. Report No. AMR 861-87 GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)	N

KCA3 6.3.1 /01	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCA3 6.2.3 (report available from data owner)	Lin P.T., Scott M.T.,	1989	Metabolism of [pyrimidine-2-14C]DPX-V9360 and [pyridine 2 14C]DPX-V9360 in lactating goats Syngenta Report No. AMR 947-87 GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (Study no longer has data protection)	N
KCA3 6.6.1 (report available from data owner)	Dietrich R.F.	1989	Confined accumulation study of 14C-DPX-V9360 on rotational crops Report No. AMR 874-87 Non-GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)	N
KCA3 6.6.1 (report available from data owner)	Scott M.T.	2004	Confined accumulation study of 14C-DPX-V9360 on rotational crops. Report No. AMR 874-87, Supplement No. 1 Non-GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)	N

Environmental Fate and Behaviour

List of data submitted by the Applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 8.5.3	Hardy I., Agostini F.	2021	Organic carbon and clay dependency of nicosulfuron adsorption in soils: correlation analyses based on three adsorption studies Battelle UK Ltd., UK, TH/19/001A ADAMA Doc ID 000109197 Not GLP not published	N	N	Not relevant	ADAMA	Not relevant
KCP 9.2.4.1/01	Llanderal J.	2015	Dicamba - A Leaching Assessment for Parent and One Soil Metabolite (DCSA) Using the FOCUS Groundwater Scenarios Following Spray Application to Maize in the EU Syngenta RIFCON GmbH, Hirschberg, Germany, R1520411-1 Not GLP not published Syngenta File No SAN837_11572 <u>This is CONFIDENTIAL INFORMATION *</u>	N	N		SYN (ADAMA has LoA)	Not relevant
KCP 9.2.5 / 01	Llanderal J.	2016	Dicamba - A Surface Water Assessment for Parent and Metabolite DCSA Using the FOCUS Surface Water Scenarios at Step 1 and 2 Following Spray Applications to Maize in Europe Syngenta RIFCON GmbH, Hirschberg, Germany, R1520411-2 Not GLP not published Syngenta File No SAN837_11574 <u>This is CONFIDENTIAL INFORMATION *</u>	N	N		SYN (ADAMA has LoA)	Not relevant

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 9.2.5 / 02	Ibrahim L.	2017a	Mesotrione - A European Environmental Fate Assessment for Parent Using the FOCUS Surface Water Models at Steps 3 to 4 Following Spray Application to Maize and an Analysis of its FOCUS Step 3 and 4 Exposure Patterns Using the EPAT Tool Syngenta RIFCON GmbH, Hirschberg, Germany, R1520528-2 Not GLP not published Syngenta File No ZA1296_10482 <u>This is CONFIDENTIAL INFORMATION *</u>	N	N		SYN (ADAMA has LoA)	Not relevant
KCP 9.2.5 / 03	Carnall J.	2017a	Nicosulfuron - A European Fate Assessment Using the FOCUS Surface Water Step 1-2 Tool Following Spray Application to Maize Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1863 Not GLP not published Syngenta File No ASF628_11334 <u>This is CONFIDENTIAL INFORMATION *</u>	N	N	Not relevant	SYN (ADAMA has LoA)	Not relevant
KCP 9.2.5 / 04	Carnall J.	2017b	Nicosulfuron - A European Fate Assessment Using the FOCUS Surface Water Scenarios at Step 3 and Step 4 Following Spray Application to Maize Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1864 Not GLP not published Syngenta File No ASF628_11312 <u>This is CONFIDENTIAL INFORMATION *</u>	N	N	Not relevant	SYN (ADAMA has LoA)	Not relevant

* Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta commercial interests by providing access to Syngenta specific know-how.

Ecotoxicology

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Document No. Source (where different from company) GLP / Officially recognised testing facilities Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 7.1.1	xxxxxxxxxxxxxxxxxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) – Acute Oral Toxicity Study in the Rat (Up and Down Procedure). xxxxxxxxxxxxxxxxxxxxxx GLP, Unpublished Syngenta File No. A18032E_10018	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has access)	N
KCP 10.1.2	Alvarez T.	2019	Mesotrione: refined risk assessments for mammals. Syngenta, Jealott's Hill, Bracknell, United Kingdom. Syngenta Unpublished Report (Syngenta File No. A18032E_10335) <u>This is CONFIDENTIAL INFORMATION*</u>	N	N	Not relevant	SYN (ADAMA has access)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.1.2.2/07	Grimm T & Katzschner I	2019	Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, Germany Report No. R1740045 GLP, Unpublished Syngenta File No. NA_14950	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.1.2.2	North, L.	2016	Mesotrione – Foliage Decline Study with A12739A on Maize in Northern France and the United Kingdom in 2015. Eurofins Agrosience Services Ltd., Slade Lane, Wilson, Melbourne, Derbyshire, DE73 8AG, UK Report No. S15-02057 GLP, Unpublished Syngenta File No. A12739A_11065	N	Y	Data/study never submitted before to Poland	SYN	Y (Callisto, Calaris, final Core of 2020)
KCP 10.1.2.2/12	Allen L.	2019	Mesotrione – Mesotrione – Study on Clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2018. CEMAS, Imperial House, Oaklands Park, Wokingham, Berkshire, RG41 2FD, , UK Report No. CEMR-8397 GLP, Unpublished Syngenta File No. A12738A_10535	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)

KCP 10.2.1	Falk, S.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Testing of Effects on the Single Cell Green Alga <i>Pseudokirchneriella subcapitata</i> Eurofins Agrosience Services EcoChem GmbH, Eutinger Str.24, 75223 Niefern-Öschelbronn, Germany Report No. S12-02296 GLP, Unpublished Syngenta File No. A18032E_10002	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.2.1	Gonsior, G.	2017	Mesotrione – Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH Eutinger Strasse 24, 75223 Niefern-Öschelbronn, Germany Report No. S16-06273 GLP, Unpublished Syngenta File No. ZA1296_10504	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.2.1	Hengsberger A., Wydra V. (amendment 2; Kosak L., Wydra V.	2015 (amend.2 2016)	Mesotrione Wet Paste (ZA1296) - Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Semi-Static Growth Inhibition Test with a Subsequent Recovery Period. Ibacon GmbH Arheilger Weg 17 64380 Rossdorf Germany. Report No. 105732240 GLP, Unpublished Syngenta File No. ZA1296_10438	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.2.1	Weber, K.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) – Assessment of Toxic Effects on <i>Daphnia magna</i> using the 48 h Acute Immobilisation Test Eurofins Agrosience Services EcoChem GmbH, Eutinger Strasse 24, 75223 Niefern-Öschelbronn, Germany Report No. S12-02294 GLP, Unpublished Syngenta File No. A18032E_10008	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N

KCP 10.2.1	Weber, K.	2012a	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) – Assessment of Toxic Effects on the duckweed <i>Lemna gibba</i> in a Semi-Static Test Eurofins Agrosience Services EcoChem GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany Report No. S12-02297 GLP, Unpublished Syngenta File No. A18032E_10009	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.2	xxxxxxxxxxxxxxxx	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) – Acute Toxicity Testing in Rainbow Trout (<i>Oncorhynchus mykiss</i>) (Teleostei, Salmonidae) xxxxxxxxxxxxxxxx Report No. S12-02295 GLP, Unpublished Syngenta File No. A18032E_10001	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.2 (report available from data owner)	Wenzel, A.	2010	Macrophyte Growth Test with Nicosulfuron Technical. Test with a subsequent Recovery Period. Fraunhofer IME study No. CHE-009/4-80 Report No. 185 NIS GLP, Unpublished	N	No information provided	No information provided	Cheminova (ADAMA has LoA from FMC, owner of Cheminova)	No information provided
KCP 10.3.1.1.1 and 10.3.1.1.2	Kling, A.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) – Acute Oral and Contact Toxicity to the Honeybee <i>Apis mellifera</i> L. in the Laboratory Eurofins Agrosience Services EcoChem GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany Report Number S12-02293 GLP, Unpublished Syngenta File No. A18032E_10005	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.3.2.1	Fallowfield, L.	2012	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus A12127R (Adigor adjuvant) – A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite, <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Mambo-Tox Ltd., 2 Venture Road, Chilworth Science Park, Southampton, SO16 7NP, UK Report No. SYN-12-28 GLP, Unpublished Syngenta file No. A18032E_10003	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N

KCP 10.3.2.1	Stevens, J.	2012	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) – A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) Mambo-Tox Ltd., 2 Venture Road, Chilworth Science Park, Southampton SO16 7NP, United Kingdom Report No. SYN-12-29 GLP, Unpublished Syngenta File No. A18032E_10000	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.3.2.2	Stevens, J.	2012a	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) 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) Mambo-Tox Ltd., 2 Venture Road, Chilworth Science Park, Southampton SO16 7NP, United Kingdom Report No. SYN-12-45 GLP, Unpublished Syngenta File No. A18032E_10010	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.3.2.2	Tew, G.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor A12127R – A rate-response extended laboratory bioassay of the effects of fresh residues on the rove beetle, <i>Aleochara bilineata</i> (Coleoptera; Staphylinidae) Mambo-Tox Ltd., 2 Venture Road, Chilworth Science Park, Southampton SO16 7NP, United Kingdom Report No. SYN-12-46 GLP, Unpublished Syngenta File No. A18032E_10015	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N
KCP 10.4.1.1	Friedrich, S.	2012	Friedrich S, (2012). Mesotrione/Dicamba/Nicosulfuron WG (A18032E) plus Adigor (A12127R) – Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil BioChem agrar Labor für biologische und chemische Analytik GmbH, Kupferstraße 6 04827 Gerichshain, Germany Report Number 12 10 48 147 S GLP, Unpublished Syngenta File No. A18032E_10007	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LOA)	N

KCP 10.4.2.1	Dickinson, R.A.	2015	R169649 - Collembola (<i>Folsomia candida</i>) Reproduction Test in Soil Agrochemex Ltd., Aldhams research station, Manningtree, Essex, CO11 2NF, United Kingdom Report No. ENV-14-015 GLP, Unpublished Syngenta File No. CA3511_10011	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.4.2.1	Friedrich, S.	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) plus Adigor (A12127R) – Effects on the Reproduction of the Collembolan <i>Folsomia candida</i> BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany Report No. 12 10 48 090 S GLP, Unpublished Syngenta File No. A18032E_10011	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 10.4.2.1	Ramsden, C.	2015	R169649 – Predatory Mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) Reproduction Test in Soil AgroChemex Environmental Ltd., Aldhams Farm Research Station, Dead Lane, Manningtree, Essex, CO11 2NF, United Kingdom Report No. ENV-14-012 GLP, Unpublished Syngenta File No. CA3511_10010	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LOA)	Y (Callisto, Calaris, final Core of 2020)
KCP 10.4.2.1	Schulz, L.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) – Effects on the Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> BioChem agrar Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany Report Number 12 10 48 148 S GLP, Unpublished Syngenta File No. A18032E_10012	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 10.5	Schulz, L.	2012	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) – Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany Report Number 12 10 48 048 C/N GLP, Unpublished Syngenta File No. A18032E_10004	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

KCP 10.6.2	Bramby-Gunary, J.	2013	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test AgroChemex Ltd, Aldhams Farm, Dead Lane, Manningtree, Essex, CO11 2NF, United Kingdom Report Number ACE-12-149 GLP, Unpublished Syngenta File No. A18032E_10025	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N
KCP 10.6.2	Bramby-Gunary, J	2013a	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test AgroChemex Ltd, Aldhams Farm, Dead Lane, Manningtree, Essex, CO11 2NF, United Kingdom Report No. ACE-12-148 GLP, Unpublished Syngenta File No. A18032E_10024	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)	N

*Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta commercial interests by providing access to Syngenta specific know-how.