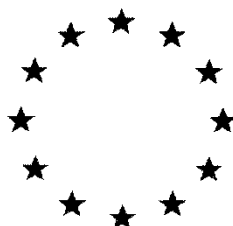


European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

Napropamide-M

Volume 2

Rapporteur Member State: United Kingdom

Version History

When	What
June 2017	Initial DAR

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A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED

A.1. IDENTITY

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No studies submitted								

PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No studies submitted								

A.2. PHYSICAL AND CHEMICAL PROPERTIES

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 2.1/01 2.1/02 2.1/03	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None
CA 2.2/01	Patel, A.H.	2013	Vapour pressure of napropamide-M purified Company Report No. 207-2-11-6176 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data	N	Y	As above	UPL	None

			requirements					
CA 2.2/02	Peatman, M.H.	2014	Napropamide-M: Calculation of Henry's Law Constant Company Report No. UPL/16/01-HLC1 JSC International Limited, UK Not GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.3/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.4/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01	N	Y	As above	UPL	None

			Study submitted to meet data requirements					
CA 2.4/02	Marshall, I.	2013	Provision of NMR and Chiral HPLC data for napropamide-M purified active ingredient (Batch: UPH-08/DNE-263/D-STD/20121221) Company Report No. SEL/7234/1 Selcia Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
B.2.4/03	Marshall, I	2013	Provision of NMR and Chiral HPLC data for napropamide-M purified active ingredient (Batch: UPH-08/DNE-263/D-STD/20121221) Company report No: SEL/7234/1 Selcia Ltd, UK GLP, Unpublished	N	Y	As above	UPL	None
B.2.4/04	Bates, G	2014	Physical and chemical determinations on Napropamide-M technical and purified material Final report Company report No: J19544	N	Y	As above		None

			GC Laboratories Ltd., UK GLP, Unpublished					
B.2.4/05	Marshall, I	2013	Provision of NMR and Chiral HPLC data for napropamide-M purified active ingredient (Batch: UPH-08/DNE-263/D-STD/20121221) Company report No:SEL/7234/1 Selcia Ltd, UK GLP, Unpublished	N	Y	As above	UPL	None
B.2.5/01 B.2.6/01	Bates, G	2014	Physical and chemical determinations on Napropamide-M technical and purified material Final report Company report No: J19544 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	As above	UPL	N/A
CA 2.7/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	As above	UPL	None

			⇒ CA 2.1/01 Study submitted to meet data requirements					
CA 2.7/02 2.7/03 2.7/04 2.7/05	Bates, G.J.D.	2015	Partition coefficient testing metabolites of Napropamide-M according to OECD 107 Company Report No. J20145 GC Laboratories Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.8/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.9/01 2.9/02	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544	N	Y	As above	UPL	None

			GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements					
CA 2.11/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide- M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.12/01	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide- M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 2.13/01	Bates, G.J.D.	2014	Physical and chemical determinations on	N	Y	As above	UPL	None

			napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements					
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PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 2.1/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	Product data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None

CP 2.2/01 2.2/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.3/01 2.3/02 2.3/03	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.4/01 2.4/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data	N	Y	As above	UPL	None

			requirements					
CP 2.5/01 2.5/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.6/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.7/01 2.7/02 2.7/03	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to	N	Y	As above	UPL	None

			meet data requirements					
CP 2.8.2/01	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.8.3/01 2.8.3/02	Bates, G.	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
B.2.8.4/0 2	Bates, G	2015	Storage stability trial for the D-Devrinol 450 SC (HBW03) formulation Final Report Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	As above	UPL	
CP	Bates, G.	2015	Storage	N	Y	As above	UPL	None

2.8.5.1/0 1			stability trial for the D- Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements					
CP 2.8.5.1/0 2	Morgan, L.	2015	Particle size distribution of D-Devrinol before and after storage for 8 weeks at 40°C Company Report No. NZ/14/021/1 Battelle UK Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 2.8.7/01	Bates, G.	2015	Storage stability trial for the D- Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CP	Bates, G.	2015	Storage	N	Y	As above	UPL	None

2.11/01			stability trial for the D- Devrinol 450 SC (HBW03) formulation Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements					
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A.3. DATA ON APPLICATION AND EFFICACY

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No Studies submitted								

PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No studies submitted								

A.4. FURTHER INFORMATION

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 3.8/01	Anon.	2015	Safety Data Sheet for napropamide-M Company Report No. not applicable Not GLP, Published Latest safety data sheet for technical grade active substance	N	N	N/A	UPL	None

PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 4.2/01	Anonymous	2015	Safety data sheet D-Devrinol Company Report No. not stated Not GLP, Published Latest safety data sheet for formulated product	N	N	N/A	UPL	None
CP 4.2/02	Bates, G.	2015	Storage stability trial	N	Y	Product data submitted	UPL	None

			for the D-Devrinol 450 SC (HBW03) formulation Interim Report 2 Company Report No. J19547 GC Laboratories Ltd., UK GLP, Unpublished ⇒ CP 2.1/01 Study submitted to meet data requirements			with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009		
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A.5. METHODS OF ANALYSIS

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 4.1.1/01	Ghate, D.B.	2013	Validation of analytical method for active ingredient analysis of napropamide-M technical Company Report No. 228-2-12-6268 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None
CA 4.1.1/02	Amruskar, A.S.	2014	Method validation of napropamide-M technical grade active ingredient (TGAI) to determine% napropamide-M and to quantify its associated impurities Company Report No.	N	Y	As above	UPL	None

			228-2-12-7332 Jai Research Foundation, India GLP, Unpublished ⇒ Document JCA Study submitted to meet data requirements					
CA 4.1.2/01	Weir, A.	2010	Validation of the analytical method “Napropamide & 2- naphthoxypropi onic Acid/Soil/DB/1 0/1” for the analysis of napropamide and 2- naphthoxypropi onic acid in soil (2010) Company Report No. S10-00191 Eurofins Agroscience Services Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/02	Pay, J.	1990a	The determination of (RS)-N,N- diethyl-2-(1- naphthoxy)pro pionamide (napropamide, R7465) in soil Company Report No. ARAM 178 ICI Agrochemicals , United Kingdom Not GLP,	N	Y	As above	UPL	None

			Unpublished Study submitted to meet data requirements					
CA 4.1.2/03	Raithatha, A.	2015	Validation of analytical method for determination of napropamide-M technical material concentration, homogeneity and stability in test diet + Amendment No. 1 Company Report No. 228-2-13-6178 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/04	Raithatha, A.	2013	Additional validation of analytical method for determination of napropamide-M technical material concentration in test diet Company Report No. 228-2-13-7271 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/05	Sriram, N.	2014	Validation of analytical method for	N	Y	As above	UPL	None

			measurement of napropamide-M concentration in rat plasma by LC-MS-MS Company Report No. 228-2-14-7333 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements					
CA 4.1.2/06	Katague, B.	1979	Determination of napropamide in animal feed Company Report No. RRC-79-26 Stauffer Chemical Company, RRC, USA Not GLP, Unpublished Study submitted to support data requirements	N	Y	As above	UPL	None
CA 4.1.2/07	Earley, E.M.	1988	Determination of R-7465 in rodent diet by HPLC Company Report No. EHC-88-11 CIBA-GEIGY Corp., Environmental Health Center, USA Not GLP, Unpublished Study submitted to support data requirements	N	Y	As above	UPL	None
CA 4.1.2/08	Mays, R.W.	1989	Determination of R-7465 in rodent diet by	N	Y	As above	UPL	None

			capillary gas chromatography Company Report No. EHC-89-7 CIBA-GEIGY Corp., Environmental Health Center, USA Not GLP, Unpublished Study submitted to support data requirements					
CA 4.1.2/09	Li, F.	2013	Method validation study for the determination of napropamide-M in crops Company Report No. AU-2012-62 JRF America, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/10	Norris, D.	2002	Determination of napropamide residues in samples of brassicas treated with Devrinol in compliance with Good Laboratory Practice Company Report No. OA00567 Oxford Analytical Ltd., United Kingdom GLP, Unpublished ⇒ CA	N	Y	As above	UPL	None

			6.3.1/01B Study submitted to meet data requirements					
CA 4.1.2/11	Pay, J.	1990b	The determination of (RS)-N,N-diethyl-2-(1-naphthoxy) propionamide (napropamide, R7465) in crops Company Report No. ARAM 177 ICI Agrochemicals, United Kingdom Not GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/12	Goodband, T.	2002	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity oilseed rape resulting from a single overall application of Devrinol 45FL to the ground in Northern France (2000-2002) Company Report No. AF/5056/US Agriseach UK Limited, United Kingdom GLP, Unpublished ⇒ CA 6.3.2/02 Study submitted to	N	Y	As above	UPL	None

			meet data requirements					
CA 4.1.2	H. Harper	2017b	Napropamide: Validation of method ARAM 178 for the determination of residues in soil Company Report No. BH69LF Envigo CRS Limited, United Kingdom Unpublished GLP: Yes	N	Y	Study submitted to meet data requirements.	UPL	None.
CA 4.1.2/13	Schwab, G.W.	1983	Determination of napropamide residues in crops by gas chromatography Company Report No. RRC 83-68 Stauffer Chemical Company, USA Not GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/14	Clark, D.	2002a	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity head cabbage resulting from a single overall application of Devrinol 45FL in the UK during 2001 Company Report No. AS/5631/US	N	Y	As above	UPL	None

			Agrisearch UK Limited, United Kingdom GLP, Unpublished ⇒ CA 6.3.1/02 Study submitted to meet data requirements					
CA 4.1.2	H. Harper	2017c	Napropamide: Validation of method ARAM 177 for the determination of residues in wheat Company Report No. KB98WY Envigo CRS Limited, United Kingdom Unpublished, GLP: Yes	N	Y	Study submitted to meet data requirements.	UPL	None.
CA 4.1.2/15	Balluf, M.	2005a	Determination of residues of napropamide after a single application with soil incorporation of Devrinol 45FL in head cabbage outdoor, Southern Europe, 2004/2005 Company Report No. 20044048/11-FPCA GAB Biotechnologie GmbH, Germany GLP, Unpublished ⇒ CA 6.3.1/05 Study submitted to meet data	N	Y	As above	UPL	None

			requirements					
CA 4.1.2/16	Balluf, M.	2005b	Determination of residues of napropamide after a single application with soil incorporation of Devrinol 45FL in head cauliflower outdoor, Southern Europe, 2004/2005 Company Report No. 20044048/11-FPCF GAB Biotechnologie GmbH, Germany GLP, Unpublished ⇒ CA 6.3.1/06 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/17	Naik, T.	2013	Validation of analytical method for determination of napropamide-M active ingredient concentration in test media Company Report No. 228-2-13-6179 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/18	██████	1990	Napropamide: A dietary LC50 study with the mallard Company	N	Y	As above	UPL	None

			Report No. 123-153 GLP, Unpublished ⇒ CA 8.1.1.2/01 Study submitted to meet data requirements					
CA 4.1.2/19		2011	D- Napropamide: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour test Company Report No. D03458 GLP, Unpublished ⇒ CA 8.2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/20	Jenkins, C.A.	2002a	Napropamide Algal growth inhibition assay (<i>Anabaena</i>) Company Report No. UPH021/01321 3 Huntingdon Life Sciences Ltd., United Kingdom GLP, Unpublished ⇒ CA 8.2.6.2/01 Study submitted to meet data requirements	N	Y	As above	UPL	None

CA 4.1.2/21	Juckeland, D.	2012a	Effects of napropamide metabolite Isomer I on <i>Lemna minor</i> in a growth inhibition test under semi- static test conditions Company Report No. 11 10 48 017 W BioChem agrar, Germany GLP, Unpublished ⇒ CA 8.2.7/02 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/22	Juckeland, D.	2012b	Effects of napropamide metabolite Isomer II on <i>Lemna minor</i> in a growth inhibition test under semi- static test conditions Company Report No. 11 10 48 018 W BioChem agrar, Germany GLP, Unpublished ⇒ CA 8.2.7/03 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.1.2/23	Juckeland, D.	2012c	Effects of diethylamine on <i>Lemna minor</i> in a growth inhibition test under semi- static test conditions Company Report No. 12 10 48 017 W BioChem	N	Y	As above	UPL	None

			agrar, Germany GLP, Unpublished ⇒ CA 8.2.7/04 Study submitted to meet data requirements					
CA 4.1.2/24	Bates, G.J.D.	2014	Physical and chemical determinations on napropamide-M technical and purified material Company Report No. J19544 GC Laboratories Ltd., United Kingdom GLP, Unpublished ⇒ CA 2.1/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.2/01	White, G.	2013	Independent Laboratory Validation of analytical method AU-265R0 “Determination of napropamide-M in crops” Company Report No. J19552 GC Laboratories Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.2/02	Chambers, J.G.	2003	Analytical method and validation for	N	Y	As above	UPL	None

			the post-registration monitoring of napropamide residues in soil Company Report No. SYN/3002 Synergy Laboratories Limited, United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 4.2/03	Shrimali, A.	2013	Analytical method validation for the determination of napropamide-M concentration in surface water (river water) and drinking water Company Report No. 228-2-12-6177 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 4.2/04	Bianca, C.	2014	Independent Laboratory Validation for the method of analysis for napropamide-M in drinking water Company Report No. AU-2012-63 JRF America, USA	N	Y	As above	UPL	None

			GLP, Unpublished Study submitted to meet data requirements					
CA 4.2/05	Flack, I. / Burton, D.	2015	Napropamide. Development and validation of a method of analysis in air + Amendment No. 1 Company Report No. UPH 020/003673 Huntingdon Life Sciences Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None

PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 5.1.1/01	Atkins, B.	2013	Validation of analytical method M774 “High Performance Liquid Chromatographic determination of napropamide-M in formulations” for the d-Devrinol 450 SC (HBW03)	N	Y	Product data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product.	UPL	None

			formulation Company Report No. J19546 GC Laboratories Ltd., UK GLP, Unpublished Study submitted to meet data requirements			Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009		
CP 5.1.1/02	Bos, M.W.S.	2011	Validation of SOP DLA- 278.1 “d- Napropamide technical and formulations, determination of d- napropamide by HPLC Company Report No. DL 10-069 Cerexagri B.V., The Netherlands GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 5.1.1/03	Kelly, K.	2014	Validation of analytical method M811 “GC determination of residual toluene in technical material and formulations” for the 450SC D-Devrinol (HBW03) formulation Company Report No. J19904 GC Laboratories Ltd., UK GLP, Unpublished	N	Y	As above	UPL	None

			Study submitted to meet data requirements					
CP 5.1.2/01	██████████ ████	2011	D-Devrinol 450 SC: 4 hour acute inhalation toxicity study in the rat Company Report No.: D03526 ██████████ ██████████ ██████████ GLP, Unpublished ⇒ CP 7.1.3/01 Study submitted to meet data requirements	Y	Y	As above	UPL	None
CP 5.1.2/02	Amruskar, A.S.	2013	Validation of analytical method for determination of D-Devrinol 450 SC (HBW03) active ingredient concentration in test media Company Report No. 228-2-13-6185 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 5.1.2/03	██████████	2011	D-Devrinol 450SC: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour test Company Report No. D03572	N	Y	As above	UPL	None

			<p>██████████ ██████████ ██████████ ██████████ GLP, Unpublished ⇒ CP 10.2.1/01 Study submitted to meet data requirements</p>					
B.5.1.2.1.2.	G.J.D. Bates	2016	<p>‘For the determination of metabolites of napropamide-M in octanol and water phases for support of partition testing’ UPL Europe Ltd, Report No.: J19544 Unpublished GLP: Yes</p>	N	Y	As above	UPL	None.

A.6. TOXICOLOGY AND METABOLISM DATA

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 5	EFSA	2010	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance napropamide. EFSA Journal 2010; 8(4):1565. [73 pp.]. doi:10.2903/j.efsa.2010.1565.	N	N/A	N/A	EFSA	No
CA 5.1.1/01	██████████ ████	1988	Napropamide: tissue distribution in animal (Supplement dated 13 Feb 1990) Company Report No. CTL/C/2689 ██████████ ██████████ ██████████ Not GLP Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.1.1/02	██████████ ██████████ ████	1991	Napropamide: repeat dose metabolism study in the rat (30 mg/kg) Company Report No. ██████/P/3403	Y	N	N/A	UPL	None

			<p>██████████</p> <p>██████████</p> <p>██████████</p> <p>██████████</p> <p>GLP Unpublished Study submitted to meet data requirements</p>					
CA 5.1.1/03	<p>██████████</p> <p>██████████</p> <p>██████████</p>	1991	<p>Napropamide: Biotransformation study in the rat</p> <p>Company Report No. ██████████/P/3404</p> <p>██████████</p> <p>██████████</p> <p>██████████</p> <p>GLP Unpublished Study submitted to meet data requirements</p>	Y	N	N/A	UPL	None
CA 5.1.1/04	<p>██████████</p> <p>██████████</p> <p>██████████</p>	2015	<p>Napropamide-M: the metabolism of [14C]napropamide-M following oral administration in the rat</p> <p>Company Report No. 34510</p> <p>██████████</p> <p>██████████</p> <p>GLP Unpublished Study submitted to meet data requirements</p>	Y	Y	<p>Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product.</p> <p>Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009</p>	UPL	None
CA 5.1.1/05	<p>██████████</p> <p>██████████</p> <p>██████████</p>	1970	<p>Metabolism of R-7465-¹⁴C[2-α-naphthoxy) <u>N</u>.</p>	Y	N	N/A	UPL	Yes

			N- diethylpropiona mide]: balance and tissue residue elimination studies in the rat ██████ ██████ ██████ Company report No.: ARC-B-27 GLP: No Published: No					
CA 5.2.1/01	██████ ██	2010a	D- napropamide: acute oral toxicity study in rats Company Report No. D03381 ██████ ██████ ██ ██████ GLP, Unpublished Study submitted to meet data requirements (study conducted for global regulatory purposes)	Y	Y	As above	UPL	None
CA 5.2.2/01	██████ ██	2010b	D- napropamide: acute dermal toxicity study in rats Company Report No. D03392 ██████ ██████ ██ ██████ GLP, Unpublished Study submitted to meet data requirements (study conducted for global regulatory	Y	Y	As above	UPL	None

			purposes)					
CA 5.2.3/01	████████ ██	2011	D- napropamide: 4 hour acute inhalation toxicity study in the rat Company Report No. D03403 ██████ ██████████ ██████ ██████████ Not GLP, Unpublished Study submitted to meet data requirements (trial aerosol generation study)	N	Y	As above	UPL	None
CA 5.2.3/02	████████	1989	Napropamide: 4-hour acute inhalation toxicity study in the rat Company Report No. ██████/P/2418 ██████████ ██████████ ██████████ ██████ GLP Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.2.4/01	████████ ██	2010c	D- napropamide: Primary skin irritation study in rabbits (4- hour semi- occlusive application) Company Report No. D03414 ██████ ██████████ ██████ ██████████ GLP,	Y	Y	As above	UPL	None









			Unpublished Study submitted to meet data requirements (study conducted for global regulatory purposes)					
CA 5.2.5/01	██████ ██	2011	D- napropamide: primary eye irritation study in rabbits Company Report No. D03425 ██████ ██████████ ███ ██████████ GLP, Unpublished Study submitted to meet data requirements (study conducted for global regulatory purposes)	Y	Y	As above	UPL	None
CA 5.2.6/01	██████	2011	Local lymph node assay (LLNA) in mice with d- napropamide Company Report No. 1365601 ██████ ██████████ ██████████ ██████████ ██████ ██████████ GLP, Unpublished Study submitted to meet data requirements (study conducted for global regulatory	Y	Y	As above	UPL	None

			purposes)					
CA 5.3.1.1/01	██████	2013	28-day dose range finding dietary toxicity study of napropamide-M technical in Wistar rats Company Report No. 410-1-02-6144 ██████ ██████ ██████ GLP, Unpublished Study submitted to meet data requirements	Y	Y	As above	UPL	None
CA 5.3	██████ ██████	1988a	Memorandum report for T-13275: 4-week dietary range-finding study with R-7465 in rats ██████ ██████ Company report No.: T-13275 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.3	██████ ██████	1988b	Memorandum report for T-13271: 6-week dietary range-finding study with R-7465 in mice ██████ ██████ Company report No.: T-13271 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.3	██████ ██████	1987	An oral dose range finding study of Devrinol technical in the Beagle dog ██████ ██████ ██████ Company report No.: T-12921 GLP: Yes Published: No	Y	N	N/A	UPL	Yes
CA 5.3.2.2/0	██████	2014	90-day dietary toxicity study	Y	Y	As above	UPL	None

1			of napropamide-M technical in Wistar rats Company Report No. 443-1-03-6145 [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished Study submitted to meet data requirements					
CA 5.3	[REDACTED]	1970	R-7465: Safety evaluation by dietary feeding to rats for 13 weeks [REDACTED] [REDACTED] [REDACTED] Company report No.: T-2203 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.3	[REDACTED]	1970	R-7465: Safety evaluation by repeated dietary administration to dogs for 13 weeks [REDACTED] [REDACTED] [REDACTED] Company report No.: T-2166 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.3	[REDACTED]	1988	A 52-week toxicity study of Devrinol technical in the Beagle dog [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] Company report No.: T-12924 GLP: Yes Published: No	Y	N	N/A	UPL	Yes
CA 5.3.2.3/0 1	[REDACTED]	1995	Napropamide: toxicity to dogs by repeated oral administration for 52 weeks Company	Y	N	N/A	UPL	None

			Report No. █/C/2860 █ █ █ GLP, Unpublished Study submitted to meet data requirements					
CA 5.3.3/01	█ █ █ █	1991	Napropamide: 21-day dermal toxicity to the rat Company Report No. █/P/3397 █ █ █ █ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.4.1.1/01	Sokolowski, A.	2011/ 2010	<i>Salmonella typhimurium</i> and <i>Escherichia coli</i> reverse mutation assay with d-napropamide (report amendment 1) Company Report No. 1365602 Harlan, Cytotest Cell Research GmbH (Harlan CCR), Germany GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 5.4.1.2/01	Wollny, H-E.	2011	Cell mutation assay at the thymidine kinase locus	N	Y	As above	UPL	None

			(TK ^{+/+}) in mouse lymphoma L5178Y cells with d-napropamide Company Report No. 1365603 Harlan, Cytotest Cell Research GmbH (Harlan CCR), Germany GLP, Unpublished Study submitted to meet data requirements					
CA 5.4	Ballantyne, M.	2017	Napropamide-M: <i>In vitro</i> L5178Y gene mutation assay at the <i>tk</i> locus. UPL Europe Ltd, Unpublished report No.: 8357643	N	Y	N/A	UPL	No
CA 5.4	EFSA	2011	EFSA Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA, 2011)	N	N/A	N/A	EFSA	No
CA 5.4	Majeska, J.B.	1984a	Mutagenicity evaluation in mouse lymphoma multiple endpoint test – forward mutation assay Stauffer Chemical Company Company report No.: T-11912 GLP: No Published: No	N	N	N/A	UPL	Yes
CA 5.4	Pirovano, R.	1986a	Study of the capacity of the test article	N	N	N/A	UPL	Yes

			technical napropamide to induce gene mutation in V79 Chinese hamster lung cells Istituto di Ricerche Biomediche (RBM) Company report No.: RIC0011 GLP: No Published: No					
CA 5.4.1.3/0 1	Bohnenber ger, S.	2011	Chromosome aberration test in human lymphocytes <i>in vitro</i> with d- napropamide Company Report No. 1365604 Harlan, Cytotest Cell Research GmbH (Harlan CCR), Germany GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 5.4		2017	Napropamide- M: Rat Alkaline Comet Assay,   Unpublished report No.: 8361879	Y	Y	N/A	UPL	No
CA 5.4.2/01		1984b	Devrinol® Technical (Lot No. WRC 4921-27-24). Mutagenicity evaluation in bone marrow micronucleus Company Report No. T- 11822    	Y	N	N/A	UPL	None

			Not GLP, Unpublished Study submitted to meet data requirements					
CA 5.4.2/02	██████ ██	1986	Devrinol® Technical (Lot No. WRC 4921-27-24). Mutagenicity evaluation in bone marrow micronucleus Company report no. T- 12813 ██████ ██████ ██████ ██ Not GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.5/01	██████ ██ ██████ ██	1991a	Two-year chronic toxicity/oncoge nicity study with R-7465 in rats Company Report No. T- 13276 ██████████ ██████ ██████████ ██████████ ██ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.5/02	██████ ██████	1993	Two-year chronic toxicity/oncoge nicity study with R-7465 (Napropamide) in rats Supplement to T-13276, histopathology	Y	N	N/A	UPL	None

			report and overall study discussion Company Report No. [REDACTED]/P/4137 [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished Study submitted to meet data requirements					
CA 5.5/03	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	1978	24-Month chronic feeding study in rats – Devrinol Technical Company Report No. T-6158 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Not GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.5/04	[REDACTED]	1986	Addendum to final report– 24-month chronic feeding study in rats Company Report No. T-6158 [REDACTED] [REDACTED] [REDACTED] [REDACTED] Not GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.5/05	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	1991b	18-Month dietary mouse oncogenicity study with R-7465	Y	N	N/A	UPL	None

			Company Report No. T- 13272 [REDACTED] [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished Study submitted to meet data requirements					
CA 5.5/06	[REDACTED]	2015	Statistical analysis of selected tumour data from R-7465 (Napropamide) : Two-year Chronic Toxicity/Onco genicity Study in the Rat Company Report No. 8328131 [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished	N	Y	As above	UPL	None
CA 5.5/07	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	2004	Compilation of spontaneous neoplastic lesions and survival in [REDACTED]:CD®(SD) rats from control groups [REDACTED] [REDACTED] Not GLP, Published	N	N	N/A	Publish ed	None
CA 5.6.1/01	[REDACTED] [REDACTED]	1978b	Three- generation reproduction study in rats Company Report No. T- 6334 [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	Y	N	N/A	UPL	None

			Not GLP, Unpublished Study submitted to meet data requirements					
CA 5.6.1/02	██████ ██████	1981	Three generation reproduction study in rats—amendment to the final report Company Report No. T-6334 ██████ ██████ ██████ ██████, ██████ Not GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.6.1/03	██████	2007	Devrinol tech: three generation reproduction study in rats, statistical assessment of parental body weight data Company Report No. not stated Not GLP, Unpublished Assessment submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.6.2/01	██████ ██████	1982	A teratology study in rats with Devrinol Company Report No. T-11038 ██████ ██████ ██████ Not GLP, Unpublished Study	Y	N	N/A	UPL	None

			submitted to meet data requirements					
CA 5.6.2/02	██████ ██████	1990a	A teratology study in CD rats with R- 7465 technical Company Report No. T- 13274 ██████████ ██████████ ██████████ ██████ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.6.2/03	██████ ██████	1990b	T-13589: A teratology study in CD rats with R- 7465 technical Company Report No. T- 13589 ██████████ ██████████ ██████████ ██████ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.6.2/04	██████████	1990	T-13270: A teratology study in rabbits with R-7465 technical Company Report No. T- 13270 ██████████ ██████████ ██████████ ██████ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None

CA 5.6	██████████ ██████████ ██████████	1984	A range finding teratology study in New Zealand white rabbits with Devrinol ██████████ ██████████ ██████████ Company report No.: T-11851 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.6	██████████	1984	A teratology study in New Zealand White rabbits with Devrinol Company Report No. T-11898 ██████████ ██████████ ██████████ ██████████ Not GLP, Unpublished	Y	N	N/A	UPL	Yes
CA 5.6	██████████	1985	Addendum to T-11898 (██████████ ██████████ 1984): a teratology study in New Zealand White rabbits with Devrinol	Y	N	N/A	UPL	Yes
CA 5.6	██████████	1989	A range finding teratology probe in rats with R-7465 technical ██████████ ██████████ ██████████ ██████████ Company report No.: T-13273 GLP: No Published: No	Y	N	N/A	UPL	Yes
CA 5.6	██████████ ██████████ ██████████	1971	R-7465: safety evaluation by a teratological study in rats Company Report No. T-6392 ██████████ ██████████ ██████████ ██████████ Not GLP, Unpublished	Y	N	N/A	UPL	Yes
CA 5.8.1/01	██████████ ██████████	1970	α-Naphthoxy propionic acid: acute toxicity	Y	N	N/A	UPL	None

			Company Report No. T- 1501 ██████ ██████ ██████ ██████ Not GLP, Unpublished Study submitted to meet data requirements					
CA 5.8.1/02	Thompson, P.W.	2008	NOPA: reverse mutation assay “Ames test” <i>Salmonella</i> <i>typhimurium</i> and <i>Escherichia</i> <i>coli</i> Company Report No. 0237/0224 SafePharm Laboratories Limited, UK GLP, Unpublished Study submitted to meet data requirements	N	N	N/A	UPL	None
CA 5.8.1/03	Flanders, L.	2008	NOPA: L5178Y TK +/- mouse lymphoma assay Company Report No. 0237/0226 SafePharm Laboratories Limited, UK GLP, Unpublished Study submitted to meet data requirements	N	N	N/A	UPL	None
CA 5.8.1/04	Pickard, F.E.	2008	NOPA: chromosome aberration test in human lymphocytes <i>in</i> <i>vitro</i> Company	N	N	N/A	UPL	None

			Report No. 0237/0225 SafePharm Laboratories Limited, UK GLP, Unpublished Study submitted to meet data requirements					
CA 5.8.1/05	██████ ██	2008	NOPA: micronucleus test in the mouse Company Report No. 0237/0227 ██████ ██████ ██████ GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 5.8.1/06	Rose, P.H.	2015	Toxicological assessment of plant metabolites 2- hydroxy-1,4- naphthoquinon e, o-phthalic acid and 1- naphthol Company Report No. UPL/16/01- TOX1 Not GLP, Unpublished Assessment submitted to meet data requirements	N	N	N/A	UPL	None
CA 5.9.1/01	Desai, A.	2015	Medical surveillance of manufacturing personnel napropamide- M technical material Company Report No. 2015/01 UPL Limited,	N	Y	As above	UPL	None

			India Not GLP, Unpublished Report submitted to meet data requirements					
CA 5.10.	Wilkinson, D., Tucker, K., 2016	2016	Napropamide-M Literature Review Report Submission of Scientific Peer- Reviewed Open Literature under Regulation (EC) No 1107/2009	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009.	UPL	No

PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 7.1.1/01	██████	2010a	D-Devrinol 450 SC: acute oral toxicity study in rats Company Report No.: D03504 ██████ ██████ ██████ ██████. GLP, Unpublished Study conducted for global regulatory purposes and is submitted to meet data requirements	Y	Y	Product data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None
CP	██████	2010b	D-Devrinol	Y	Y	As above	UPL	None

7.1.2/01			450 SC: acute dermal toxicity study in rats Company Report No.: D03515 [REDACTED] [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished Study conducted for global regulatory purposes and is submitted to meet data requirements					
CP 7.1.3/01	[REDACTED] [REDACTED]	2011	D-Devrinol 450 SC: 4 hour acute inhalation toxicity study in the rat Company Report No.: D03526 [REDACTED] [REDACTED] [REDACTED] [REDACTED] GLP, Unpublished Study conducted for global regulatory purposes and is submitted to meet data requirements	Y	Y	As above	UPL	None
CP 7.1.4/01	[REDACTED]	2010c	D-Devrinol 450 SC: primary skin irritation study in rabbits (4 hour semi-occlusive application) Company Report No.: D03537 [REDACTED] [REDACTED] [REDACTED]	Y	Y	As above	UPL	None

			<p>██████████ GLP, Unpublished</p> <p>Study conducted for global regulatory purposes and is submitted to meet data requirements</p>					
CP 7.1.5/01	██████████	2011	<p>D-Devrinol 450 SC: primary eye irritation study in rabbits. Company Report No.: D03548 ██████████ ██████████ ██████████ ██████████ GLP, Unpublished</p> <p>Study conducted for global regulatory purposes and is submitted to meet data requirements</p>	Y	Y	As above	UPL	None
CP 7.1.6/01	██████████	2011	<p>Local lymph node assay (LLNA) in mice with D-Devrinol 450 SC Company Report No.: 1365301 ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ GLP, Unpublished</p> <p>Study conducted for global regulatory purposes and is submitted to meet data</p>	Y	Y	As above	UPL	None

			requirements					
CP 7.3.1/01	Johnson, I.R.	2014	Napropamide- M 450 g/L SC – <i>in vitro</i> absorption through human dermatomed skin using [¹⁴ C]- napropamide- M. Company Report No.: JV2242-REG Dermal Technology Laboratory Ltd., UK GLP, Unpublished Study conducted to refine estimates of human exposure for risk assessment	N	Y	As above	UPL	None

A.7. RESIDUE DATA

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 6.1/01	Norris, D.	2002a	Determination of the freezer storage stability of napropamide residues in samples of brassicas (to include cauliflower, cabbage and Brussels sprouts), over a maximum period of twelve months, in compliance with Good Laboratory Practice Company Report No. OA00567 B Oxford Analytical Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.1/02	Brown, D.	2001	Study to determine the stability of napropamide residues in oilseed rape seed and specimens following frozen storage at ca. -18°C for	N	N	NA	UPL	For Napropamide DAR (2005).

			0 days, 1 month, 3, 6 and 12 months Company Report No. AD/5287/US Agriseach UK Limited, United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.2.1/01	Ahmad, S.	2015	[naphthyl-1- ¹⁴ C] napropamide-M: Metabolism in oilseed rape crop Company Report No. AU-2012-49 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 6.2.1/02	Langford-Pollard, A.D.	2002	Napropamide oilseed rape metabolism Company Report No. UPH/028/1446 1 Huntingdon Life Sciences Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.2.1/03	Emburey, S., Joseph, R.S.I.	1992	Napropamide: Uptake and Metabolism in Cabbage Company Report No.	N	N	NA	UPL	For Napropamide DAR (2005).

			RJ1224B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.2.1/04	Webb, J., Allin, R., Joseph, R.S.I.	1992	Napropamide: Uptake and Metabolism in Tomatoes Company Report No. RJ1153B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.2.1/05	Hurt, A.D., Joseph, R.S.I.	1992	Napropamide: Uptake and Metabolism in Apples Company Report No. RJ1128B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.2.1/06	Spillner, C.J.	1983	Uptake and metabolism of [¹⁴ C] Devrinol in potatoes Company Report No. MRC-83-07 Stauffer Chemical Company, USA Not GLP,	N	N	NA	UPL	For Napropamide DAR (2005).

			Unpublished Study submitted to meet data requirements					
CA 6.2.2/01	Hurt, A.D., Downey, C.J., Joseph, R.S.I.	1993	Napropamide: Metabolism of orally administered multiple doses in the laying hen Company Report No. RJ1408B ICI Agrochemicals, United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.2.3/01	Webb, J., Allin, R., Joseph, R.S.I.	1993	Napropamide: Metabolism of orally administered multiple doses in the lactating goat Company Report No. RJ1388B ICI Agrochemicals, United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.3.1/01A	Bamber, A.	2001	The production of brassica samples after one pre-plant application of Devrinol Company Report No. 688-00-UPL-BRA Oxford Agricultural	N	N	NA	UPL	None

			Trials Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.3.1/01B	Norris, D.	2002b	Determination of napropamide residues in samples of brassicas treated with Devrinol in compliance with Good Laboratory Practice Company Report No. OA00567 Oxford Analytical Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.3.1/02	Clark, D.	2002a	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity head cabbage resulting from a single overall application of Devrinol 45FL in the UK during 2001 Company Report No. AS/5631/US Agrisearch UK Limited, United Kingdom	N	N	NA	UPL	For Napropamide DAR (2005).

			GLP, Unpublished Study submitted to meet data requirements					
CA 6.3.1/03	Clark, D.	2002b	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity cauliflower resulting from a single overall application of Devrinol 45FL in the UK during 2001 Company Report No. AS/5633/US Agrisearch UK Limited, United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.3.1/04	Clark, D.	2002c	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity Brussels sprouts resulting from a single overall application of Devrinol 45FL in the UK during 2001 Company Report No. AS/5634/US Agrisearch UK Limited,	N	N	NA	UPL	For Napropamide DAR (2005).

			United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.3.1/05	Balluf, M.	2005a	Determination of residues of napropamide after a single application with soil incorporation of Devrinol 45FL in head cabbage outdoor, Southern Europe, 2004/2005 Company Report No. 20044048/I1 - FPCA GAB Biotechnologie GmbH, Germany GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 6.3.1/06	Balluf, M.	2005b	Determination of residues of napropamide after a single application with soil incorporation of Devrinol 45FL in head cauliflower outdoor, Southern Europe, 2004/2005 Company Report No. 20044048/I1 - FPCF GAB Biotechnologie GmbH,	N	N	NA	UPL	None

			Germany GLP, Unpublished Study submitted to meet data requirements					
CA 6.3.2/01	Chadwick, G.	2015	d-napropamide 450 g/L Determination of residues of d-napropamide after one application of d-napropamide 450 g/L SC to winter oilseed rape at 3 sites in Northern Europe and 4 sites in Southern Europe 2012 Company Report No. S12-03756 Eurofins Agroscience Services Ltd., United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 6.3.2/02	Goodband, T.	2002	To determine the magnitude of napropamide residues at harvest in the raw agricultural commodity oilseed rape resulting from a single overall application of Devrinol 45FL to the ground in Northern France (2000- 2002) Company Report No.	N	N	NA	UPL	For Napropamide DAR (2005).

			AF/5056/US Agriseach UK Limited, United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.3.2/03	Pay, J., Simmons, N.D.	1990	Napropamide: Residues in oil seed rape from trials carried out in West Germany during 1988 Company Report No. RJ0829B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.3.2/04	Simmons, N.D.	1992a	Napropamide: Residues in oil seed rape from trials carried out in Denmark during 1990 Company Report No. RJ1006B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.6.1/01	Parker, S., Steel, T.R., Harris, M., Hurt, A.D., Allin, R.	1993	Napropamide: Uptake and metabolism in confined rotational crops Company Report No.	N	N	NA	UPL	For Napropamide DAR (2005).

			RJ1348B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements					
CA 6.6.2/01A	Simmons, N.D.	1992b	Napropamide: Residue levels in soil and rotated winter wheat, following application to oil seed rape, from trials carried out in Germany during 1988-90 Company Report No. RJ1035B ICI Agrochemicals , United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).
CA 6.6.2/01B	Purser, D.	1991	Napropamide: Determination of residues in crop and soil + Amendment No. 1 Company Report No. 38/155D Hazleton UK, United Kingdom GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	For Napropamide DAR (2005).

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
All data relevant to “Residues in or on treated products, food or feed” are presented in L-CA Section 6 – Residues in or on treated products, food and feed and plant metabolism.								

A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 7.1.1.1/0 1	Ahmad, S.	2015a	[naphthyl-1- ¹⁴ C] Napropamide-M: aerobic soil metabolism and transformation Company Report No. AU-2014-01 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None
CA 7.1.1.2/0 1	Ahmad, S.	2015b	[naphthyl-1- ¹⁴ C] Napropamide-M: anaerobic soil metabolism and transformation Company Report No. AU-2014-02 Jai Research Foundation, USA GLP, Unpublished	N	Y	As above	UPL	None

			Study submitted to meet data requirements					
CA 7.1.1.3/01	Bianca, C.M.	2015a	[naphthyl-1- ¹⁴ C] Napropamide-M: photodegradation on soil Company Report No. AU-2012-52 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.1.1.3/02	Croucher, A., Ford, S.	2015a	Napropamide-M: kinetic assessment for laboratory photodegradation on soil Company Report No. UPL/16/01-KIN4 JSC International Ltd, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 7.1.2.1.1/01	Ahmad, S.	2015a	[naphthyl-1- ¹⁴ C] Napropamide-M: aerobic soil metabolism and transformation Company Report No. AU-2014-01 Jai Research Foundation, USA GLP, Unpublished ⇒ CA	N	Y	As above	UPL	None

			7.1.1.1/01 Study submitted to meet data requirements					
CA 7.1.2.1.1/02	Croucher, A., Ford, S.	2015b	Napropamide-M: kinetic assessment for laboratory aerobic soil degradation study Company Report No. UPL/16/01-KIN2 JSC International Ltd, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 7.1.2.1.3/01	Ahmad, S.	2015b	[naphthyl-1- ¹⁴ C] Napropamide-M: anaerobic soil metabolism and transformation Company Report No. AU-2014-02 Jai Research Foundation, USA GLP, Unpublished ⇒ CA 7.1.1.2/01 Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.1.2.1.3/02	Croucher, A., Ford, S.	2015c	Napropamide-M: kinetic assessment for laboratory anaerobic soil degradation study Company Report No.	N	N	NA	UPL	None

			UPL/16/01-KIN3 JSC International Ltd, UK Not GLP, Unpublished Study submitted to meet data requirements					
CA 7.1.2.2.1/ 01	Wilson, A.	2015	Terrestrial field dissipation study with a suspension concentrate formulation containing 450 g/L napropamide-M applied to bare soil in Italy, Spain, United Kingdom and Germany, 2013 Company Report No. ACI3-033 Agrochemex International Ltd., UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.1.2.2.1/ 02	Croucher, A., Ford, S.	2015d	Napropamide-M: Kinetic assessment of field dissipation studies Company Report No. UPL/16/01-KIN1 JSC International Limited, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None

CA 7.1.3.1.1/ 01	Dubey, P.	2013	Determination of the adsorption coefficient (K _{oc}) for [naphthyl-1- ¹⁴ C]napropamide-M Company Report No. AU-2012-54 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.2.1.1/0 1	Li, F.	2013	Hydrolytic stability of [naphthyl-1- ¹⁴ C]napropamide-M in buffered aqueous solutions at pH 4, 7 and 9 Company Report No. AU-2012-55 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.2.1.2/0 1	Bianca, C.M.	2014	Photodegradation of [naphthyl-1- ¹⁴ C]napropamide-M in sterile buffer Company Report No. AU-2012-56 Jai Research Foundation, USA GLP, Unpublished Study submitted to	N	Y	As above	UPL	None

			meet data requirements					
CA 7.2.1.2/02	Croucher, A., Ford, S.	2015e	Napropamide-M: kinetic assessment of degradation in a laboratory aqueous photolysis study Company Report No. UPL/16/01-KIN6 JSC International Ltd, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 7.2.2.1/01	Raithatha, A.	2014	Ready biodegradability of napropamide-M technical Company Report No. 604-3-15-8445 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.2.2.2/01	Bianca, C.M.	2015b	[naphthyl-1- ¹⁴ C] Napropamide-M: aerobic mineralisation in surface water (pelagic test) Company Report No. AU-2012-58 Jai Research Foundation, USA GLP, Unpublished Study	N	Y	As above	UPL	None

			submitted to meet data requirements					
CA 7.2.2.2/02	Croucher, A., Ford, S.	2015f	Napropamide-M: kinetic assessment for aerobic mineralisation in surface water study Company Report No. UPL/16/01-KIN5 JSC International Ltd, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None
CA 7.2.2.3/01	Ahmad, S.	2015c	Aerobic transformation in sediment/water systems for [naphthyl-1- ¹⁴ C] napropamide-M Company Report No. AU-2012-59 Jai Research Foundation, USA GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 7.2.2.3/02	Croucher, A., Ford, S.	2015g	Napropamide-M: kinetic evaluation of water sediment study Company Report No. UPL/16/01-KIN7 JSC International Ltd, UK Not GLP,	N	N	NA	UPL	None

			Unpublished Study submitted to meet data requirements					
CA 7.3.1/01	Croucher, A.	2015	Estimation of the atmospheric oxidation rate for napropamide-M Company Report No. UPL/16/01-AIR1 JSC International Limited, UK Not GLP, Unpublished Study submitted to meet data requirements	N	N	NA	UPL	None

Additional information

Study author	Date	Title	Relevance to evaluation	Used in previous DAR of napropamide (racemate)
Lee, K.S.	1989	Aqueous Photolysis of Napropamide: Lab Project Number: WRC 88-80: ENV-002. Unpublished study prepared by ICI Americas Inc. 82 p.	The factor for conversion of experimental days to equivalent natural sunlight days was derived from this study on napropamide. This was used to verify the Applicant's calculations in the soil photolysis study of napropamide-M (section 3CA B.8.1.1.3)	yes

PLANT PROTECTION PRODUCT D-Devinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
No studies submitted								

A.9. ECOTOXICOLOGY DATA

ACTIVE SUBSTANCE NAPROPAMIDE-M

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CA 8.1.1.1/0 1	████████	2013	Acute oral toxicity (LD ₅₀) study of napropamide- M technical in Japanese quail, <i>Coturnix coturnix japonica</i> Company report No. 516- 3-08-6173 ████████ ████████ ████████ GLP, Unpublished Study submitted to meet data requirements	Y	Y	Active substance data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	None
CA 8.1.1.2/0 1	████████ ████████ ████████ ████████ ████████ ████████	1990	Napropamide: a dietary LC ₅₀ study with the mallard Wildlife International Ltd, USA Company report No. 123- 153 ████████ ████████ ████████ GLP, Unpublished Study submitted to	Y	N	N/A	UPL	None

			meet data requirements					
CA 8.1.1.2/0 2	██████ ██████	1975	Safety evaluation of devrinol technical by a five-day feeding study in mallard ducks Company report no T-5469 ██████ ██████ ████████ ██████ Not GLP, Unpublished Study submitted to meet data requirements	Y	N	N/A	UPL	None
CA 8.2.1/01	██████████	2011a	D-Napropamide: acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96-hour test Company report No. D03458 ██████ ██████████ ██████ ██████████ GLP, Unpublished Study submitted to meet data requirements	Y	Y	As above	UPL	None
CA 8.2.2.1/0 1	██████████ ██	2015a	Assessment of the effect of napropamide-M on fish, early life stage toxicity test Company report No. ENV-13-040 ██████████ ██████████ ██████ ████████ GLP, Unpublished	Y	Y	As above	UPL	None

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			<p>Napropamide-M technical over a period of 21 days Company report No. 509-3-07-6174 Jai Research Foundation, India GLP, Unpublished</p> <p>Study submitted to meet data requirements</p>					
CA 8.2.6.2/01	Jenkins, C.A.	2002a	<p>Napropamide: algal growth inhibition assay (<i>Anabaena</i>) Company report No. UPH021/013213 Huntingdon Life Sciences Ltd, UK GLP, Unpublished</p> <p>Study submitted to meet data requirements</p>	N	N	N/A	UPL	None
CA 8.2.7/01	Ramsden, C.	2015b	<p>Assessment of the effect of napropamide-M technical (HBW07) on <i>Lemna</i>, growth inhibition test + Amendment No 1. Company report No. ENV-13-046 AgroChemex Environmental Ltd, UK GLP, Unpublished</p> <p>Study submitted to meet data requirements</p>	N	Y	As above	UPL	None

CA 8.2.7/02	Hermes, H.	2015	Napropamide-M (HBW07): Toxicity to the aquatic plant <i>Myriophyllum spicatum</i> in a semi static growth inhibition test with a prior rooting phase Company report No. 98011215 Ibacon GmbH, Germany GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.2.7/03	Juckeland, D.	2012a	Effects of napropamide metabolite Isomer I on <i>Lemna minor</i> in a growth inhibition test under semi-static test conditions Company report No. 11 10 48 017 W BioChem GmbH, Germany GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.2.7/04	Juckeland, D.	2012b	Effects of napropamide metabolite Isomer II on <i>Lemna minor</i> in a growth inhibition test under semi-static test conditions Company report No. 11	N	Y	As above	UPL	None

			10 48 018 W BioChem GmbH, Germany GLP, Unpublished Study submitted to meet data requirements					
CA 8.3.1.1.1/ 01	Rana, J.R.	2014a	Acute oral toxicity (LD ₅₀) of D-devrinol 450 SC (HBW03) to the Honeybee, <i>Apis Mellifera</i> L Company report No. 523- 3-08-6181 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.3.1.1.2/ 01	Rana, J.R.	2014b	Acute contact toxicity (LD ₅₀) of D-devrinol 450 SC (HBW03) to the Honeybee, <i>Apis Mellifera</i> L Company report No. 523- 3-08-6182 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.3.2.1/0 1	Gamblin, C.	2014	Acute dose- response toxicity of D- devrinol SC to the parasitic	N	Y	As above	UPL	None

			wasp <i>Aphidius rhopalosiphii</i> (De Stefani-Perez) (Hymenoptera, Braxonidae, Aphidiinae) Company report No. ENV-14-004 AgroChemex Environmental, Ltd, UK GLP, Unpublished Study submitted to meet data requirements					
CA 8.3.2.2/01	Cockroft, R.	2014	Acute dose-response toxicity of D-devrinol SC to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) Company report No. ENV-14-006 AgroChemex Environmental, Ltd, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.4.1/01	Rana, J.R.	2014c	Reproduction toxicity test of D-Devrinol 450 SC (HBW03) to earthworm, <i>Eisenia foetida foetida</i> Company report No. 522-3-08-6183 Jai Research Foundation, India GLP,	N	Y	As above	UPL	None

			Unpublished Study submitted to meet data requirements					
CA 8.4.2.1/0 1	Vinall, S.	2014	Napropamide-M tech- Laboratory determination of toxicity to the predatory mite <i>Hypoaspis aculeifer</i> (Acari, Laelapidae) in an artificial soil substrate Company report No. UPL-14-1 Mambo-Tox, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.4.2.1/0 2	Geary, N.	2015	Napropamide-M tech (HBW07) a laboratory test to determine the effects of fresh residues on the springtail <i>Folsomia candida</i> (Collembola, Isomidae) Company report No. UPL-15-1 Mambo-Tox, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.5/01	Shrimali, A.	2013	Effect of d-Devrinol 450 SC (HBW03)	N	Y	As above	UPL	None

			on soil microorganism s – nitrogen transformation test Company report No. 608- 3-15-6184 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements					
CA 8.6.2/01	Dickinson, R.A.	2014a	d-Devrinol 450 SC Evaluation of the phytotoxicity to non-target terrestrial plant – seedling emergence test Company report No. ACE-13-164 AgroChemex, Ltd, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CA 8.6.2/02	Dickinson, R.A.	2014b	d-Devrinol 450 SC Evaluation of the phytotoxicity to non-target terrestrial plant –Vegetative vigour test Company report No. ACE-13-165 AgroChemex, Ltd, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None

CA 8.8/01	Hertl, J.	2003	Toxicity of Napropamide technical to activated sludge in a respiration inhibition test Company report No. 18941171 Ibacon, GmbH, Germany GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
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PLANT PROTECTION PRODUCT D-Devrinol

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 10.2.1/01	████████	2011b	D-Devrinol 450 SC: Acute toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) in a 96 hour test Company Report No. D03572 ████████ ████████ ████████ ████████ GLP, Unpublished Study submitted to meet data requirements	Y	Y	Product data submitted with an application under Article 7 of the Regulation (NAS under Regulation) and with the application for authorisation of the corresponding product. Data protection is claimed in accordance with Article 59 of Regulation (EC) No	UPL	None

						1107/2009		
CP 10.2.1/02	Liedtke, A.	2011d	D-Devrinol 450 SC: Acute toxicity to <i>Daphnia</i> <i>magna</i> in a 48 hour test Company Report No. D03561 Harlan Laboratories Ltd, Switzerland GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.2.1/03	Kamle, K.	2014	Alga (<i>Pseudokirchneriella</i> <i>subcapitata</i>), growth inhibition test with D- Devrinol 450 SC (HBW03) Company Report No. 501-3-07-6180 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.2.1/04	Ramsden, C.	2015	Assessment of the effect of d- Devrinol 450 SC (HBW03) on <i>Lemna</i> , growth inhibition test Company Report No. ENV-14-005 AgroChemex Environment Ltd, UK GLP, Unpublished Study	N	Y	As above	UPL	None

			submitted to meet data requirements					
CP 10.3.1.1.1 /01	Rana, J.R.	2014a	Acute oral toxicity (LD ₅₀) of D-Devrinol 450 SC (HBW03) to the Honey bee, <i>Apis mellifera</i> L Company Report No. 523-3-08-6181 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.3.1.1.2 /01	Rana, J.R.	2014b	Acute contact toxicity (LD ₅₀) of D-Devrinol 450 SC (HBW03) to the Honey bee, <i>Apis mellifera</i> L Company Report No. 523-3-08-6182 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.3.2.1/ 01	Gamblin, C.	2014	Acute dose-response toxicity of d-Devrinol 450 SC to the parasitic wasp <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) (<i>Hymenoptera</i> , <i>Brachonidae</i> , <i>Aphidiinae</i>) Company	N	Y	As above	UPL	None

			Report No. ENV-14-004 AgroChemex Environmental Ltd, UK GLP, Unpublished Study submitted to meet data requirements					
CP 10.3.2.1/ 02	Cockroft, R.	2014	Acute dose- response toxicity of d- Devrinol 450 SC to the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) Company Report No. ENV-14-006 AgroChemex Environmental Ltd, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.4.1.1/ 01	Rana, J.	2014c	Reproduction toxicity test of D-Devrinol 450 SC (HBW03) to earthworm, <i>Eisenia foetida foetida</i> Company Report No. 522-3-08-6183 Jai Research Foundation, India GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None
CP 10.6.2/01	Dickinson, R.	2014a	d-Devrinol 450 SC- Evaluation of the phytotoxicity	N	Y	As above	UPL	None

			to non-target terrestrial plants- Seedling emergence test Company Report No. ACE-13-164 AgroChemex Environmental Ltd, UK GLP, Unpublished Study submitted to meet data requirements					
CP 10.6.2/02	Dickinson, R.	2014b	d-Devrinol 450 SC- Evaluation of the phytotoxicity to non-target terrestrial plants- Vegetative vigour test Company Report No. ACE-13-165 AgroChemex Environmental Ltd, UK GLP, Unpublished Study submitted to meet data requirements	N	Y	As above	UPL	None