

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

B.1. IDENTITY

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
JCA. 1.11/01 J-CA 4.1.1		2011	Qualitative and quantitative profile of the test substance Flazasulfuron Tecnico ISK (Five batch analysis). BIOAGRI Laboratorios Ltda. Report number A01846.030.579.10. GLP, Unpublished	N		2015	Analysis of five representative production batches of Flazasulfuron Technical Grade Active Ingredient (TGAI) to identify and quantify Flazasulfuron and its associate impurities. RRL, Jiangsu China. Report N° 1348 GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
J-CA.1.11/01 J-CA. 4.1.1		2015	Flazasulfuron (SL-160) Technical, Five-Batch Analysis. Final report, Season P. Kerns. Laboratory: MRI Global 425 Volker Boulevard Kansas City, Missouri Project: 310260.01.170 July 2015 GLP, unpublished	N			See above				Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
JCA. 1.11/02		2003	Content of active ingredient and impurities in technical SL 160, lot 0208. Midwest Research Institute. Report number 310260.1.017 GLP, Unpublished	N		2017	STUDY ON THE METHOD VALIDATION OF FLAZASULFURON 250 g/kg WATER DISPERSIBLE GRANULES Study n°2056 RRL Jiangsu China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Not Acceptable, The alternative study provided (Padmanaban A. 2017) is for the PPP, nevertheless, the Data Requirement point is covered with Gu C, 2013 (see above)
JCA. 1.11/03		2011	Certificate of analysis SL 160, Lot No Y 920205 MRI Global Project Number 310260.01.116.01 GLP, Unpublished	N			See above				Not Acceptable, The alternative study provided (Padmanaban A. 2017) is for the PPP, nevertheless, the Data Requirement Point is covered with Gu C, 2013 (see above)

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B.2. PHYSICAL AND CHEMICAL PROPERTIES

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 2.7/05		2014	SSRE 003: PARTITION COEFFICIENT BY HPLC Report No.: JSM0701 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	STUDY ON THE PARTITION COEFFICIENT OF FLAZASULFURON METABOLITE (DMPU) Report n° 2053 RRL, Jiangsu China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 2.7/06		2014	SSRE 006: PARTITION COEFFICIENT BY HPLC Report No.: JSM0640 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	HMTU: Determination of Octanol: Water Partition Coefficient Study n° 3201885 Smithers Viscient (ESG) Ltd.UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 2.7/07		2014	SSRE 008: PARTITION COEFFICIENT BY HPLC Report No.: JSM0674 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	STUDY ON THE PARTITION COEFFICIENT OF FLAZASULFURON METABOLITE (HTPP) Report n° 2052 RRL, Jiangsu China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 2.7/08		2014	SSRE-018: PARTITION COEFFICIENT BY HPLC Report No.: JSM0629 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	GTPS: Determination of Octanol:Water Partition Coefficient Study n° 3201886 Smithers Viscient (ESG) Ltd.UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 2.7/09		2014	SSRE-020: PARTITION COEFFICIENT BY HPLC Report No.: JSM0635 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	HTPU: Determination of Octanol:Water Partition Coefficient Study n° 3201886 Smithers Viscient (ESG) Ltd.UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 2.7/10		2014	SSRE-021: PARTITION COEFFICIENT BY HPLC Report No.: JSM0702 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2017	Study on the PARTITION COEFFICIENT OF FLAZASULFURON METABOLITE (HTF) Report n° 2052 RRL, Jiangsu - China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 2.7/11		2014	SSRE 002: PARTITION COEFFICIENT BY HPLC Report No.: JSM0739 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom	N			LoA	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force. Rotam has requested a Letter of access to that study to the data owner ISK	N		Acceptable, Proof of LoA provided Letter of access to that study to the data owner ISK available (7 June 2019)
KCA 2.12/01		2014	SL 160: SURFACE TENSION Report No.: JSM0619 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		2015	STUDY ON THE PHYSICO CHEMICAL PROPERTIES OF FLAZASULFURON TECHNICAL Report n° 1497 RRL Jiangsu China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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B.3 DATA ON APPLICATION AND EFFICACY

Not needed

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B.4. FURTHER INFORMATION

No study

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B.5 METHODS OF ANALYSIS

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 4.1.2 (a)/01		2014	SSRE-006, SSRE-008, SSRE-018, SSRE-020: VALIDATION OF METHODOLOGY FOR THE DETERMINATION OF RESIDUES IN SOIL Report No.: JSM0627 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished				See below (soil degradation studies with HMTU, HTPP, GTPS and HTF)	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided See below (soil degradation studies with HMTU, HTPP, GTPS and HTF)
KCA 4.2(a)/01		2009	FLAZASULFURON - VALIDATION OF ANALYTICAL METHOD FOR FLAZASULFURON IN CROPS Report No.: S09-03106 Eurofins/ADME Bioanalyses, Vergèze, France GLP, unpublished			2015	Validation of an Analytical Method for the Determination of Residues of Flazasulfuron in Plant Commodities (aqueous, acidic, dry and fatty) Report: 15J08023-01-VMPL CIP GmbH - Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 4.2 (a)/02		2010	INDEPENDENT LABORATORY VALIDATION OF AN ANALYTICAL METHOD FOR FLAZASULFURON IN CROPS Report No.: ISK-0902V G09-0241 S09-03361 Eurofins Dr. Specht GLP GmbH, Hamburg, Germany GLP, unpublished	N		2015	INDEPENDENT LABORATORY VALIDATION OF A METHOD FOR THE DETERMINATION OF RESIDUES OF FLAZASULFURON IN CROPS Report n° CEMR-7340 CEM Analytical Services Ltd, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 4.2 (a)/04		2004	INDEPENDENT LABORATORY VALIDATION STUDY OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF FLAZASULFURON IN GRAPES Report No.: R A4116 A4116 Anadiag, Haguenau, France GLP, unpublished	N		2015	INDEPENDENT LABORATORY VALIDATION OF A METHOD FOR THE DETERMINATION OF RESIDUES OF FLAZASULFURON IN CROPS Report n° CEMR-7340 CEM Analytical Services Ltd, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 4.2 (b)/01		2009	FLAZASULFURON - VALIDATION OF ANALYTICAL METHOD FOR THE ACTIVE SUBSTANCE FLAZASULFURON IN SOIL Report No.: S09-03108 Eurofins/ADME Bioanalyses, Vergèze, France GLP, unpublished	N		2015	Validation of an Analytical Method for the Determination of Residues of Flazasulfuron in Soil Report n° 15J08023-01-VMSC CIP GmbH - Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 4.2 (b)/02		2010	FLAZASULFURON - VALIDATION OF ANALYTICAL METHOD FOR THE ACTIVE SUBSTANCE FLAZASULFURON IN WATER Report No.: S09-03107 Eurofins/ADME Bioanalyses, Vergèze, France GLP, unpublished	N		2015	Validation of an Analytical Method for the Determination of Residues of Flazasulfuron in Water Report n° 5J08023-01-VMWA CIP GmbH - Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 4.2 (b)/03		2014	SL-160: INDEPENDENT LABORATORY VALIDATION OF METHODOLOGY FOR THE DETERMINATION OF RESIDUES OF SL-160 IN WATER Report No.: JSM0686 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2015	Independent Laboratory Validation of a Method for the Determination of Residues of Flazasulfuron in Drinking Water Report n° CEMR-7296 CEM Analytical Services Ltd, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 4.2 (c)/01		2014	SL-160: VALIDATION OF METHODOLOGY FOR THE DETERMINATION OF RESIDUES IN AIR Report No.: JSM0620 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2015	Validation of an Analytical Method for the Determination of Flazasulfuron in Air Report n° 15J08023-01-VMAI CIP GmbH - Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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B.6. TOXICOLOGY AND METABOLISM DATA

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.1.1/11		2014	SL 160: RAT, DOG AND HUMAN LIVER MICROSOMAL METABOLISM Report No.: JSM0675 GLP, unpublished	N		2018	Flazasulfuron: Rat, Dog and Human liver microsomial metabolism Study n° DY03CD Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Signed study plan provided Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 5.2.7/01		2014	SL-160: IN VITRO 3T3 NEUTRAL RED UPTAKE PHOTO TOXICITY TEST Report No.: JSM0621 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	In vitro 3T3 NRU Phototoxicity Test according to the OECD guideline N°432 Study n° 6.43-32574-ID-16/03040 IDEA Lab Martillac France GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.4.1/05		2014	SL-160 TGAI: CHROMOSOME ABERRATION TEST IN CULTURED MAMMALIAN CELLS (RE-EXAMINATION OF IN VITRO CYTOGENETICS TEST, STUDY NO. 87-0123) Report No.: IET 14-0032 Institute of Environmental Toxicology, Ibaraki,	N		xx	Signed Study Plan: Flazasulfuron TG: <i>in vitro</i> micronucleus test in human lymphocytes Study n° YJ06CH Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided
KCA 5.7.1/01		2002	A RANGE-FINDING ACUTE NEUROTOXICITY STUDY IN RATS WITH SL-160 Report No.: 5605-95- 0123-TX- 001 GLP, unpublished	Y		-		No needed as the active substance doesn't meet the criteria to perform this sort of study according to EU regulation N°283/2013 (5.7.1 & 5.7.2) Applicant comment: The EU regulation 283/2013 point 5.7.1 (Neurotoxicity studies in rodents) clearly indicates that "Such studies shall be performed for active substances with structures that are similar or related to those capable of inducing neurotoxicity, and for active substances which			Not acceptable. The study was included in the list of studies relied upon and essential for the assessment. Since these are vertebrate studies, LoA to protected studies should be provided (or negotiations on access to protected vertebrate data). In case of failure to reach an agreement and according to article 62 of Regulation 1107/2009, this failure shall not prevent the competent authority of that Member

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								<p>induce specific indications of potential neurotoxicity, neurological signs or neuropathological lesions in toxicity studies at dose levels not associated with marked general toxicity. Performance of such studies shall also be considered for substances with a neurotoxic mode of pesticidal action." Flazasulfuron structure or toxicity database do not indicate potential for neurotoxicity action and this study is therefore not triggered according to the current regulation. Including this not necessary study into the study list doesn't make it mandatory. Moreover, the toxicity end point found in this study is not used in the toxicological end points of flazasulfuron. Then it is not deemed essential for the assessment.</p>			<p>State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.</p> <p>The reasoning is not Acceptable The justification is not in compliance with EU legislation. The study was included in the list of studies relied upon and essential for the assessment. Since these are vertebrate studies, LoA to protected studies should be provided (or negotiations on access to protected vertebrate data). In case of failure to reach an agreement and according to article 62 of Regulation 1107/2009, this failure shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.</p>

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KCA 5.7.1/02		2002	AN ACUTE NEUROTOXICITY SCREENING STUDY IN RATS WITH SL-160 Report No.: 5606-96-0054-TX-002 GLP, unpublished	Y				No needed as the active substance doesn't meet the criteria to perform this sort of study according to EU regulation N°283/2013 (5.7.1 & 5.7.2)			See KCA 5.7.1/01 above.
KCA 5.7.1/03		2012	A 90-DAY DIETARY NEUROTOXICITY STUDY OF FLAZASULFURON IN RATS (VOLUME 1 - 5) Report No.: WIL-282030 GLP, unpublished	Y				No needed as the active substance doesn't meet the criteria to perform this sort of study according to EU regulation N°283/2013 (5.7.1 & 5.7.2)			See KCA 5.7.1/01 above.
KCA 5.8.1/19		2014	SSRE-006: MUTAGENICITY STUDY IN VITRO Report No.: JSM0670 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		xx	Signed Study Plan: HMTU: Bacterial reverse mutation test Study n° XP09VL Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/20		2014	SSRE-018: MUTAGENICITY STUDY IN VITRO Report No.: JSM0633 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		xx	Signed Study Plan: GTPS: Bacterial reverse mutation test Study n° VD62RJ Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided
KCA 5.8.1/21		2014	SSRE-020: MUTAGENICITY STUDY IN VITRO Report No.: JSM0671 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, United Kingdom GLP, unpublished	N		xx	Signed Study Plan: HTPU: Bacterial reverse mutation test Study n° KQ17MV Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided
KCA 5.8.1/22		2014	SSRE-003: MUTAGENICITY STUDY IN VITRO Report No.: JSM0709 44807/118 Huntingdon Life Sciences Ltd., Cambridgeshire, United Kingdom GLP, unpublished	N		2017	SALMONELLA TYPHIMURIUM REVERSE MUTATION ASSAY (AMES TEST) WITH DMPU Report n° 2047 RRL, Jiangsu - China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/23		2014	SSRE 021: MUTAGENICITY STUDY IN VITRO Report No.: JSM0710 44807/119 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	SALMONELLA TYPHIMURIUM REVERSE MUTATION ASSAY (AMES TEST) WITH HTF Report n° 2048 RRL Jiangsu China GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/24		2014	SSRE 021: ACUTE ORAL TOXICITY TO THE RAT (ACUTE TOXIC CLASS METHOD) Report No.: JSM0708 GLP, unpublished	Y			LoA	Rotam has requested a Letter of access to that study to the data owner ISK	N		Negotiations on access to protected vertebrate data was provided but results of this negotiations and a LoA is not available yet Acceptable pending on the results of the negotiations. In case of failure to reach an agreement and according to article 62 of Regulation 1107/2009, this failure shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant. Acceptable Letter of access to that study to the data owner ISK available (7 June 2019)

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/25		2014	SSRE-021: IN VITRO MUTATION TEST USING MOUSE LYMPHOMA L5178Y CELLS Report No.: JSM0750 GLP, unpublished	N		2017	HTF: In vitro HPRT mutation using Chinese Hamster ovary cells Study n° CB41LL Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 5.8.1/27		2016	IN VITRO HPRT GENE MUTATION ASSAY F SSRE-006 IN CHINESE HAMESTER LUNG (V79) CELLS Report N°: K08-0007 Chemicals Evaluations and Research Institute, Hita-shi, Japan GLP unpublished	N		xx	Signed Study Plan: HMPU: <i>in vitro</i> HPRT mutation test using Chinese Hamster ovary cells Study n° TW87JH Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/28		2016	IN VITRO HPRT GENE MUTATION ASSAY OF SSRE-018 IN CHINESE HAMSTER LUNG (V79) CELLS Report N°: K08-0008 Chemicals Evaluations and Research Institute, Hita-shi, Japan GLP unpublished	N		xx	Signed Study Plan: GTPS: <i>in vitro</i> HPRT mutation test using Chinese Hamster ovary cells Study n° RX33GT Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided
KCA 5.8.1/29		2016	CHROMOSOMAL ABERRATION TEST OF SSRE-006 USING CULTURED MAMMALIAN CELLS Report N°: K06-1508 Chemicals Evaluations and Research Institute, Hita-shi, Japan GLP unpublished	N		xx	Signed Study Plan: HMPU: <i>in vitro</i> mammalian chromosome aberration test in Human lymphocytes Study n° SX32JX Envigo, Eye Research Centre, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, Signed study plan provided

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 5.8.1/30		2014	SSRE 018: IN VITRO MAMMALIAN CHROMOSOME ABERRATION TEST IN HUMAN LYMPHOCYTES Report N°: JMS7047 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N			LoA	Rotam has requested a Letter of access to that study to the data owner ISK	N		Letter of access to that study to the data owner ISK available (7 June 2019)
KCP 7.3/01		2009	IN VITRO SKIN PENETRATION SKIN OF FLAZASULFURON Report No.: ISK/FLA/08001R ADME Bioanalyses, Vergèze, France GLP, unpublished	N			-	No need, use of EFSA default values in the risk assessment			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

B.7. RESIDUE DATA

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/02		2014	FLAZASULFURON STORAGE STABILITY OF FLAZASULFURON IN CROPS UNDER FROZEN STORAGE CONDITIONS UP TO 12 MONTHS Report No.: S13 02929 Eurofins Agrosience Services Chem SAS, Vergèze, France GLP, unpublished	N		2016	Frozen Storage Stability Study: Flazasulfuron in Olives Report n° QG/16/001 Battelle UK Ltd UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 6.1/04		2013	SL 160: RESIDUE ANALYSIS IN GRAPES AND WINE FRANCE 1995 Report No.: RCC 610503 Amendment 1 (ISK 95 010 HF), FZR/VITSS 01/F/95 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016a	Determination of Residues of Flazasulfuron in Grape Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Northern Europe (France 2015) Report No. QG/15/003 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/05		2013	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN A VINEYARD IN AUSTRIA 1996 Report No.: RCC 619470 Amendment 1 FZR/VITSS 02/AU/96 Harlan Laboratories Ltd. (formerRCC Ltd.), Itingen, Switzerland GLP, unpublished	N			-	Not a data requirement according to EU regulation 283/2013 and 284/2013 Application for registration only in SEU			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/06		2014	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN A VINEYARD IN GERMANY 1996 Report No.: RCC 619503 Amendment 2 and 3 FZR/VITSS 03/D/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N			-	Not a data requirement according to EU regulation 283/2013 and 284/2013 Application for registration only in SEU			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/07		2013	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN VINEYARDS IN NORTHERN FRANCE 1996 Report No.: RCC 619514 Amendment 1 FZR/VITSS 04/F/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016	See KCA 6.1-4 Determination of Residues of Flazasulfuron in Grape Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Northern Europe (France 2015) Report No. QG/15/003 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/08		2013	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN VINEYARDS IN ITALY 1996 Report No.: RCC 619525 Amendment 2 FZR/VITSS 07/I96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016	Determination of Residues of Flazasulfuron in Grape Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Southern Europe (France and Spain 2015) Report No. QG/15/004 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/09		2013	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN VINEYARDS IN SOUTHERN FRANCE 1996 Report No.: RCC 619536 Amendment 1 FZR/VITSS 05/F/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished				Same as above			Acceptable	

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/10		2013	DETERMINATION OF SL 160 RESIDUES IN GRAPES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN VINEYARDS IN SPAIN 1996 Report No.: RCC 619547 Amendment 1 FZR/VITSS 06/E/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016	See KCA 6.1-08 Determination of Residues of Flazasulfuron in Grape Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Southern Europe (France and Spain 2015) Report No. QG/15/004 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable, a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/11		2014	DETERMINATION OF SL-160 RESIDUES IN MANDARINS FOLLOWING APPLICATION OF SL-160 25 % WG FORMULATED PRODUCT IN GROVES IN SPAIN, 1996 Report No.: RCC 620853 - Amendment 2 and 3 FZR/CIDRE/01/E/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016	Determination of Residues of Flazasulfuron in Lemons Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Southern Europe (Spain - 2015) Report No. QG/15/002 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/12		2014	DETERMINATION OF SL 160 RESIDUES IN ORANGES & MANDARINS FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN CITRUS TREE GROVES IN GREECE, 1998 Report No.: RCC 711538 Amendment 1 and 2 FZR/CIDRE 02/GR/98 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished				Same as above				Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/13		2013	DETERMINATION OF SL 160 RESIDUES IN ORANGES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN ORANGE TREE GROVES IN ITALY & SPAIN, 1998 Report No.: RCC 711540 Amendment 1 FZR/CIDSI 03/E/98 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished				Same as above			Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y	

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/14		2013	DETERMINATION OF SL 160 RESIDUES IN OLIVES FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN GROVES IN SPAIN, 1996 Report No.: RCC 620864 Amendment 1 FZR/OLVEU 01/E/96 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished	N		2016	Determination of Residues of Flazasulfuron in Olives Following Single Application of Flazasulfuron 250 g/kg WG Under Open Field Conditions in Southern Europe (Spain 2015 Report No. QG/15/002 Battelle UK Ltd, Essex, UK GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/15		2014	PROCESSING OF OLIVES TO OLIVE OIL AND DETERMINATION OF SL 160 RESIDUES IN OLIVES, OLIVE OIL AND PRESS CAKE MEAL FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN GROVES IN SPAIN, 1997 Report No.: RCC 688061 Amendment 1 and 2 FZR/OLVEU 04/E/97 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished					No requested according to EU regulation N° 283/2017 (6.5.1, residue level below 0.01 mg/kg)			Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 6.1/16		2014	PROCESSING OF OLIVES TO OLIVE OIL AND DETERMINATION OF SL 160 RESIDUES IN OLIVES, OLIVE OIL AND PRESS CAKE MEAL FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN GROVES IN ITALY, 1997 Report No.: RCC 688072 Amendment 1 and 2 FZR/OLVEU 03/1/97 Harlan Laboratories Ltd. (former RCC Ltd.), Itingen, Switzerland GLP, unpublished					No requested according to EU regulation N° 283/2017 (6.5.1, residue level below 0.01 mg/kg)			Acceptable
KCA 6.3.1/05		1999	DETERMINATION OF SL 160 RESIDUES IN WINE (RAC GRAPES) FOLLOWING APPLICATION OF SL 160 25 % WG FORMULATED PRODUCT IN VINEYARDS IN GREECE & SPAIN, 1998	N				No requested according to EU regulation N° 283/2017 (6.5.1, residue level below 0.01 mg/kg)	N		Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			(analytical report) Including field reports titled: GENERATION OF SAMPLES OF GRAPES (WINE) RAW AGRICULTURAL COMMODITY (RAC) FOLLOWING TREATMENTS WITH FLAZASULFURON FORMULATIONS FOR RESIDUE ANALYSIS; Corts, V., 1998; Report 98-011-H-E-01; Recerca Agricola S.L., Catarroja, Spain FLAZASULFURON RESIDUE GRAPE SPECIMENS GENERATION AT HARVEST AFTER 2 APPLICATIONS; Legakis, Ph., 1998; Reports 98- 005-H-GR-01 and 98-005-H-GR-02; Hellafarm SA, Maroussi, Greece Including amendment to								

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			analytical report titled as analytical report; Koop, K., 2013 and 2014; Amendments 1 and 2; Harlan Laboratories Ltd. (former RCC Ltd), Itingen, Switzerland Report No.: RCC 710932 RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland GLP, unpublished								

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 7.1.1.1/05		2013	DETERMINATION OF THE AEROBIC DEGRADATION RATE AND ROUTE OF SL-160 IN SOIL UNDER OUTDOOR CONDITIONS Report No.: 496912 203299/A WIL Research Europe B.V., 's-Hertogenbosch, The Netherlands GLP, unpublished	N		1995	Flazasulfuron [¹⁴ C-SL-160] aerobic soil metabolism study PTRL West Inc Report n° 5279-92-0129-EF-001 GLP, unpublished	These 3 unprotected studies have been reviewed and accepted without limitation Applicant comment: This study was planned and payments done (see signed quotation attached dated 2015); that study was however overlooked in the Rotam flazasulfuron DMT testing program that contained more than 100 studies. Rotam asked the CRO to start the study and a signed protocol is available. Alternatively Rotam will approach the applicant ISK in order to obtain a Letter of Access.	N		<p>Not Acceptable The three previous studies did not completely address the route of degradation</p> <p>Acceptable Letter of access to that study to the data owner ISK available (7 June 2019)</p>
						1996	Degradation of ¹⁴ C-SL-160 (P) in soils incubated under various experimental condition (flazasulfuron) Report N°RCC 629752 RCC AG GLP, unpublished				
						1996	Degradation of ¹⁴ C-SL-160 (P) in soils incubated under outdoor condition (flazasulfuron) Report N°RCC 631383 RCC AG GLP, unpublished				
KCA 7.1.1.3/01		2005	PHOTODEGRADATION OF [¹⁴ C]FLAZASULFURON	N		2016	Flazasulfuron: Soil Photolysis Study n° PII0035 Envigo Ltd., Suffolk, UK	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			(SL 160) IN/ON SOIL BY ARTIFICIAL LIGHT Report No.: IB 2004 JLW 008 01 01 1347W1347W 1 PTRL West, Inc., California, USA GLP, unpublished				GLP, unpublished				
KCA 7.1.2.1.1/07		2013	DETERMINATION OF THE AEROBIC DEGRADATION RATE AND ROUTE OF SL 160 IN SOIL UNDER OUTDOOR CONDITIONS Report No.: 496912 203299/A WIL Research Europe B.V., 's Hertogenbosch, The Netherlands GLP, unpublished	N			See KCA 7.1.1.1/05	See KCA 7.1.1.1/05			Acceptable Although the Brands study is necessary to cover annex point KCA 7.1.1.1/07 because it was used to conclude on the route of degradation under light conditions, it was not used to conclude on rate of degradation
KCA 7.1.2.1.1/08		2005	PHOTODEGRADATION OF [14C]FLAZASULFURON (SL 160) IN/ON SOIL BY ARTIFICIAL LIGHT Report No.: IB 2004 JLW 008 01 01 1347W	N		2016	See KCA 7.1.1.3/01 Flazasulfuron: Soil Photolysis Study n° PII0035 Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			1347W 1 PTRL West, Inc., California, USA GLP, unpublished								
KCA 7.1.2.1.2/05		2014	SSRE 006: RATE OF DEGRADATION IN SOIL Report No.: JSM0641 44807/29 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2018	HMTU: Rate of Degradation in Aerobic Soil Study n° WL42JP Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.2.1.2/06		2014	SSRE 020: STUDY OF DEGRADATION IN SOIL Report No.: JSM0636 44807/56 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2018	HTPU: Rate of Degradation in Aerobic Soil Study n° CS29HQ Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.2.1.2/07		2014	SSRE 018: STUDY OF DEGRADATION IN SOIL Report No.: JSM0630 44807/44 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2018	GTPS: Rate of Degradation in Aerobic Soil Study n° WL73NK Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 7.1.2.1.2/08		2014	SSRE-021: RATE OF DEGRADATION IN SOIL Report No.: JSM0704 44807/109 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2018	HTF: Rate of Degradation in Aerobic Soil Study n° HP35FP Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.2.1.2/09		2014	SSRE-008: RATE OF DEGRADATION IN SOIL Report No.: JSM0677 44807/100 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2018	HTPP: Rate of Degradation in Aerobic Soil Study n° KK70MR Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.2.1.2/10		2014	SSRE-003: RATE OF DEGRADATION IN SOIL Report No.: JSM0703 44807/108 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2018	DMPU: Rate of Degradation in Aerobic Soil Study n° YB86XR Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable, a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 7.1.3.1.1/01	[REDACTED]	2006	SOIL ADSORPTION/DESORPTION OF [¹⁴ C]SL-160, DTPU, DTPP, ADMP, AND TPSA BY THE BATCH EQUILIBRIUM METHOD Report No.: 1420W 1420W-1 PTRL West, Inc., California, USA GLP, unpublished	N	[REDACTED]	2016	Flazasulfuron: Adsorption/Desorption in Four Soils Study n° PII0036 Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
						2016	DTPU: Adsorption/Desorption in Three Soils Study n° 3201011 Smithers Viscient (ESG) Limited, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
						2016	DTPP: Adsorption/Desorption in Three Soils Study n° 3201010 Smithers Viscient (ESG) Limited, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
						2016	ADMP: Adsorption/Desorption in Three Soils Study n°3201008 Smithers Viscient (ESG) Limited, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
						2016	TPSA: Adsorption/Desorption in Three Soils Study n°3201009 Smithers Viscient (ESG) Limited, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/01		1995	ADSORPTION / DESORPTION OF ¹⁴ C-ADMP ON FOUR SOILS Report No.: 384478 RCC Umweltchemie AG, Itingen, Switzerland GLP, unpublished	N		2016	See KCA 7.1.3.1.1/01 ADMP: Adsorption/Desorption in Three Soils Study n°3201008 Smithers Viscient (ESG) Limited, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/02		2014	SSRE-018: ADSORPTION DESORPTION ON SOIL Report No.: JSM0631 44807/45 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2020	GTPS - Adsorption and Desorption of GTPS in three soils Study n°3202053 Smithers Viscient (ESG) Limited, UL GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/03		2014	SSRE-006: ADSORPTION DESORPTION ON SOIL Report No.: JSM0642 44807/30	N		2018	See KCA 7.1.3.2-4 HMTU: Estimation of Soil Adsorption Coefficient Study n° 3202052	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished				Smithers Viscient (ESG) Ltd.UK GLP unpublished				
KCA 7.1.3.1.2/04		2014	SSRE-006: ADSORPTION COEFFICIENT Report No.: JSM0727 44807/121 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2018	HMTU: Estimation of Soil Adsorption Coefficient Study n° 3202052 Smithers Viscient (ESG) Ltd.UK GLP unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/05		2014	SSRE-020: ADSORPTION DESORPTION ON SOIL Report No.: JSM0637 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2018	See KCA 7.1.3.1.2-6 HTPU: Estimation of Soil Adsorption Coefficient Study n° 3201889A Smithers Viscient (ESG) Ltd.UK GLP unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP-compliant: Y b) Guideline compliant: Y e) Equivalent endpoint: Y
KCA 7.1.3.1.2/06		2014	SSRE-020: ADSORPTION COEFFICIENT Report No.: JSM0726 44807/120 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK	N		2018	HTPU: Estimation of Soil Adsorption Coefficient Study n° 3201889A Smithers Viscient (ESG) Ltd.UK GLP unpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP-compliant: Y b) Guideline compliant: Y e) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 7.1.3.1.2/07		2014	GLP, unpublished SSRE-008: ADSORPTION DESORPTION ON SOIL Report No.: JSM0676 44807/99 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2020	HTPP - Adsorption and Desorption of HTPP in three soils Study n° 3201888 Smithers Viscient (ESG) Ltd.UK GLPunpublished	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/08		2014	SSRE-003: ADSORPTION DESORPTION ON SOIL Report No.: JSM0705 44807/110 Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished	N		2000	Adsorption in three soils Code AE F099095 Covance, Germany Report n° COO7786 GLP, unpublished	SSRE-003 is a common metabolite with mesosulfuron methyl. In the DAR of mesosulfuron, a study on adsorption- desorption of this metabolites (AE F099095) was submitted and accepted. It is also included into the AIR dossier of mesosulfuron, indicated as non-protected.	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.1.3.1.2/09		2014	SSRE-021: ADSORPTION DESORPTION ON SOIL Report No.: JSM0706 44807/111	N		2018	HTF - Adsorption and Desorption of HTPP in three soils Study n° BL24QG Smithers Viscient (ESG) Ltd.UK	New equivalent study carried out according to current guidelines and GLP	Y	?	Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Huntingdon Life Sciences, Eye Research Centre, Eye, Suffolk, UK GLP, unpublished				GLP, unpublished				
KCA 7.2.1.2/01		2014	SL-160: PHOTODEGRADATION IN WATER AND DETERMINATION OF THE QUANTUM YIELD Report No.: JSM0624 44807/9 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2016	Flazasulfuron: Photodegradation in Water and Determination of the Quantum Yield Report No.: PII0037 Envigo Ltd., Suffolk, UK GLP, unpublished	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 7.2.2.1/01		2014	READY BIODEGRADABILITY OF SL-160 TGAI IN A MANOMETRIC RESPIROMETRY TEST Report No.: 86101163 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished				-	This is not an EU requirement			Acceptable
KCA 7.2.2.2/01		2014	SL-160: AEROBIC MINERALISATION IN SURFACE WATER (PELAGIC TEST)	N		2016	Flazasulfuron: Aerobic Mineralisation in Surface Water (Pelagic Test) Report No.: PII0038	New equivalent study carried out according to current guidelines and GLP			Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			Report No.: JSM0625 44807/11 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished				Envigo Ltd., Suffolk, UK GLP, unpublished				

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

B.9. ECOTOXICOLOGY DATA

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.1/05		1997	ACUTE TOXICITY OF ADMP TO RAINBOW TROUT (ONCORHYNCHUS MYKISS) IN A 96-HOUR STATIC TEST Report No.: 658034 GLP, unpublished	Y				This study was already evaluated at EU level since it is also a metabolite of nicosulfuron. During Annex I inclusion of this active substance, the study was accepted and endpoints agreed by MMS, therefore this study is not protected	N		Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.2.1/01		2004	SL 160 TECHNICAL EARLY LIFE STAGE TOXICITY TEST WITH RAINBOW TROUT (ONCORHYNCHUS MYKISS) Re rt No.: 13562.6128 GLP, unpublished	Y			LoA	Rotam has requested a Letter of access to that study to the data owner ISK	N		Negotiations on access to protected vertebrate data was provided but results of this negotiations and a LoA is not available yet Acceptable pending on the results of the negotiations. In case of failure to reach an agreement and according to article 62 of Regulation 1107/2009, this failure shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant. Acceptable: Letter of access to that study to the data owner ISK available (7 June 2019)

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.4.1/05		1997	ACUTE TOXICITY OF ADMP TO <i>DAPHNIA MAGNA</i> IN A 48 HOUR IMMOBILIZATION TEST Report No.: 658012 RCC Umweltchemie AG, Itingen, Switzerland GLP, unpublished	N			-	This study was already evaluated at EU level since it is also a metabolite of nicosulfuron. During Annex I inclusion of this active substance, the study was accepted and endpoints agreed by MMSS, therefore this study is not protected	N		Acceptable
KCA 8.2.5.1/01		2013	FLAZASULFURON: A SEMISTATIC LIFE CYCLE TOXICITY TEST WITH THE CLADOCERAN (<i>DAPHNIA MAGNA</i>) Report No.: 272A 129A Wildlife International Ltd., Easton, USA GLP, unpublished	N			-	There is a non protected, GLP and acceptable study in the Flazasulfuron DAR (Wuethrich, V., 1995)	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.6.1/05		1997	TOXICITY OF ADMP TO SCENEDESMUS SUBSPICATUS IN A 72 HOUR ALGAL GROWTH INHIBITION TEST Report No.: 657990 RCC Umweltchemie AG, Itingen, Switzerland GLP, unpublished	N			-	This study was already evaluated at EU level since it is also a metabolite of nicosulfuron. During Annex I inclusion of this active substance, the study was accepted and endpoints agreed by MMSS, therefore this study is not protected	N		Acceptable

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA8.2.6.1/11		2011	Growth inhibition test of SL 160 technical with algae (<i>Pseuokirchneriella subcapitata</i>) Report n°A110279 Mitsubishi Chemical Medience Corporation, Tokyo Japan GLP, unpublished	N		2015	Flazasulfuron TG: toxicity to <i>Pseuokirchneriella subcapitata</i> in an algal growth inhibition test Study n° 97181210 Ibacon GmbH, Rossdorf Germany GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/03		2014	TOXICITY OF SL 160 TGAI TO THE AQUATIC PLANT MYRIOPHYLLUM AQUATICUM IN A STATIC GROWTH INHIBITION TEST WITH A PRIOR ROOTING PHASE Report No.: 86102215 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		016	Flazasulfuron 250 g/kg WG: Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a static growth inhibition test with a prior rooting phase Study n° 97231215 Ibacon GmbH, Rossdorf Germany GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/12		2014	TOXICITY OF SL 160 TGAI TO THE REED MANNAGRAS GLYCERIA MAXIMA IN A STATIC GROWTH	N			-	Not needed as 2 GLP aquatic plant studies (<i>Lemna gibba</i> and <i>Myriophyllum spicatum</i>) are available	Y	--	Not acceptable The study is considered as Cat. 4 and should be provided

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
			INHIBITION TEST Report No.: 86103245 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany					<p>Applicant comment:</p> <p>The EU regulation 283/2013, point 8.2.7 indicates that for herbicides 2 aquatic plants should be used (lemna and either myriophyllum or glyceria):</p> <p><i>8.2.7. Effects on aquatic macrophytes</i></p> <p><i>A test shall be provided establishing EC10, EC20, EC50 and corresponding NOEC values for Lemna species growth rate and yield, based on measurements of number of fronds and at least one additional measurement variable (dry weight, fresh weight or frond area).</i></p> <p><i>For other species of aquatic macrophytes, a test shall provide sufficient information to evaluate impact on aquatic plants and provide EC10, EC20, EC50 and corresponding NOEC values based on</i></p>			Acceptable

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								<p><i>measurement of appropriate biomass parameters.</i></p> <p><i>Circumstances in which required</i></p> <p><i>A laboratory test with Lemna species shall be performed for herbicides and plant growth regulators and for substances where there is evidence from information submitted under point 8.6 of Part A of this Annex or point 10.6 of Part A of the Annex to Regulation (EU) No 284/2013 that the test substance has herbicidal activity. Additional testing may be required by the national competent authorities on other macrophyte species depending on the mode of action of the substance, or if clear indications of higher toxicity are apparent to dicotyledonous (for example auxin inhibitor, broad leaf herbicides) or other monocotyledonous (for</i></p>			

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								<p><i>example grass herbicides/ plant species from efficacy or terrestrial non target plants tests (see point 8.6 of Part A of this Annex and point 10.6 of Part A of the Annex to Regulation (EU) No 284/2013).</i></p> <p><i>Additional aquatic macrophyte species tests may be undertaken on a dicotyledonous species, such as Myriophyllum spicatum, Myriophyllum aquaticum or a monocotyledonous species, such as aquatic grass Glyceria maxima, as appropriate. The need to perform such studies shall be discussed with the national competent authorities.</i></p> <p>Rotam carried out studies with Lemna (monocotyledonous) and Myrophilum (dicotyledonous) in order to have results on the 2 plants groups, matching the mandatory studies requested</p>			

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
								by the EU regulation and performed by ISK. ISK has chosen to produce an additional species which should not be protected as not requested, especially as no EU end point is derived from this study.			
KCA 8.2.7/04		2014	TOXICITY OF SSRE-003 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 92001240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-003 (DMPU): Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102531240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.7/05		2014	TOXICITY OF SSRE 004 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A SEMI STATIC GROWTH INHIBITION TEST Report No.: 72561240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 004 (DTPU): Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102541240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/06		2014	REVISED FINAL REPORT NO. 1 TOXICITY OF SSRE 006 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 86121240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 006: Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Semi Static Growth Inhibition Test Report No.: 102561240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.7/07		2014	REVISED FINAL REPORT NO. 1 TOXICITY OF SSRE 008 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 86131240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 008: Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102571240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/08		2014	TOXICITY OF SSRE 018 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A SEMI STATIC GROWTH INHIBITION TEST Report No.: 86141240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 018: Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Semi Static Growth Inhibition Test Report No.: 102581240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.7/10		2014	TOXICITY OF SSRE 021 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 92011240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany	N		2017	SSRE 021 (HTF): Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102601240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/11		2014	TOXICITY OF SSRE 002 TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 94011240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2002	LoA to: IN J0290: Influence on Growth and Reproduction of <i>Lemna gibba</i> G3 Report n° DuPont 9339 GLP, unpublished	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force Rotam has requested a Letter of access to that study to the data owner DuPont	N		Proof of negotiation for a LoA provided Acceptable pending on the results of the negotiations Acceptable : Letter of access to that study to the data owner ISK available (7 June 2019)

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.7/16		2015	SSRE 005: TOXICITY TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 105161240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 005: Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102551240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.2.7/17		2015	SSRE 001: TOXICITY TO THE AQUATIC PLANT <i>LEMNA GIBBA</i> IN A STATIC GROWTH INHIBITION TEST Report No.: 105151240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 021 (HTF): Toxicity to the Aquatic Plant <i>Lemna gibba</i> in a Static Growth Inhibition Test Report No.: 102601240 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.2.8/01		2002	RECOVERY OF THE AQUATIC HIGHER PLANT <i>LEMNA GIBBA</i> AFTER 7 DAYS OF EXPOSURE TO ¹⁴ C-SL-160(P) Report No.: 827807 RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Toxicity to the Aquatic Plant <i>Lemma gibba</i> in a Static Growth Inhibition Test Study n° 97231240 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.3.1.1/02		2014	EFFECTS OF SL-160 TGAI (ACUTE CONTACT AND ORAL) ON BUMBLEBEES (<i>BOMBUS TERRESTRIS</i> L.) IN THE LABORATORY Report No.: 86101105 Institut für Biologische Analytik und Consulting IBA CON GmbH, Rossdorf, Germany GLP, unpublished	N		2015	Flazasulfuron 250 g/kg WG: Effects (Acute Contact and Oral) on Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory Study n°101441105 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4/01		1996	TOXIC ACTIVITIES OF SL-160 (FLAZASULFURON) METABOLITES ON EARTHWORM Report No.: AD 96026-I-02 Ishihara Sangyo Kaisha, Ltd., Central Research Institute, Shiga-Ken, Japan Not GLP, unpublished	N			-	This is not a GLP study, therefore cannot be protected according to EU regulation 1007/2009 art 63			Acceptable Not in the list of Annex II studies relied upon
KCA 8.4.1/01		2013	EFFECTS OF FLAZASULFURON TECHNICAL (SL-160 TECHNICAL) ON EARTHWORM (EISENIA FETIDA) REPRODUCTION IN A CHRONIC TOXICITY TEST Report No.: 776.449.4233 TOXI-COOP ZRT., Balatonfuered, Hungary GLP, unpublished	N		2016	Earthworm (<i>Eisenia fetida</i>) reproduction test with flazasulfuron technical in artificial soil Report N° 1566 RRL, Jiangsu, China GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1/02		2014	SSRE 003: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0699 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2016	SSRE 003 (DMPU): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102531022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.1/03		2011	EFFECTS OF DTPU ON REPRODUCTION AND GROWTH OF EARTHWORMS EISENIA FETIDA IN ARTIFICIAL SOIL WITH 5% PEAT Report No.: 67801022 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE 004 (DTPU): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102541022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1/04		2014	SSRE 006: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0643 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	SSRE 006 (HMTU): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102561022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.1/05		2014	SSRE 008: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0645 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2016	EARTHWORM (<i>EISENIA FETIDA</i>), REPRODUCTION TEST WITH HTPP IN ARTIFICIAL SOIL Study n° 2045 RRL Jiangsu, China GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1/06		2014	SSRE 018: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0632 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	SSRE 018 (GTPS): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102581022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.1/07		2014	SSRE 020: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0638 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	SSRE 020 (HTPU): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102591022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.1/08		2014	SSRE 021: TO DETERMINE THE EFFECTS ON REPRODUCTION AND GROWTH OF THE EARTHWORM, EISENIA FETIDA Report No.: JSM0700 Huntingdon Life Sciences Ltd., Cambridgeshire, UK GLP, unpublished	N		2017	SSRE 021 (HTF): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102601022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.1/09		2005	METABOLITES OF SL 160 (DTPU, DTPP, TPSA): EFFECTS ON SURVIVAL, GROWTH, AND REPRODUCTION OF THE EARTHWORM EISENIA FETIDA Report No.: 858704 RCC Ltd, Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland GLP, unpublished	N		2016	See KCA 8.4.1/03 SSRE 004 (DTPU): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102541022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
						2016	SSRE 005 (DTPP): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 102551022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
						2016	SSRE-001 (TPSA): Effects on Reproduction and Growth of earthworms <i>Eisenia fetida</i> in Artificial Soil Study n° 101461022 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.1/10		2014	SSRE-002: EARTHWORM REPRODUCTION STUDY Report No.: 94011022 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2010	LoA to: IN-J0290: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat Report n° DuPont-30060 GLP, unpublished	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force Rotam has requested a Letter of access to that study to the data owner DuPont	N		Proof of negotiation for a LoA provided Acceptable pending on the results of the negotiations Acceptable: Letter of access to that study to the data owner ISK available (7 June 2019)
KCA 8.4.2.1/01		2014	SL-160 TGAI: COLLEMBOLA STUDY Report No.: 86106016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 101441016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/02		2014	SSRE-001: COLLEMBOLA STUDY Report No.: 72571016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-001 (TPSA): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 101461016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/03		2014	SSRE-003: COLLEMBOLA STUDY Report No.: 92001016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-003 (DMPU): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102532016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/04		2014	SSRE-004: COLLEMBOLA STUDY Report No.: 72561016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-004 (DTPU): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102542016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/05		2014	SSRE-005: COLLEMBOLA STUDY Report No.: 86162016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-005 (DTPP): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102551016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/06		2014	SSRE-006 COLLEMBOLA STUDY Report No.: 86123016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-006 (HMTU): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102561016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/07		2014	SSRE-008 COLLEMBOLA STUDY Report No.: 86133016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-008 (HTPP): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102561016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/08		2014	SSRE 018: COLLEMBOLA STUDY Report No.: 86143016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 018 (GTPS): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102581016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/09		2014	SSRE 020 COLLEMBOLA STUDY Report No.: 86153016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 020 (HTPU): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102591016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/10		2014	SSRE 021: COLLEMBOLA STUDY Report No.: 92011016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 021 (HTF): Effects on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n° 102601016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/22		2014	SSRE-002: COLLEMBOLA STUDY Report No.: 9401 1016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2010	LoA to: IN-J0290: Effects on the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Report n° DuPont-30446 GLP, unpublished	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force Rotam has requested a Letter of access to that study to the data owner DuPont			Proof of negotiation for a LoA provided Acceptable pending on the results of the negotiations Acceptable: Letter of access to that study to the data owner ISK available (7 June 2019)
KCA 8.4.2.1/11		2014	SL-160 TGAI: PREDATORY SOIL MITE STUDY Report No.: 86107089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 101441089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/12		2014	SSRE-001: PREDATORY SOIL MITE STUDY Report No.: 72572089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-001 (TPSA): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 101461089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/13		2014	SSRE-003: PREDATORY SOIL MITE STUDY Report No.: 92001089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-003 (DMPU): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102532089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/14		2014	SSRE-004: PREDATORY SOIL MITE STUDY Report No.: 72562089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-004 (DTPU): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102542089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/15		2014	SSRE-005: PREDATORY SOIL MITE STUDY Report No.: 86161089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-005 (DTPP): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102551089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/16		2014	SSRE-006 PREDATORY SOIL MITE STUDY Report No.: 86124089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-006 (HMTU): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102561089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/17		2014	SSRE-008 PREDATORY SOIL MITE STUDY Report No.: 86134089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-008 (HTPP): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102571089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/18		2014	SSRE-018: PREDATORY SOIL MITE STUDY Report No.: 86144089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-018 (GTPS): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102581089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.4.2.1/19		2014	SSRE-020 PREDATORY SOIL MITE STUDY Report No.: 86154089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-020 (HTPU): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102591089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/20		2014	SSRE-021: PREDATORY SOIL MITE STUDY Report No.: 92011089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-021 (HTF): Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Study n° 102601089 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.4.2.1/21		2014	SSRE-002: PREDATORY SOIL MITE STUDY Report No.: 94011089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2010	LoA to: IN-J0290: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat Report n° DuPont-30054 GLP, unpublished	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force Rotam has requested a Letter of access to that study to the data owner DuPont			Proof of negotiation for a LoA provided Acceptable pending on the results of the negotiations Acceptable: Letter of access to that study to the data owner ISK available (7 June 2019)

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.5/02		2014	SSRE 001: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 72573080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE 001 (TPSA): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 101461080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/03		2014	SSRE 003: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 92001080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE 003 (DMPU): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102531080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/04		2014	SSRE 004: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 72563080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE 004 (DTPU): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102541080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.5/05		2014	SSRE-005: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 86161080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE-005 (DTPP): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102551080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/06		2014	SSRE-006 THE SOIL ACTIVITY IN THE LABORATORY Report No.: 86125080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-006 (HMTU): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102561080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/07		2014	SSRE-008 THE SOIL ACTIVITY IN THE LABORATORY Report No.: 86135080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE-008 (HTPP): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102571080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.5/08		2014	SSRE 018 THE SOIL ACTIVITY IN THE LABORATORY Report No.: 86145080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 018 (GTPS): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102571080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/09		2014	SSRE 020 THE SOIL ACTIVITY IN THE LABORATORY Report No.: 86155080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2017	SSRE 020 (HTPU): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102591080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCA 8.5/10		2014	SSRE 021: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 92011080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	SSRE 021 (HTF): Effects on the Activity of the Soil Microflora in the Laboratory (Nitrogen Transformation) Study n° 102601080 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCA 8.5/11		2014	SSRE-002: THE SOIL ACTIVITY IN THE LABORATORY Report No.: 94011080 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2002	LoA to: IN-J0290: Assessment of Effects on Soil Microflora Report n° DuPont-9199 GLP, unpublished	This report is included into the nicosulfuron AIR dossier of the Nicosulfuron AIR Task Force. Rotam is part of this Task Force Rotam has requested a Letter of access to that study to the data owner DuPont			Proof of negotiation for a LoA provided Acceptable pending on the results of the negotiations Acceptable: Letter of access to that study to the data owner ISK available (7 June 2019)
KCA 8.8/01		2014	TOXICITY OF SL-160 TGAI TO ACTIVATED SLUDGE IN A RESPIRATION INHIBITION TEST Report No.: 86108171 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N			-	This is not an EU data requirement.			Acceptable The study was not used in the final risk assessment. As such, this study is not necessary and there is no requirement to be matched.

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCP 10.3.1.2/0 1		2014	CHRONIC ORAL TOXICITY TEST OF SL-160 AIR-3 ON THE HONEY BEE (APIS MELLIFERA L.) IN THE LABORATORY Report No.: 86111136 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2015	Flazasulfuron 250 g/kg WG: Chronic Oral Toxicity Test on the Honey Bee (Apis mellifera L.) in the Laboratory Study n°101441136 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCP 10.3.1.3/0 1		2014	HONEY BEE (APIS MELLIFERA L.) LARVAL TOXICITY TEST ON SL-160 AIR-3, SINGLE EXPOSURE Report No.: 86111032 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Honey Bee (Apis mellifera L.) Larval Toxicity Test, Single Exposure Laboratory Study n° 101441032 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE APPROVAL OF JOGG (confidential)

Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCP 10.4.2.1/0 1		2014	SL 160 AIR 3: COLLEMBOLA STUDY Report No.: 86114016 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Effects on reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat Study n°101441016 Ibacon GmbH, Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCP 10.4.2.1/0 2		2014	SL 160 AIR 3: PREDATORY SOIL MITE STUDY Report No.: 86115089 Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany GLP, unpublished	N		2016	Flazasulfuron 250 g/kg WG: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat 101441089 Ibacon GmbH Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y

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Rapporteur Member State	Month and year	Active Substance	Notifier
Spain	24/04/2022	Flazasulfuron	Rotam Agrochemical Europe Ltd.

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision	Cat. 4 data		RMS Opinion
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
KCP 10.6.2/01		2010	FLAZASULFURON 25% WG TERRESTRIAL (NONTARGET) PLANT GROWTH TEST SEEDLING EMERGENCE Report No.: JSM0028 Huntingdon Research Centre, Ltd., Cambridgeshire, United Kingdom GLP, unpublished	N		2015	Flazasulfuron 250g/kg WG: Effects on Terrestrial (Non Target) Plants: Seedling Emergence and Seedling Growth Test Report n° 97231086 Ibacon GmbH, Arheilger Weg 17, 64380 Rossdorf GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP.	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y
KCP 10.6.2/02		2001	FLAZASULFURON 25 % WG (COMMERCIAL NAME KATANA 25 % WG) TERRESTRIAL PLANTS TOXICITY, VEGETATIVE VIGOR, TIER II Report No.: 000803IS TNW75161 TNW7516 Dr. U. Noack Laboratorien, Sarstedt, Germany GLP, unpublished	N		2015	Flazasulfuron 250g/kg WG: Effects on Terrestrial (Non Target) Plants: Vegetative Vigour Test Report n° 97231087 Ibacon GmbH, Rossdorf, Germany GLP, Unpublished	New equivalent study carried out according to current guidelines and GLP.	N		Acceptable a) GLP-compliant: Y b) Guideline compliant: Y c) Equivalent endpoint: Y