

Product name: Mighty
Product code: SHA 4300 A
Active Substance: mesotrione 100 g/L

REGISTRATION REPORT – POLAND

Part B, Sec. 1 to 9

Reference List

Application for authorisation (Article 33)

Applicant: Sharda Cropchem España S.L.

MS Finalisation date: 04/06/2024

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 KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Mónica Berrios	2016	PHYSICAL AND CHEMICAL PROPERTIES AND ACCELERATED STORAGE STABILITY TEST FOR MESOTRIONE 10% SC (SUSPENSION CONCENTRATE, 10.2% W/W MESOTRIONE) - SPAIN 2015- Labs & Technological Services AGQ, S.L., study number E-15-0004 GLP/Unpublished	Y	Y	Sharda Cropchem Ltd.
KCP 2.7.1	Micaela Banos Gonzalez	2020	Determination of impurities and mesotrione in mesotrione 10% SC. Laboratorios Munuera Report: 18-4150-28 GLP Unpublished	Y	Y	Sharda Cropchem Ltd.
KCP 2.7.4	Idris Al Amin	2018	Mesotrione 10% SC. Wet sieve test after low temperature storage. Institute of Industrial Organic Chemistry Report: BF-15/18 GLP Unpublished	Y	Y	Sharda Cropchem Ltd.
KCP 2.7.5	Mª DEL MAR DEL VALLE GARCÍA	2020	Long term storage stability test for mesotrione 10% sc (suspension concentrate, 10.2% w/w mesotrione) -spain 2015- Labs & Technological Services AGQ, S.L., study number E-15-0019	Y	Y	Sharda Cropchem Ltd.

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			GLP/Unpublished			
KCP 2.7.5	Micaela Banos Gonzalez	2022	Determination of impurities in mesotrione 10% SC during storage stability for two years at 25±2°C. Laboratorios Munuera Report: 18-4150-29 GLP Unpublished	Y	Y	Sharda Cropchem Ltd.

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
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrione 10% SC and S-Metolachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services Ltd, United Kingdom S15-01089-01 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% Ec, Mesotrione 10% Sc and S-Metolachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services, France S15-01089-02 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% Ec, Mesotrione 10% Sc and S-Metolachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Service GmbH, Germany S15-01089-03 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% Ec, Mesotrione 10% Sc and S-Metolachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Service GmbH, Germany S15-01089-04 yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.2.2 3.2.3	Luboinski A.	2015	Efficacy evaluation of S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU108W yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Luboinski A.	2015	Efficacy evaluation of S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU109W yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Luboinski A.	2015	Efficacy evaluation of S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU114Z yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Auškalnienė O.	2015	Efficacy of herbicide S Metolachlor 96% EC (S Metolachlor 960 g/L) and Mesotrion 10% in maize Institute of Agriculture LRCAF, Lithuania 151542521 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Auškalnienė O.	2015	Efficacy of herbicide S Metolachlor 96% EC (S Metolachlor 960 g/L) and Mesotrion 10% in maize Institute of Agriculture LRCAF, Lithuania 151542531 yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.2.2 3.2.3 1	Auškalnienė O.	2015	Efficacy of herbicide S Metolachlor 96% EC (S Metolachlor 960 g/L) and Mesotrion 10% in maize Institute of Agriculture LRCAF, Lithuania 151542541 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Mintale Z.	2015	Efficacy evaluation of herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2254 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Mintale Z.	2015	Efficacy evaluation of herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2255 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Mintale Z.	2015	Efficacy evaluation of Herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2256 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Miziniak W.	2015	Efficacy evaluation of herbicides S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU110T yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.2.2 3.2.3	Miziniak W.	2015	Efficacy evaluation of herbicides S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU111T yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Konecki R.	2015	Testing of effectiveness of the herbicides S Metolachlor 96% EC and Mesotrion 10% SC used post-emergence in corn Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU113B yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Snarska K.	2015	Testing of effectiveness of the herbicides S Metolachlor 96% EC and Mesotrion 10% SC used post-emergence in corn Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland SH15KU112B yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services Sp z o.o., Poland S15-01089-05 yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Sevices S.R.L., Romania S15-01089-06 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services, France S15-01088-01 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services SRL, Italy S15-01088-02 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins Agroscience Services SRL, Italy S15-01088-03 yes Unpublished	Y	Y	Sharda Cropchem Limited

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3.2.2 3.2.3	Motais F.	2015	Determination of the efficacy of S-Metolachlor 96% EC, Mesotrion 10% SC and S-Metalachlor + Mesotrione 400+40 g/L SE for the control of weeds in Maize Eurofins, Agrosience Services SL, Spain S15-01088-04 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC, Mesotrion 10% SC when applied post-emergence to Maize Eurofins Agrosience Services Ltd, UK S15-01093-01 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC, Mesotrion 10% SC when applied post-emergence to Maize Eurofins Agrosience Services, France S15-01093-02 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC, Mesotrion 10% SC when applied post-emergence to Maize Eurofins Agrosience Service GmbH, Germany S15-01093-03 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC, Mesotrion 10% SC when applied post-emergence to Maize Eurofins Agrosience Service GmbH, Germany S15-01093-04 yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.4.1 3.4.2 3.4.3	Luboinski A.	2015	Phytotoxicity evaluation of S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland FH15KU117W yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Luboinski A.	2015	Phytotoxicity evaluation of S Metolachlor 96% EC and Mesotrion 10% SC applied post-emergence in maize Institute of Plant Protection - National Research Institute, Department of Plant Protection Products Poznan, Poland FH15KU118W yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Drzewiecki S.	2015	Biological assessment of selectivity of herbicides S Metolachlor 96 EC, Camix 560 SE / A 12807 J, Mesotrion 10 SC, Callisto 100 SC/A 12739 A applied postemergence in maize Institute of Plant Protection - National Research Institute, Sośmnicowice, Poland FiHPwKu-15-43 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Mintale Z.	2015	Selectivity evaluation of Herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2260 yes Unpublished	Y	Y	Sharda Cropchem Limited

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
3.4.1 3.4.2 3.4.3	Mintale Z.	2015	Selectivity evaluation of Herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2261 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Mintale Z.	2015	Selectivity evaluation of Herbicides S Metolachlor 96% EC and Mesotrion 10% SC in maize Latvian Plant Protection Research Centre Ltd., Latvia H-15-1-14-ZM-2262 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post- emergence to Maize Eurofins Agroscience Services Sp z o.o., Poland S15-01093-05 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post- emergence to Maize Eurofins AgroScience Services, Bulgaria S15-01092-04 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post- emergence to Maize Eurofins Agroscience Sevices S.R.L., Romania S15-01093-06 yes Unpublished	Y	Y	Sharda Cropchem Limited

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3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post-emergence to Maize Eurofins Agrosience Services, France S15-01092-01 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post-emergence to Maize Eurofins Agrosience Services SRL, Italy S15-01092-02 yes Unpublished	Y	Y	Sharda Cropchem Limited
3.4.1 3.4.2 3.4.3	Motais F.	2015	Determination of the crop safety of S-Metolachlor 96% EC and Mesotrione 10% SC when applied post-emergence to Maize Eurofins, Agrosience Services SL, Spain S15-01092-03 yes Unpublished	Y	Y	Sharda Cropchem Limited

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	Mónica Berrios	2016	PHYSICAL AND CHEMICAL PROPERTIES AND ACCELERATED STORAGE STABILITY TEST FOR MESOTRIONE 10% SC (SUSPENSION CONCENTRATE, 10.2% W/W MESOTRIONE) - SPAIN 2015- Labs & Technological Services AGQ, S.L., study number GLP/Unpublished	Y	Y	Sharda Cropchem Ltd.
KCP 5.1.1-02	Micaela Banos Gonzalez	2020	Determination of impurities and mesotrione in mesotrione 10% SC. Laboratorios Munuera Report: 18-4150-28 GLP Unpublished	Y	Y	Sharda Cropchem Ltd.
KCP 5.2.1	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in forage by liquid chromatography. Chelab Report No. 18.629767.0002 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.2	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in grain (maize) by liquid chromatography. Chelab Report No. 18.629767.0001 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.3	E. Signore	2019	Independent Laboratory Validation of analytical method for the determination of Mesotrione in Maize forage and grain validated in a study conducted by Chelab. Biospheres Report No. RAU-100-18 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.4	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in milk by liquid chromatography. Chelab Report No. 18.629767.0004 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.5	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-	Y	Y	Sharda Cropchem

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
			82-8) in eggs by liquid chromatography. Chelab Report No. 18.629767.0005 GLP Unpublished			Limited
KCP 5.2.6	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in meat by liquid chromatography. Chelab Report No. 18.629767.0008 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.7	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in fat by liquid chromatography. Chelab Report No. 18.629767.0006 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.8	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in kidney by liquid chromatography. Chelab Report No. 18.629767.0007 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.9	E. Signore	2019	Independent Laboratory Validation of analytical methods for the determination of Mesotrione in animal matrices (eggs, fat, kidney and meat) validated in Studies conducted by Chelab. BioSpheres Report No. RAU 008-19 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.10	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in soil by liquid chromatography. Chelab Report No. 18.629767.0009 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.11	M. Rubino	2018	Validation of the analytical procedure for the determination of MNBA (CAS: 110964-79-9) in soil by liquid chromatography. Chelab Report No. 18.640093.0001 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP	M. Rubino	2018	Validation of the analytical procedure for the	Y	Y	Sharda

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
5.2.12			determination of AMBA (CAS: 393085-45-5) in soil by liquid chromatography. Chelab Report No. 18.640093.0002 GLP Unpublished			Cropchem Limited
KCP 5.2.13	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in ground water by liquid chromatography. Chelab Report No. 18.629767.0015 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.14	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in surface water by liquid chromatography. Chelab Report No. 18.629767.0012 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.15	M. Rubino	2018	Validation of the analytical procedure for the determination of MNBA (CAS: 110964-79-9) in ground water by liquid chromatography. Chelab Report No. 18.629767.0017 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.16	M. Rubino	2018	Validation of the analytical procedure for the determination of AMBA (CAS: 393085-45-5) in ground water by liquid chromatography. Chelab Report No. 18.629767.0016 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.17	M. Rubino	2018	Validation of the analytical procedure for the determination of MNBA (CAS: 110964-79-9) in surface water by liquid chromatography. Chelab Report No. 18.629767.0014 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.18	M. Rubino	2018	Validation of the analytical procedure for the determination of AMBA (CAS: 393085-45-5) in surface water by liquid chromatography. Chelab Report No. 18.629767.0013 GLP Unpublished	Y	Y	Sharda Cropchem Limited

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 5.2.19	Z. Hordyjewicz-Baran	2019	Independent Laboratory Validation of the analytical procedure for the determination of residues of Mesotrione (CAS 104206-82-8) in drinking water by Liquid Chromatography. Institute of Heavy Organic Synthesis Report No. 163/2019 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.20	E. Signore	2019	Independent Laboratory Validation of analytical method for the determination of Mesotrione metabolites (AMBA and MNBA) in drinking water validation a Study conducted by Chelab. Biospheres Report No. RAU-007-19 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.21	M. Rubino	2018	Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in air by LC-MS. Chelab Report No. 18.629767.0018 GLP Unpublished	Y	Y	Sharda Cropchem Limited
KCP 5.2.22	M. Rubino		Validation of the analytical procedure for the determination of mesotrione (CAS: 104206-82-8) in blood by liquid chromatography Chelab Report No. 18.629767.0003 GLP Unpublished	Y	Y	Sharda Cropchem Limited

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	xxxxx	2017	Mesotrione 10% SC: Acute Oral Toxicity Study in Rat, xxxxxxxxxxxx, Report No. R/15342/AOR/17 GLP, Unpublished	Y	Y	SHARDA Cropchem Ltd.
KCP 7.1.2	xxxxxx	201	Mesotrione 10% SC: Acute Dermal Toxicity Study in Rat xxxxxxxxxxxx, Report No. R/15343/ADR/17 GLP, Unpublished	Y	Y	SHARDA Cropchem Ltd.
KCP 7.1.3	xxxxxx	2017	Mesotrione 10% SC: Acute Inhalation Toxicity Study in Rat xxxxxxxx, Report No. R/15344/AIR/17 GLP, Unpublished	Y	Y	SHARDA Cropchem Ltd.
KCP 7.1.6	xxxxxx	2017	Mesotrione 10% SC: Skin Sensitisation Study by Guinea Pig Maximization Test (GPMT) xxxxxxxxxxxx, Report No. Report No. R/15347/SS-GPMT/17 GLP, Unpublished	Y	Y	SHARDA Cropchem Ltd.
KCP 7.6.2	A.A. Reus	2018	In vitro percutaneous absorption of Mesotrione, formulated as Mesotrione 10% SC, through human skin, A.A. Reus., 2018, STUDY REPORT V21130/10 GLP, Unpublished	Y	Y	SHARDA Cropchem Ltd.

Section 7

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 8.3.1	Barnes J.P. et al.	1995-1996	Residue Levels in Maize from Trials Carried out in Germany and France (59806, 59808, 59810, 59812) Zeneca Agrochemicals, Jealott's Hill, United Kingdom Yes Published	N	Y	SYN
KCP 7.2.1.1	Wiebe LA, Peyton CS	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Zeneca Agrochemicals, Jealott's Hill, United Kingdom. RR 97-042B FIN GLP, published Syngenta File No ZA1296/0125	N	Y	SYN
KCP 7.2.2.1	Wei, Y. et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B Yes Published	N	Y	SYN
KCP 7.2.2.1	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn Yes Published	N	Y	SYN
KCP 7.2.2.2	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate Yes Published	N	Y	SYN
KCP 7.2.2.5	Hand, L.H.	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow Yes Published	N	Y	SYN
KCP 7.2.6.1	Barnes, J.P., Wiebe, L.A.	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B Yes Published	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
KCP 9.1.3 KCP 9.2.4 KCP 9.2.5	-	2020	Calculations of PECsoil, PECgw and PECsw. Sharda Non GLP Unpublished	N	Y	Sharda

Section 9

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 10.2.1-01	xxxxxx	2016	Mesotrione 10% SC Rainbow trout Acute toxicity test Study code: W/112/16 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.2.1-02	Brzozowska-Wojczech, K.	2016	Mesotrione 10 % SC <i>Daphnia magna</i> , Acute Immobilization Test Study code: W/148/16 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.2.1-03	Brzozowska-Wojczech, K.	2016	Mesotrione 10% SC <i>Pseudokirchneriella subcapitata</i> SAG 61.81 Growth inhibition test Study code: W/147/16 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.2.1-04	Brzozowska-Wojczech, K.	2016	Mesotrione 10% SC <i>Lemna gibba</i> CPCC 310 Growth inhibition test Study code: W/149/16 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.1.1.1	Pawel Parma	2015	Mesotrione 10% SC; Honeybees (<i>Apis mellifera</i> L.), Acute Oral Toxicity Test Study code: B/132/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.1.1.2	Pawel Parma	2015	Mesotrione 10% SC; Honeybees (<i>Apis mellifera</i> L.), Acute Contact Toxicity Test Study code: B/133/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.1.2	Gimeno, I.	2019	Mesotrione Technical – Chronic Toxicity to the Honey Bee, <i>Apis mellifera</i> L. under laboratory Conditions Study code: TRC17-006BA Trialcamp S.L.U. GLP, unpublished	Y	Y	Sharda Cropchem Limited

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KCP 10.3.1.3	Scheller, K.	2018	Mesotrione Technical - Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (in vitro) Study code: 17 48 BLC 0088 BioChem agrar GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.2.2-01	Pawel Parma	2016	An extended laboratory test for evaluating the effects of Mesotrione 10% SC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani - Perez) Study code: B/131/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.2.2-02	Parma, P.	2017	An extended laboratory test for evaluating the effects of Mesotrione 10% SC on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Study code: B/130/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.2.2-03	Luna, F.	2017	Aged residue test with the formulation Mesotrione 10% SC on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Study code: TRC17-090BA Trialcamp S.L.U. GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.3.2.2-04	Soler, E.	2017	Side-effects of the formulated product Mesotrione 10% SC on <i>Aleochara bilineata</i> (Coleoptera:Staphylinidae) under extended laboratory conditions Study code: TRC17-115BA Trialcamp S.L.U. GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.4.1.1	Weronika Dec	2016	Mesotrione 10% SC Earthworm Reproduction Test (<i>Eisenia fetida</i>) Study code: B/243/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.4.2.1	Weronika Dec	2016	Mesotrione 10% SC Collembolan (<i>Folsomia candida</i>) Reproduction Test Study code: G/244/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited

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KCP 10.5-01	Weronika Dec	2016	Mesotrione 10% SC; Soil Microorganisms: Nitrogen Transformation Test Study code: G/242/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.6.2-01	Weronika Dec	2017	Mesotrione 10% SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G/246/15 Institute of Industrial Organic Chemistry GLP, unpublished	Y	Y	Sharda Cropchem Limited
KCP 10.6.2-02	Sadananda, T. S.	2019	Terrestrial plant test: Vegetative vigour test of Mesotrione 10% SC on plants Study code: BIO-ETX 034 Bioneds India Private Limited GLP, unpublished	Y	Y	Sharda Cropchem Limited