

REGISTRATION REPORT

Master Reference List

Product code: GF-3969

Chemical active substances:

Rimsulfuron, 148.15 g/kg

Thifensulfuron methyl, 92.60 g/kg

Isoxadifen ethyl, 111.1 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva/DuPont/DowAgroScience/Pioneer*

Submission date: December 2020

MS Finalisation date: December 2021 (initial Core Assessment)

*Corteva Agriscience is new Legal Entity in most of EU countries and should be treated as an Applicant for GF-3969 registration. Information about Applicant for each country is provided in dRR Part A.

Part	Purpose	Section	Title	Document ID
A	Risk Management	A	Risk management	DuPont-50795 (to be provided under separate cover)
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B0	Product background, regulatory Context and GAP information	DuPont-50796 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B1, B2, B4	Section 1: Identity Section 2: Physical and chemical properties Section 4: Further information	DuPont-50797 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B3	Efficacy data and information	DuPont-50798 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B5	Analytical methods	DuPont-50799 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B6	Mammalian toxicology	DuPont-50800 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B7	Metabolism and residues	DuPont-50801 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B8	Environmental fate	DuPont-50802 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B9	Ecotoxicology	DuPont-50803 CEU
B	Data Evaluation and Risk Assessment (Detailed summary of the risk assessment)	B10	Assessment of the relevance of metabolites in groundwater	DuPont-50804 CEU
C	Confidential information	C	Confidential information	DuPont-50794 EU

List of data submitted by the applicant and relied on – all documents

B0

Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 2.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.2/01	Jones, J.S.	2017	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isxadifen ethyl 50PX (DPX-V4B07) 24.08 WG blend of water dispersible granules (14.82% + 9.26% + 11.11%): Laboratory study of explosive and oxidizing properties, flammability of solids and the relative self ignition temperature DuPont-48798 E. I. du Pont de Nemours and Company GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 2.3/01	Jones, J.S.	2017	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isxadifen ethyl 50PX (DPX-V4B07) 24.08 WG blend of water dispersible granules (14.82% + 9.26% + 11.11%): Laboratory study of explosive and oxidizing properties, flammability of solids and the relative self ignition temperature DuPont-48798 E. I. du Pont de Nemours and Company GLP: Yes Published: No	N	DuPont	Y
KCP, 2.4/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.6/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.7/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.7/02	Comb, T.	2021	GF-3969 (DPX-V4B07) blend of paste extruded granules: ambient storage stability in HDPE – Two Years. 190496 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont/Corteva	Y
KCP, 2.8.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 2.8.2/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.8.3/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.8.5.1/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.8.5.2/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.8.5.3/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 2.8.7/01	Comb, T.	2020	GF-3969 (DPX-V4B07) blend of paste extruded granules: bulk density, flowability and two-week accelerated storage stability in HDPE 190492 AgroChemex Environmental Ltd GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 2.9/01	Huby, J.P.	2017	DPX-V4B07 35.18% WG: Laboratory study of physical compatibility in water AT-18-004 DuPont de Nemours ERDC GLP: No Published: No	N	DuPont	Y
KCP, 2.9/02	Huby, J.P., Callemeyn, J.	2021	GF-3969 + Vivolt® and GF-3969 + Codacide®: Physical and Chemical Compatibility evaluation Corteva Agriscience Laboratory Report No: AT-21-023 GLP: No Published: No	N	Corteva	Y
KCP, 2.11/01	Huby, J.P.	2021	Practical value test in a 200L sprayer to evaluate procedure to mitigate foaming created by a mixture made of GF-3969 + Vivolt® (DPX-KG691) AT-21-021 Corteva Agriscience™ Agriculture division of DowDupont Application Technology service GLP: No Published: No	N	Corteva	Y
KCP, 4.2/01	Huby, J.P.	2018	Rimsulfuron 14.8% + Thifensulfuron-methyl 9.25% + Isxadifen 11.11% WG (DPX-V4B07 35.18% WG) laboratory study of spray tank clean out AT-18-009 DuPont de Nemours (France) S.A.S. GLP: No Published: No	N	DuPont	Y

B3
Efficacy data and information

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 6.0/01	Freitag, N.	2020	Biological assessment dossier Detailed summary Product name: GF-3969 Chemical active substance(s): Rimsulfuron, 148.15 g/kg Thifensulfuron methyl, 92.6 g/kg Isoxadifen-ethyl, 111.1 g/kg Central registration zone Zonal rapporteur member state: Poland Core assessment DuPont-51169 CEU DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	DuPont	Y
KCP, 6.0/02	Freitag, N.	2020	GF-3969 (rimsulfuron 148.15 g/kg, thifensulfuron methyl 92.6 g/kg, isoxadifen-ethyl 111.1 g/kg): Trial reports efficacy, selectivity, and yield (central zone) DuPont-51170 CEU DuPont European Research and Development Centre (ERDC) GEP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 6.1/01	Monteix, B.	2017	Field efficacy trial to evaluate DPX-V4B07 at different water volumes in corn PEH-17-108 DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	DuPont	Y
KCP, 6.1/02	Notter, J.-S.	2018	Growth chamber studies to justify each rate of active ingredient in GF-3969 (rimsulfuron + thifensulfuron + isoxadifen) on major corn weeds (2017 & 2018 Studies) PEH-18-101 DuPont European Research and Development Centre (ERDC) GLP: No Published: No	N	DuPont	Y
KCP, 6.5.1/01	Siemoneit-Gast, S.	2018	DPX-V4B07 35.18WG + surfactant Trend90. Standardised bioassay for the determination of the EC ₁₀ (NOEL) and EC ₅₀ values for herbicides and selected following crops in soil GEP03 Rheinland-Pfalz (RLP) AgroScience GmbH GEP: Yes Published: No	N	DuPont	Y
KCP, 6.5.2/01	Arnie, J.R., McKelvey, R.A., Aufderheide, J.A., Lockard, L.A., Zhang, L.	2020	DPX-V4B07 24 WG: Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure 49942 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 6.5.2/02	Spatz, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on terrestrial (non-target) plants: Seedling emergence and seedling growth test DuPont-49939 IBACON GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 6.5.3/01	Huby, J.P.	2018	DPX-V4B07 35.18WG: Laboratory study of physical compatibility in water AT-18-004 DuPont de Nemours (France) S.A.S. GLP: No Published: No	N	DuPont	Y
KCP, 6.5.3/02	Huby, J.P.	2018	Rimsulfuron 14.8% + Thifensulfuron methyl 9.25% + Isoxadifen ethyl 11.11% WG (DPX-V4B07 35.18% WG) laboratory study of spray tank clean out AT-18-009 DuPont de Nemours ERDC GLP: No Published: No	N	DuPont	Y
KCP, 6.5.3/03	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron 50SG/Isoxadifen ethyl 50WG (DPX-V4B07). A blend paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate response test to evaluate the effect on the parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49972 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 6.5.3/04	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49973 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 6.5.3/05	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49934 IBACON GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 6.5.3/06	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 Surfactant: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (acari, phytoseiidae) DuPont-49935 IBACON GLP: Yes Published: No	N	DuPont	Y

B5
Analytical methods

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 5.1.1/01	Robson, D.D.	2017	Validation of the analytical method for determination of thifensulfuron methyl (DPX-M6316), dicamba (DPX-Y0727), nicosulfuron (DPX-V9360), rimsulfuron (DPX-E9636) and isoxadifen ethyl (DPX-X4145) in DPX-V4B07 24.08WG and DPX-VRF36 60.42 blends of paste-extruded products DuPont-44927 DuPont Stine-Haskell Research Center GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.1/02	Robson, D.D.	2017	Determination of thifensulfuron methyl (DPX-M6316), dicamba (DPX-Y0727), nicosulfuron (DPX-V9360), rimsulfuron (DPX-E9636) and isoxadifen ethyl (DPX-X4145) in DPX-V4B07 24.08WG and DPX-VRF36 60.42WG blends of paste-extruded products DuPont-50247 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
KCP, 5.1.1/03	Baker L.	2022	GF-3969 (DPX-V4B07) - Example Chromatograms E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 5.1.2/01	Arnie, J.R., Aufderheidie, J, Lockard, L., Zhang, L.	2020	Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure 49942 Eurofins EAG Agrosience LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/02	Bergfield, A.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49944 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/03	Cornement, M.	2018	Rimsulfuron-toxicity to Honey bees (<i>Apis mellifera</i> L.) larvae after repeated exposure under <i>in vitro</i> laboratory conditions 20170301 Innovative Environmental Services (IES) Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/04	xxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 5.1.2/05	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 48-Hour static renewal, acute toxicity test with the cladoceran, <i>Daphnia magna</i> DuPont-49949, Revision No. 1 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 5.1.2/06	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus crop oil (Codacide): 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49978 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/07	Hoover, E.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) a blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> DuPont-49943 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/08	Spence, C.	2020	Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active) – EU, initiated 2017 DuPont-49732 Charles River Laboratories Edinburgh Ltd GLP: Yes Published: No	N	DuPont	Y
KCP, 5.1.2/09	Verge, E.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + codacide oil: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48951 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 5.1.2/10	Verge, E.	2019	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + surfactant DPX-KG691: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48899, Revision No. 1 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Charles, E., Doran, A. M., Klems, J. P.	2017	Independent laboratory validation of analytical method DuPont-13412 for the determination of thifensulfuron methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl and chlorimuron ethyl in olives and soybean seed using SPE purification and LC/MS/MS detection DuPont-13398, Supplement No. 1 Inveresk GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2012	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Gant, A.G.	2012	Independent laboratory validation of DuPont-30449 "Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS" DuPont-30450 ABC Laboratories, Inc. (Missouri) GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Henze, R. M., Stry J. J.	2016	Analytical method for the determination of chlorsulfuron, metsulfuron methyl, thifensulfuron methyl and tribenuron methyl in plasma and urine by LC/MS/MS DuPont-47394 Stine-Haskell Research Center GLP: No Published: No	N	FMC*	Y
KCP 5.2/02	Henze, R.M., Stry, J.J.,	2013	Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-35704 GLP: No Published: No	N	DuPont	Y
KCP 5.2/07	Mason, B.J.	2013	Independent laboratory validation of DuPont-35704, "Analytical method for the determination of thifensulfuron methyl in water using LC/MS/MS" Morse Laboratories, Inc. DuPont-36531 GLP: Yes Published: No	N	DuPont	Y

*FMC Letter of Access available

B6 Mammalian toxicology

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 7.1.1/01	xxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute oral toxicity study in rats - up-and-down procedure DuPont-49958 xx GLP: Yes Published: No	Y	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 7.1.2/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute dermal toxicity study in rats DuPont-49959 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.3/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Inhalation median lethal concentration (LC ₅₀) study in rats DuPont-49960 xx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.4/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary skin irritation in rabbits DuPont-49965 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.4/02	Costin, G.E., Pham, R., Sadowski, N.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50 SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Skin irritation test (SIT) using the epiderm skin model DuPont-50172 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	DuPont	Y
KCP, 7.1.5/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary eye irritation in rabbits DuPont-49964 xx GLP: Yes Published: No	Y	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 7.1.5/02	Wilt, N., Pham, R., Sadowski, N.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50 SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): epiocular™ eye irritation test (EIT) for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage DuPont-50173 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	DuPont	Y
KCP, 7.1.6/01	xxxxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Local lymph node assay (LLNA) in mice DuPont-49966 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.7/01	Clare, K.	2018	Rimsulfuron metabolite (IN-E9260) (CAS # 117671-01-9): Genetic toxicity evaluation using a micronucleus test in TK6 human lymphoblastoid cells MNT00515 Gentronix Limited GLP: Yes Published: No	N	Helm AG, SAPEC AGRO S.A., DuPont	Y
KCP, 7.1.7/02	Ruwona, T., Sheehan, D., Koch, W.T.	2018	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Induction of antioxidant-response-element dependent gene activity and cytotoxicity (using MTT) in the keratinocyte ARE-reporter cell line keratinosens DuPont-50245 Institute for In Vitro Sciences, Inc. GLP: Yes Published: No	N	DuPont	Y
KCP 7.4/01	xxxxxxxxxxxxxxxxxxxx	1999	Oral toxicity test after 28-day repeated administration in the rat. TF375/99-0777 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	FMC	Y

B7
Metabolism and residues

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCA, 6.3.1/01	Spence, C.	2020	Magnitude of residues in/on maize following foliar application of DPX-TNS43, a blend of paste extruded granules (62.12% Mesotrione 50WG + 24.24% Rimsulfuron 25SG + 9.09% Thifensulfuron methyl 50SG Active)-EU, initiated 2017 DuPont-49732 Charles River Laboratories (UK) GLP: Yes Published: No	N	DuPont	Y

B8
Environmental fate

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 9.1.1.1/01	Huber, A.	2007	The degradation of rimsulfuron in soil and aquatic systems - Summary of kinetic calculations DuPont-23315 DuPont de Nemours (Deutschland) GmbH GLP: No Published: No	N	DuPont	N EU data sufficient to finalise the exposure assessment
KCP, 9.1.2.1/01	Khanijo, I., Huang, M.X.	2015	Degradation of rimsulfuron (DPX-E9636) and its metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290 in field dissipation studies - a kinetic calculation report DuPont-41948 E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	N EU data sufficient to finalise the exposure assessment

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 9.2.4.1/01	Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in groundwater following application to maize – A modelling assessment for Europe using the 2018 EFSA endpoints DuPont-51202 EU E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	Y
KCP, 9.2.4.1/02	Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron (DPX-E9636) and metabolites in groundwater: A modeling study conducted for maize with FOCUS PEARL 4.4.4 and PELMO 5.5.3 with the 2005 EFSA-recommended endpoints DuPont-51201 EU, Revision No. 1 E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	Y
KCP, 9.2.5/01	Yamsani, S., Mishra, N., Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in surface water following applications to maize - a modelling assessment with the 2018 EFSA endpoints DuPont-51210 EU E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	Y
KCP, 9.2.5/02	Yamsani, S., Mishra, N., Huang, M.X.	2020	Predicted environmental concentrations of rimsulfuron and its metabolites in surface water following applications to maize - a modeling assessment for Europe with the 2005 EFSA endpoint DuPont-51207 EU, Revision No. 1 E. I. du Pont de Nemours and Company GLP: No Published: No	N	DuPont	Y

B9
Ecotoxicological studies

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.2.1/01	xxxxxxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 10.2.1/02	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 48-Hour static renewal, acute toxicity test with the cladoceran, <i>Daphnia magna</i> DuPont-49949, Revision No. 1 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 10.2.1/03	Hoover, E.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) a blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> DuPont-49943 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 10.2.1/04	Bergfield, A.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49944 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.2.1/05	Goudie, O.J.	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus crop oil (Codacide): 7-Day growth inhibition test with the freshwater aquatic plant, duckweed, <i>Lemna gibba</i> DuPont-49978 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y
KCP, 10.3.1.1.1/01 and KCP, 10.3.1.1.2/01	Tome, H.V.V.	2018	Isoxadifen ethyl 50WG / Rimsulfuron 25SG / Thifensulfuron methyl 50SG (DPX-V4B07), a blend of paste extruded granules (11.11% + 14.82% + 9.26 active) plus codacide oil surfactant: An acute oral and contact toxicity study with the honey bee DuPont-48892 EAG Laboratories GLP: Yes Published: No	N	DuPont	Y
KCP, 10.3.1.1.1/02 and KCP, 10.3.1.1.2/02	Tome, H.V.V., Porch J.R.	2018	Isoxadifen ethyl 50WG / Rimsulfuron 25SG / Thifensulfuron methyl 50SG/ (DPX-V4B07), a blend of paste extruded granules (11.11% + 14.82 + 9.26% active) plus Trend 90 surfactant: An acute oral and contact toxicity study with the honey bee DuPont-48950 EAG Laboratories GLP: Yes Published: No	N	DuPont	Y
KCP, 10.3.1.1.1/03 and KCP, 10.3.1.1.2/03	Verge, E.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + codacide oil: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48951 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont	N not a data requirement

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.3.1.1.1/04 and KCP, 10.3.1.1.2/04	Verge, E.	2019	Rimsulfuron 25SG/thifensulfuron methyl 50SG/isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) + surfactant DPX-KG691: Acute oral and contact toxicity to the bumble bee, <i>Bombus terrestris</i> L. under laboratory conditions DuPont-48899, Revision No. 1 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: Yes Published: No	N	DuPont	N not a data requirement
KCP, 10.3.1.2/01	Porch, J.R., Riles, B.	2021a	GF-3969 (DPX-V4B07) + DPX-KG691 (VIVOLT): A Chronic Dietary Toxicity test with the Honey Bee (<i>Apis mellifera</i>) Rep. No. 112H-131A DAS Study No. 200439 Eurofins EAG Agroscience, LLC, USA GLP: Yes Published: No	N	Corteva	Y
KCP, 10.3.1.3/01	Cornement, M.	2018	Rimsulfuron-toxicity to Honey bees (<i>Apis mellifera</i> L.) larvae after repeated exposure under <i>In Vitro</i> laboratory conditions 20170301 Innovative Environmental Services (IES) LtdKC GLP: Yes Published: No	N	DuPont	N active substance study, not relevant for zonal evaluation
KCP, 10.3.1.3/02	Porch, J.R., Riles, B.	2021b	GF-3969 (DPX-V4B07) + DPX-KG691 (VIVOLT): A Chronic Larval Toxicity Study with the Honey Bee (<i>Apis mellifera</i>) Rep. No. 112H-130 DAS Study No. 200438 Eurofins EAG Agroscience, LLC, USA GLP: Yes Published: No	N	Corteva	Y
KCP, 10.3.2.1/01	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) DuPont-49972 IBACON GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.3.2.1/02	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: A laboratory rate-response test to evaluate the effects on the predatory mite, <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49973 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.3.2.1/03	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 Surfactant: A laboratory rate-response test to evaluate the effects on the parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) DuPont-49934 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.3.2.1/04	Moll, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: A laboratory rate-response test to evaluate the effects on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) DuPont-49935 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.4.1.1/01	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on reproduction and growth of the earthworm, <i>Eisenia andrei</i> , in artificial soil DuPont-49950 IBACON GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.4.1.1/02	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on reproduction and growth of the earthworm, <i>Eisenia andrei</i> , in artificial soil DuPont-49980 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.4.2.1/01	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil DuPont-49955 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.4.2.1/02	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on the collembola <i>Folsomia candida</i> in artificial soil DuPont-49954 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.4.2.1/03	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil DuPont-49982 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.4.2.1/04	Pavic, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codacide: Effects on the collembola <i>Folsomia candida</i> in artificial soil with 5% peat DuPont-49981 IBACON GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.5/01	Hammesfahr, U.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus KG691 surfactant: Assessment of the effects on soil microflora DuPont-49938 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.5/02	Hammesfahr, U.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active) plus codicide: Assessment of the effects on soil microflora DuPont-49976 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.6.2/01	Spatz, B.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% active) plus DPX-KG691 surfactant: Effects on terrestrial (non-target) plants: Seedling emergence and seedling growth test DuPont-49939 IBACON GLP: Yes Published: No	N	DuPont	Y
KCP, 10.6.2/02	Arnie, J.R., McKelvey, R.A., Aufderheide, J.A., Lockard, L.A., Zhang, L.	2020	Isoxadifen ethyl 50WG/Rimsulfuron 25SG/Thifensulfuron methyl 50SG (DPX-V4B07), A Blend of Paste Extruded Granules Plus Isodecylalcohol Ethoxylated (DPX-KG691) Surfactant: A Greenhouse Study to Investigate the Effects on Vegetative Vigor of Ten Terrestrial Plants Following Foliar Exposure DuPont-49942 Eurofins EAG Agrosience, LLC GLP: Yes Published: No	N	DuPont	Y N study not valid
KCP, 10.6.2/03	Ellis, S.	2022	Position paper to address zRMS comments on the risk to non-target plants from GF-3969 GLP: Not relevant, position paper Published: No	N	Corteva	Y

B10

Assessment of the Relevance of metabolites in groundwater

No studies submitted.

List of data submitted by the applicant and relied on – vertebrate studies

B0

Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

No studies submitted.

B3

Efficacy data and information

No studies submitted.

B5

Analytical methods

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 5.1.2/04	xxxxxxxxxxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (Rimsulfuron 25 SG + Thifensulfuron 50 SG + Isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions xxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

B6
Mammalian toxicology

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 7.1.1/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute oral toxicity study in rats - up-and-down procedure DuPont-49958 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.2/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% active): Acute dermal toxicity study in rats DuPont-49959 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.3/01	xxxxxxxxxxxx.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) a blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Inhalation median lethal concentration (LC ₅₀) study in rats DuPont-49960 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.4/01	xxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary skin irritation in rabbits DuPont-49965 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP, 7.1.5/01	Slonina, M.	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Primary eye irritation in rabbits DuPont-49964 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 7.1.6/01	xxxxxxxxxxxxxxxxxx	2018	Rimsulfuron 25SG/Thifensulfuron methyl 50SG/Isoxadifen ethyl 50WG (DPX-V4B07) A blend of paste extruded granules (14.82% + 9.26% + 11.11% active): Local lymph node assay (LLNA) in mice DuPont-49966 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
KCP 7.4/01	xxxxxxxxxxxxxxxxxx	1999	Oral toxicity test after 28-day repeated administration in the rat. TF375/99-0777 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	FMC	Y

B7
Metabolism and residues

No studies submitted.

B8
Environmental fate

No studies submitted.

B9
Ecotoxicological studies

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP Status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.2.1/01	xxxxxxxxxxxxxxxxxxxx	2019	DPX-V4B07 24 WG (rimsulfuron 25 SG + thifensulfuron 50 SG + isoxadifen 50 WG) A blend of paste extruded granules plus isodecylalcohol ethoxylated (DPX-KG691) surfactant: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions DuPont-49948, Revision No. 1 xx GLP: Yes Published: No	Y	DuPont	Y

B10
Assessment of the Relevance of metabolites in groundwater

No studies submitted.

List of data relied on, but not submitted and not evaluated at EU peer review

The following studies are relied upon and have not been evaluated at the EU level, but are not submitted in this dossier.

B0

Product background, regulatory Context and GAP information

Not applicable.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

Not applicable.

B3

Efficacy data and information

Not applicable.

B5

Analytical methods

Isoxadifen ethyl

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.1.2	Dacus, S.C., Neal, J. L., Cole, M.	2001	An analytical method for the determination of residues of Isoxadifen-ethyl (AE F122006) and its major metabolites AE F129431 in corn and rice and AE C637375 in rice by gas chromatography using ion trap mass selective detection, M-238876-02-1 (B003344) GLP: No Published: No	N	Bayer	Not evaluated
CP, 5.1.2	Dacus, S.C., Neal, J. L.	2000	An analytical method for the determination of residues of AE F122006 and its major metabolites AE F129431 and AE F162241 in field corn by gas and liquid chromatography using ion trap mass selective detection: AE F122006 M-238556-01-1 (B002825) GLP: No Published: No	N	Bayer	Not evaluated

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.1.2	Kaune, A.	2002	Validation of the analytical method AM01/08 for the determination of AE F122006 and its metabolites in maize using LC/MS/MS M-206994-01-1 (C018951) GLP: Yes Published: No	N	Bayer	Not evaluated
CP, 5.1.2	Freitag, Th.	2016	AM01/08 - Analytical method AM01/08 for the determination of AE F122006 and its metabolites in maize using LC/MS/MS M-206993-02-1 (C018950) GLP: Yes Published: No	N	Bayer	Not evaluated
CP, 5.2	Bacher, R.	2006	Isoxadifen-ethyl: Analytical method for the determination of isoxadifen-ethyl in air (validation) M-217537-01-1 (C029624) PTRL Europe GmbH GLP: Yes Published: No	N	Bayer	Not evaluated
CP, 5.2	Cole, M. G.; Neal, J. L.; Dacus, S. C.	2001	An Analytical Method for the Determination of Residues of Residues of Isoxadifenethyl (AE F122006) and its Major Metabolite AE F129431 in Soil by Gas Chromatography Using Nitrogen-Phosphorous or Ion Trap Mass Selective Detection, Revision 1 M-185178-02-1 (B003389) AgrEvo USA Company GLP: No Published: No	N	Bayer	Not evaluated
CP, 5.2	Meseguer, C.	2017	Independent laboratory validation of modification M029 of the analytical method 01300 (based on QuEChERS) for the determination of residues of isoxadifen-ethyl and its metabolites in different matrices of plant origin M-590984-01-1 (S16-04195) Eurofins Agroscience Services, Chem SAS GLP: Yes Published: No	N	Bayer	Not evaluated
CP, 5.2	Winter, O., Amann, S.	2016	Modification M029 of the analytical method 01300 (based on QuEChERS) for the determination of residues of isoxadifen-ethyl and its metabolites in different matrices of plant origin M-573745-01-1 (S16-03605) Eurofins Agroscience Services Chem GmbH GLP: Yes Published: No	N	Bayer	Not evaluated

B6
Mammalian toxicology

Not applicable.

B7
Metabolism and residues

Not applicable.

B8
Environmental fate

Not applicable.

B9
Ecotoxicological studies

zRMS comments:

Please note that below studies were agreed by the RMS (UK) in the course of the evaluation of the confirmatory data (for details, please refer to EFSA Supporting publication 2020:EN-1627).

Annex No., OECD Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.2.1	xxxxxxxxxxxxxxxxxxxxx	2010	Thifensulfuron Methyl (DPX-M6316) Technical: Early Life- Stage Toxicity Test with the Rainbow Trout, <i>Oncorhynchus</i> <i>mykiss</i> , xxxxxxxxxxxxxxxxxxxxx GLP: Yes DuPont-28722 Published: No	Y	FMC*, Rotam	Y
KCP, 10.2.1	Brougher, D.S., Lockard, L., Gallagher, S.P.	2017	Thifensulfuron methyl (DPX-M6316) technical: A 48-hour static acute toxicity text with the cladoceran (<i>Daphnia magna</i>) Wildlife International Ltd (USA) DuPont-46007, Revision No. 1 GLP: Yes Published: No	N	FMC*, Rotam	Y

Annex No., OECD Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.2.1	Hutton, D.G.	1989	Chronic toxicity of IN-M6316-25 to <i>Daphnia magna</i> DuPont Haskell Laboratory HLR 70-89 GLP: Yes Published: No	N	FMC*	Y
KCP, 10.2.1	Arnie, J.R., Lockard, L., Martin, K.H., Porch, J.R.	2017	Thifensulfuron methyl (DPX-M6316) technical: A 72-hour toxicity test with the freshwater alga (<i>Pseudokirchneriella subcapitata</i>) Wildlife International Ltd (USA) DuPont-46004, Revision No. 1 GLP: Yes Published: No	N	FMC*, Rotam	Y
KCP, 10.2.1	Arnie, J.R., Zhang, L., Porch, J.R., Martin, K.H.	2016	IN-D8858: A 72-hour toxicity test with the freshwater alga (<i>Pseudokirchneriella subcapitata</i>) Wildlife International Ltd. (USA) DuPont-42163, Revision No. 1 GLP: Yes Published: No	N	FMC*, Rotam	Y
KCP, 10.2.2	Arnie, J.R., Zhang, L., Porch, J.R., Martin, K.H.	2016	IN-D8858: A 7-day static-renewal toxicity test with duckweed (<i>Lemna gibba</i> G3) Wildlife International Ltd. (USA) DuPont-42164, Revision No. 1 GLP: Yes Published: No	N	FMC*, Rotam	Y
KCP, 10.4.2.1	Lühns, U.	2015a	IN-JZ789: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-42165 GLP: Yes Published: No	N	FMC*, Rotam	Y
KCP, 10.4.2.1	Lühns, U.	2015b	IN-U5F72: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-42481 GLP: Yes Published: No	N	FMC*, Rotam	Y

Annex No., OECD Data Requirement No., Reference No.	Author(s)	Year	Title Source Company Report No. GLP or GEP Status (where relevant) Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
KCP, 10.7.1/01	Pur, A. Ochoa-Acuna, H.	2015	Herbicide non-relevance screen results for Thifensulfuron methyl metabolites (IN-JZ789 and IN-U5F72) DuPont-43667 E.I. du Pont de Nemours and Company GLP: No Published: No	N	FMC*	Y

* DuPont has Letter of Access (LoA) from FMC

B10

Assessment of the Relevance of metabolites in groundwater

Not applicable.

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

B0

Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

No studies submitted.

B3

Efficacy data and information

No studies submitted.

B5

Analytical methods

Rimsulfuron

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.1.2	Siripriya, G.	2014	DPX-E9636 (Rimsulfuron): Laboratory study of n-octanol/water partition coefficient DuPont-36445 Advinus Therapeutics Limited GLP: Yes Published: No	N	DuPont	Y
CP, 5.1.2	Bacher, R.	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air (Amended) DuPont-4560 Amended PTRL Europe GmbH GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Cabusas, M.E.Y., Rodgers, C.	2012	Analytical method for the determination of rimsulfuron (DPX-E9636), nicosulfuron (DPX-V9360), and IN-V9367 in crop matrices by HPLC/ESI-MS/MS DuPont-32277 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Rogers, P.	2012	Independent laboratory validation of DuPont-32277 "Analytical method for the determination of rimsulfuron (DPX-E9636), nicosulfuron (DPX-V9360), and IN-V9367 in crop matrices by HPLC/ESI-MS/MS" DuPont-32278 Alliance Pharma, INC. GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Cabusas, M.E.Y.	2012	Analytical method for the determination of rimsulfuron (DPX-E9636) in watery, acidic, and dry crop matrices by HPLC/ESI-MS/MS DuPont-15033, Revision No. 2 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Connolly, P.	2005	Independent laboratory validation of the analytical method; DuPont-15033, Analytical method for the determination of rimsulfuron in watery and dry crop matrices by HPLC/ ESI-MS/MS DuPont-15029, Revision No. 1 Exygen Research GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Cabusas, M.E.Y.	2012	Analytical method for the determination of rimsulfuron in oily crop matrices by HPLC/ESI-MS/MS DuPont-15027, Revision No. 2 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Plastringe, B.	2005	Independent laboratory validation of the analytical method, DuPont-15027, Analytical method for the determination of rimsulfuron in oily crop matrices by HPLC/ESI MS/MS DuPont-15030 Exygen Research GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2012	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Gant, A.G.	2012	Independent laboratory validation of DuPont-30449 "Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS" DuPont-30450 ABC Laboratories, Inc. (Missouri) GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of DuPont sulfonylurea herbicides in animal matrices using HPLC/MS/MS DuPont-30449, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	xxxxxxxxxxxxxxxxx.	1991	Metabolism study of DPX-E9636 in laying hens AMR 1808-90 xxxxxxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	DuPont	Y
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2014	Analytical method for the determination of rimsulfuron (DPX-E9636) and its metabolites in soil and water using HPLC/ESI-MS/MS DuPont-38604 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Fiorito, B.	2014	Independent laboratory validation of DuPont-38604 "Analytical method for the determination of rimsulfuron (DPX-E9636) and its metabolites in soil and water using HPLC/MS/MS" DuPont-38605 Alliance Pharma GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Taoudi, M.	2015	Method validation – Determination of residues of rimsulfuron and its metabolites IN-70941, IN-70942, IN-J290, IN-E9260, IN-T5831 and IN-JF999 in water FH/14/012 Battelle UK Ltd GLP: Yes Published: No	N	Helm AG, Sapac Agro SA, DuPont*	Y
CP, 5.2	Benotti, M.J.	2015	Independent laboratory validation (ILV) of an analytical method for the determination of rimsulfuron, IN-70941, IN-70942, IN-J290, IN-T5831, IN-JF999 and IN-E9260 in drinking water Report No. 100060226B Battelle, USA GLP: Yes Published: No	N	Helm AG, Sapac Agro SA, DuPont*	Y
CP, 5.2	Pentz, A.M., Cabusas, M.E.Y.	2017	Analytical method for the determination of rimsulfuron (DPX-E9636) in plasma and urine by HPLC/ESI-MS/MS DuPont-48528 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y

*DuPont has Letter of Co-Ownership

Thifensulfuron methyl

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Devine, T.J., Nanita, S.C.	2007	Multiresidue analytical method for the determination of sulfonyurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection DuPont-13412, Supplement No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Pentz, A.M., Bramble, F.Q.	2005	Analytical method for the determination of nicosulfuron, thifensulfuron-methyl, ethametsulfuron methyl, rimsulfuron, tribenuron methyl, and chlorimuron ethyl in oily crop matrices using SPE purification and LC/MS/MS detection DuPont-13412, Revision No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Pentz, A. M., Bramble, F. Q., Devine, T. J., Nanita, S. C., Henze, R. M., Stry, J. J.	2014	Summary of multiresidue analytical method for the determination of sulfonylurea herbicides in oily, watery, acidic and dry crops using SPE purification and LC/MS/MS detection DuPont-13412, Supplement No. 4, Revision No. 1 E.I. du Pont de Nemours and Company GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Platridge, B.	2006	Independent laboratory method validation of a multi-residue method for the analysis of sulfonylurea herbicides in crops DuPont-17207, Revision No. 1 Exygen Research GLP: Yes Published: No	N	DuPont	Y
CP, 5.2	Hill, S.J. Stry, J.J	2001	Analytical method for the determination of 13 DuPont sulfonylurea herbicides in soil using LC/MS/MS DuPont-5082, Revision No. 1 DuPont Stine-Haskell Research Center GLP: No Published: No	N	DuPont	Y
CP, 5.2	Amoo, J.S., Jones, W.	2001	Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyr-sulfuron methyl in cereals (wheat grain, forage and straw) DuPont Stine-Haskell Research Center DuPont-5367 GLP: No Published: No	N	FMC	Y
CP, 5.2	Brookey, F.M., Westberg, G.L.	2007	Analytical method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyr-sulfuron methyl in lettuce and tribenuron methyl and bensulfuron methyl in citrus (oranges) Morse Laboratories, Inc. DuPont-5367, Supplement No. 1 GLP: No Published: No	N	FMC	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	Pentz, A.M. Beamble, F.Q.	2002	Independent Laboratory Validation of DuPont-5367 'Analytical enforcement method for the determination of Thifensulfuron-methyl, metsulfuron methyl, chlorsulfuron, tribenuron methyl, and flupyrsulfuron methyl in cereals (wheat grain, forage and straw)' in wheat grain, barley grain, corn grain and tomato. E.I. du Pont de Nemours and Company DuPont-8054 GLP: Yes Published: No	N	FMC	Y
CP, 5.2	Bacher, R.	2001	Development and validation of analytical methods for the determination of seven sulfonylurea herbicides in air DuPont-4560 PTRL Europe GLP: Yes Published: No	N	DuPont	Y

*FMC Letter of Access available

B6
Mammalian toxicology

Rimsulfuron

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxxxxxx	2016	IN-E9260: Rat alkaline Comet assay 8346539 xxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Helm AG and Sapac Agro SA DuPont	Y
CP, 7.1.7	Clarke, J.J.	2013	IN-E9260: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) DuPont-36588 BioReliance, Alliance Pharma, Inc. GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	Clarke, J.J.	2013	IN-70942: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) DuPont-36586 BioReliance, Alliance Pharma, Inc. GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	Forichon, A.	1992	Test to evaluate the induction of chromosome aberrations in the human lymphocytes 202380 Hazleton (France) GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	Gudi, R., Rao, M.	2004	IN-70941: <i>In vitro</i> mammalian chromosome aberration study in human peripheral blood lymphocytes DuPont-13386, Revision No. 1 BioReliance GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	2004	IN-E9260: Local lymph node assay (LLNA) in mice DuPont-15258 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	xxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single cutaneous application (Limit Test) in the rat 110303 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single oral administration (Limit Test) in the rat 110304 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxx	1992	Test to evaluate the acute ocular irritation and reversibility in the rabbit 201336 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	1992	Test to evaluate the acute primary cutaneous irritation and corrosivity in the rabbit 201335 xxxxxxxxxxxxxxxxxxxxGLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxxxx	1992	Test to evaluate sensitizing potential in the guinea-pig (Guinea-Pig Maximization Test) 202355 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	Reynolds, V.L.	1989	Mutagenicity testing of IN-E9260-1 in the <i>Salmonella typhimurium</i> Plate Incorporation Assay HLR 108-89 DuPont Haskell Laboratory GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	Reynolds, V.L.	1989	Mutagenicity testing of IN-70941 in the <i>Salmonella typhimurium</i> Plate Incorporation Assay HLR 344-89 DuPont Haskell Laboratory GLP: Yes Published: No	N	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	Roy, S., Jois, M.	2013	IN-70942: <i>In vitro</i> mammalian chromosome aberration test in human peripheral blood lymphocytes (HPBL) DuPont-36585 BioReliance GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	San, R.H.C., Clarke, J.J.	2003	IN-70941: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT Test) DuPont-13387 BioReliance GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1989	Approximate Lethal Dose (ALD) of IN-70941 in rats HLR 199-89 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1989	Ten-dose oral subchronic study of IN-70941 in rats HLR 526-89 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	Wagner, V.O., III, VanDyke, M.R.	2013	IN-70942: Bacterial reverse mutation test DuPont-36584 BioReliance GLP: Yes Published: No	N	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	1992	DPX-E9260 - 4 Week oral (gavage) toxicity study in the rat 35291 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

Thifensulfuron methyl

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	Myhre, A.	2011	IN-L9225: Bacterial reverse mutation test DuPont Haskell Laboratory DuPont-30758 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	Glover, K.P.	2011	IN-L9225: <i>In vitro</i> mammalian chromosome aberration test in human peripheral blood lymphocytes DuPont Haskell Laboratory DuPont-30759 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	Clarke, J.J.	2011	IN-L9225: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) BioReliance DuPont-30760, Revision No.1 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	Donath, C.	2011	Reverse mutation using bacteria (<i>Salmonella typhimurium</i> and <i>Escherichia coli</i>) with thifensulfuron acid. BSL Bioservice Scientific Laboratories GmbH, Germany. Study No.: 110127 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y
CP, 7.1.7	Donath, C.	2011	Reverse mutation using bacteria (<i>Salmonella typhimurium</i> and <i>Escherichia coli</i>) with 2-acid-3-sulfonamide BSL Bioservice Scientific Laboratories GmbH, Germany. Study No.: 110128 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y
CP, 7.1.7	Lloyd, M.	2011	2-acid-3-sulfonamide: Induction of chromosome aberrations in cultured human peripheral blood lymphocytes Covance Laboratories Ltd, Harrogate, UK. Study No.: 8243962 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	Lloyd, M.	2011	2-acid-3-sulfonamide: Mutation at the thymidine kinase (tk) locus of mouse lymphoma L5178Y cells (MLA) using the microtitre® fluctuation technique Covance Laboratories Ltd, Study No: 8243963 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y
CP, 7.1.7	Sxxxxxxxxxxxxxx	2011	Acute oral toxicity (fixed dose procedure) - Limit test with Thifensulfuron acid Report No: 206 GLP: Yes Published: No	Y	EU TSM AIR 2 Task Force*	Y
CP, 7.1.7	Myhre, A.	2011	IN-L9223: Bacterial reverse mutation test DuPont Haskell Laboratory DuPont-31622 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	Glover, K.P.	2011	IN-L9223: <i>In vitro</i> mammalian chromosome aberration test in human peripheral blood lymphocytes DuPont Haskell Laboratory DuPont-31623 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	Clarke, J.J.	2011	IN-L9223: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT assay) DuPont Haskell Laboratory DuPont-31624 GLP: Yes Published: No	N	FMC	Y
CP, 7.1.7	May, K.	2012	Thifensulfuron Acid (IN-L9225): <i>In vitro</i> micronucleus test in human lymphocytes Huntingdon Life Sciences Report No.: DGV0080 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y
CP, 7.1.7	May, K.	2012	O-Desmethyl Thifensulfuron Acid (IN-JZ789): Bacterial reverse mutation test Huntingdon Life Sciences Report No.: DGV0081 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	May, K.	2012	O-Desmethyl Thifensulfuron Acid (IN-JZ789): <i>In vitro</i> micronucleus test in human lymphocytes (amended report) Huntingdon Life Sciences Report No.: DGV0082 GLP: Yes Published: No	N	EU TSM AIR 2 Task Force*	Y

* Cheminova (now FMC) is owner of the study.

B7 Metabolism and residues

No studies submitted.

B8 Environmental fate

No studies submitted.

B9 Ecotoxicological studies

No studies submitted.

B10 Assessment of the Relevance of metabolites in groundwater

No studies submitted.

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

B0

Product background, regulatory Context and GAP information

No studies submitted.

B1, B2, B4

Section 1: Identity; Section 2: Physical and chemical properties; Section 4: Further information

No studies submitted.

B3

Efficacy data and information

No studies submitted.

B5

Analytical methods

Rimsulfuron

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 5.2	xxxxxxxxxxxxxx	1991	Metabolism study of DPX-E9636 in laying hens AMR 1808-90 xx GLP: No Published: No	Y	DuPont	Y

Thifensulfuron methyl

No studies submitted.

B6
Mammalian toxicology

Rimsulfuron

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	xxxxxxxxxxxxxxxxxx	2016	IN-E9260: Rat alkaline Comet assay 8346539 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	Helm AG and Saptec Agro SA DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxx	2004	IN-E9260: Local lymph node assay (LLNA) in mice DuPont-15258 xxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single cutaneous application (Limit Test) in the rat 110303 xxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxx	1991	Test to evaluate the acute toxicity following a single oral administration (Limit Test) in the rat 110304 xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxx	1992	Test to evaluate the acute ocular irritation and reversibility in the rabbit 201336 xxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxx	1992	Test to evaluate the acute primary cutaneous irritation and corrosivity in the rabbit 201335 xxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1992	Test to evaluate sensitizing potential in the guinea-pig (Guinea-Pig Maximization Test) 202355 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1989	Approximate Lethal Dose (ALD) of IN-70941 in rats HLR 199-89 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1989	Ten-dose oral subchronic study of IN-70941 in rats HLR 526-89 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	1992	DPX-E9260 - 4 Week oral (gavage) toxicity study in the rat 35291 xxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	DuPont	Y

Thifensulfuron methyl

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Relied upon Y/N
CP, 7.1.7	xxxxxxxxxxxxxxxxxxxx	2011	Acute oral toxicity (fixed dose procedure) - Limit test with Thifensulfuron acid Report No: 206 GLP: Yes Published: No	Y	EU TSM AIR 2 Task Force*	Y

* Cheminova (now FMC) is owner of the study.

B7
Metabolism and residues

No studies submitted.

B8
Environmental fate

No studies submitted.

B9
Ecotoxicological studies

No studies submitted.

B10
Assessment of the Relevance of metabolites in groundwater

No studies submitted.