

# ***European Commission***



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

**INDOXACARB**

**Volume 2**

Rapporteur Member State: France  
Co-Rapporteur Member State: Spain

**Version History**

<b>When</b>	<b>What</b>
2016-12	Initial RAR

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**A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED**

**A.1. IDENTITY**

No study submitted

**A.2. PHYSICAL AND CHEMICAL PROPERTIES****For active substance**

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.1	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96. Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR
CA, 2.1	Dobbin, J.	2002	DPX-MP062: Determination of the melting point/melting range and decomposition temperature ABC Laboratories Europe Ltd. DuPont-7557, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.1/01	Revankar, S.D.	2015	DPX-KN128: Laboratory study of boiling point Advinus Therapeutics Limited DuPont-44495 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>
CA, 2.2	Cobranchi, D.P., Schmuckler, M.E.	1997	Vapor pressure of DPX-KN128 and calculation of Henry's Law constant DuPont Jackson Laboratory AMR 4169-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 2.3	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

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CA, 2.3/01	Craig, W.B.	2004	Indoxacarb (DPX-KN128): Laboratory study of appearance and relative density Inveresk Research International (IRI) Limited (Scotland) DuPont-14115 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.4/01	Elliot, T.	2014	Indoxacarb (KN128): UV/visible absorption and molar absorptivity and spectra (mass spectrum, infrared spectrum, and NMR) Spectral Data Services, Inc., ABC Laboratories, Inc. (Missouri) DuPont-36503 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.4/02	Cukrova, M.	2015a	Characterization of IN-C0800-001 Vyzkumny ustav organickych syntez a.s. (VUOS) DuPont-45314 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.4/03	Cukrova, M.	2015b	Characterization of IN-C0800-001 Vyzkumny ustav organickych syntez a.s. (VUOS) DuPont-45315 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.4/04	Gravelle, W. D.	2014	Batch analysis of indoxacarb (DPX-KN128) technical Supplement No. 3 Title Indoxacarb (DPX-KN128) technical: Confirmation of the identity of the active ingredient and process impurities by HPLC/UV Spectroscopy Product Safety Labs DuPont-38208, Supplement No. 3, Revision No. 1, and DuPont-38208, Supplement No. 3, Revision No. 1, Confidential attachment GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.4/05	Novakova, M.	2015	Characterization of IN-R1T94-001 Vyzkumny ustav organickych syntez a.s. (VUOS) DuPont-41789 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.5	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.6/01	Craig, W.B.	2004	Indoxacarb (DPX-KN128): Laboratory study of solubility in organic solvents Inveresk Research International (IRI) Limited (Scotland) DuPont-12940, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.7	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 2.8	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR

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CA, 2.8	Lentz, N.R.	2002	Photodegradation of <sup>14</sup> C-DPX-MP062 in pH 5 buffer by simulated sunlight Ricerca Biosciences, LLC DuPont-9801 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.8/01	Clark, B.	2015	Hydrolysis of <sup>14</sup> C-Indoxacarb (DPX-KN128) in buffer solutions at pH 4, 7, and 9 ABC Laboratories, Inc. (Missouri) DuPont-35853, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.9/01	Livingston, I.	2013	Indoxacarb (DPX-KN128): Laboratory study of flammability, autoflammability, oxidizing and explosive properties Chilworth Technology Limited DuPont-36505 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.11/01	Livingston, I.	2013	Indoxacarb (DPX-KN128): Laboratory study of flammability, autoflammability, oxidizing and explosive properties Chilworth Technology Limited DuPont-36505 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 2.12/01	Siripriya, G.	2013	DPX-KN128 (indoxacarb): Laboratory study of surface tension Advinus Therapeutics Limited DuPont-36502 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 2.13/01	Livingston, I.	2013	Indoxacarb (DPX-KN128): Laboratory study of flammability, autoflammability, oxidizing and explosive properties Chilworth Technology Limited DuPont-36505 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal.

### For the preparation

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<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.1/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33102 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>
CP, 2.1/02	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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CP, 2.2/01	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.3/01	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.4/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33102 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.4/02	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.5/01	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.6/01	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.7/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33102 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.7/02	Browne, M., Cairns, S.	2009	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of shelf life stability Charles River Laboratories (UK) DuPont-20352 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.7/03	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.7/04	Shanthaveerappa, K.S.	2013	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of shelf-life stability in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33103 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.7/05	Robson, D.D.	2014	Indoxacarb 150 g/L EC (DPX-KN128): Laboratory study of persistent foaming properties after 3 years of shelf-life storage DuPont Stine-Haskell Research Center DuPont-38318 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.8.2/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33102 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.8.2/02	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.8.6/01	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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CP, 2.8.6/02	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical chemical and technical properties with accelerated storage performed in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33102 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.8.6/03	Browne, M., Cairns, S.	2009	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of shelf life stability Charles River Laboratories (UK) DuPont-20352 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 2.8.6/04	Shanthaveerappa, K.S.	2013	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of shelf-life stability in a polyethylene/ethyl vinyl alcohol (PE/EVOH) container Advinus Therapeutics Limited DuPont-33103 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 2.11/01	Browne, M., Cairns, S.	2009	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of shelf life stability Charles River Laboratories (UK) DuPont-20352 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



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CP, 2.11/02	Clipston, A.S., Craig, W.B.	2007	Indoxacarb 150 g/L emulsifiable concentrate insecticide formulation: Laboratory study of physical and chemical properties Charles River Laboratories (UK) DuPont-20351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal.

## A.3. DATA ON APPLICATION AND EFFICACY

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, 3.0/01	Bassi, A., Hane-Weijman, S.	2015	Renewal of active substances included in Annex I of Council Directive 91/414/EEC to be assessed in compliance with Regulation SANCO/10387/2010 Rev. 8 (The Renewal Regulation) Product Code: Indoxacarb 150 G/L EC, Emulsifiable concentrate formulation (EC) Active Substance: Indoxacarb 150 G/L Efficacy Information Supplemental submission in support of renewal E. I. DuPont de Nemours and Company DuPont-42916 EU GLP: No Published: No	N	N		DuPont	Submitted for the purpose of renewal
CP, 3.2/01	Andaloro, J.T.	2006	Insecticidal activity of technical grade DPX-KN128 and DPX-KN127 DuPont Stine-Haskell Research Center DuPont-21517 GLP: No Published: No	N	N		DuPont	Submitted for the purpose of renewal

## A.4. FURTHER INFORMATION

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	Reap, J.J.	2007	Indoxacarb 150 gram per liter emulsifiable concentrate insecticide formulation: Laboratory study of spray tank cleanout DuPont Stine- Haskell Research Center DuPont-24053 GLP: No Published: No	N	N	N	DuPont	N

**A.5. METHODS OF ANALYSIS**

**For active**

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.1	Hansen, S.W.	2003	Indoxacarb (DPX-KN128): Analysis of technical materials used in toxicology testing DuPont Stine-Haskell Research Center DuPont-13812 and DuPont-13812, Confidential attachment Published: No	N	N		DuPont	Study previously Reviewed for EU approval in the 2005 DAR
CA, 4.1.1	Kahler, T.W.	2006	Technical grade active ingredient indoxacarb (DPX-KN128) analysis and certification of product ingredients in support of registration of DuPont KN128 technical Exygen Research DuPont-16774 and DuPont-16774, Confidential attachment Published: No	N	N		DuPont	Study submitted in the EU Dossier and included in the first EU approval review.
CA, 4.1.1	Robson, D.D., Hansen, S.W.	2004	Recharacterization of toxicology test substance DPX-MP062-051A DuPont Stine-Haskell Research Center DuPont-13930 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 2005 and included in the Evaluation report of the technical material for the active substance Indoxacarb, 2009

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.1/01	Gravelle, W.D.	2013	Description and validation of the analytical methods for the determination of impurities in indoxacarb (DPX-KN128) technical blendbase Product Safety Labs DuPont-34934 and DuPont-34934, Confidential attachment GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.1/02	Gravelle, W.D.	2015	Description and validation of the analytical methods for the determination of IN-J1063, IN-C0800, IN-06439, and IN-R1T94 impurities in indoxacarb (DPX-KN128) technical and indoxacarb (DPX-KN128) 150 g/L EC formulation Product Safety Labs DuPont-38062, Revision No. 1 and DuPont-38062, Revision No. 1 Confidential attachment GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.1/03	Hansen, S.W.	2004	Technical grade indoxacarb (DPX-KN128) analysis and certification of product ingredients in support of registration of DuPont KN128 technical and DuPont Claridox C technical DuPont Stine-Haskell Research Center DuPont-13126 and DuPont-13126, Confidential attachment GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
KCA, 4.1.1/04	Hansen, S.W.	2013	Determination of indoxacarb (DPX-KN128) in technical grade indoxacarb and end-use products DuPont Stine-Haskell Research Center DuPont-34638 GLP: No Published: No	N	N		DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.2	Amoo, J.S., Beaver-Stetser, E.	1997	Analytical method (HPLC/column switching/UV) for the determination of residues of DPX-KN128/DPX-KN127 and IN-JT333 in animal matrices- whole and skim milk, cream, fat, muscle, liver, and kidney DuPont Experimental Station AMR 3337-95 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 1997 and included in the first EU approval review.
CA, 4.1.2	Behmke, F.D.	1997a	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-JW062 (racemic mixture of DPX-KN128 and IN-KN127) derived residues in potatoes DuPont Experimental Station AMR 3457-95 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 1997 and included in the first EU approval review.
CA, 4.1.2	Behmke, F.D.	1997b	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-JW062 (racemic mixture of DPX-KN128 and IN-KN127) derived residues in corn DuPont Experimental Station AMR 3320-95 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.1.2	Behmke, F.D.	1997c	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-JW062 (racemic mixture of DPX-KN128 and IN-KN127) derived residues in lettuce DuPont Experimental Station AMR 3315-95 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.2	Behmke, F.D.	1997d	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-MP062 (a mixture of DPX-KN128 and IN-KN127) derived residues in grapes DuPont Experimental Station AMR 4657-97 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 1997 and included in the first EU approval review.
CA, 4.1.2	Behmke, F.D.	1997e	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-MP062 (a mixture of DPX-KN128 and IN-KN127) derived residues in tomatoes DuPont Experimental Station AMR 4633-97 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 1997 and included in the first EU approval review.
CA, 4.1.2	Behmke, F.D.	1997f	Extraction efficiency of analytical methods for the determination of [ <sup>14</sup> C]DPX-MP062 (a mixture of DPX-KN128 and IN-KN127) derived residues in cotton DuPont Experimental Station AMR 4594-97 Published: No	N	N		DuPont	Study submitted in the EU Dossier in 1997 and included in the first EU approval review.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.2	Class, T.	1996	Validation of analytical enforcement method in air (by absorption on XAD-2 and GC/TSD) for KN128 and KN127 residues which might result from the use of the formulation DPX-MP062 PTRL Europe AMR 4160-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.1.2	Desmond, P.J.	1997	A study of the recovery of residues of DPX-KN128/DPX-KN127 (formulated as either DPX-JW062 or DPX-MP062) after frozen storage on: Grapes, grape wet pomace, wine, apples, lettuce, tomatoes, apple juice, and soil; and incurred residue studies on tomatoes, DuPont Experimental Station AMR 3778-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.1.2	Gagnon, M.R., Guinivan, R.A.	1996	Residue procedure for the analysis of DPX-KN128/DPX-KN127 in crops and related process fractions by GC-MSD DuPont Experimental Station AMR 3493-95, Supplement No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.2	Gagnon, M.R., Guinivan, R.A., Desmond, P.J.	1997	Analytical enforcement procedure for the analysis of DPX-KN128/DPX-KN127 in crops and related process fractions by GC-MSD DuPont Experimental Station AMR 3493-95, Supplement No. 2, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.1.2	Hill, S.J., Stry, J.J.	2002	Analytical method for the determination of DPX-MP062 (75% DPX-KN128 and 25% IN-KN127) and metabolites IN-JT333 and IN-KT413 in ground, surface, and drinking waters using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-7898 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.
CA, 4.1.2	██████	1997	Metabolism of <sup>14</sup> C-DPX-JW062 (racemic mixture of DPX-KN128 and IN-KN127) in laying hens ██ AMR 3187-94 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.1.2	Mol, J.G.J.	2003	Independent laboratory validation of DuPont 7898 "analytical method for the determination of DPX-MP062 (75% DPX-KN128 (indoxacarb) and 25% IN-KN127) and metabolites IN-JT333 and IN KT413 in ground, surface, and drinking water using LC-MS/MS TNO Nutrition and Food Research DuPont-12181 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.
CA, 4.1.2	Rhodes, B.C.	1997	Aerobic soil metabolism of <sup>14</sup> C-DPX-JW062 DuPont Experimental Station AMR 2803-93 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.1.2	Schmuckler, M.E., Cooke, L.A.	1997	Physical and chemical characteristics of DPX-KN128 DuPont Experimental Station AMR 4141-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/01	Aufderheide, J.	2014	Indoxacarb (DPX-KN128): Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-38349 GLP: Yes Published:	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/02	Connolly, P.	2004	Independent laboratory validation of the analytical method, DuPont-12739, "Analytical method for the determination of DPX-MP062 and metabolites IN-KB687, IN-KG433, IN-KT319, IN-JU873 and IN-JT333 in poultry skin, liver, muscle, fat and eggs" Amendment number 1 Exygen Research DuPont-13651, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/03	Craig, W.B.	2004	Indoxacarb (DPX-KN128): Laboratory study of solubility in organic solvents Inveresk Research International (IRI) Limited (Scotland) DuPont-12940, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/04	Dinehart, S.	2014	Indoxacarb (DPX-KN128): acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under flow-through test conditions ABC Laboratories, Inc. (Missouri) DuPont-38440 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
KCA, 4.1.2/05	Gagnon, M.R., Stry, J.J.	2005	Analytical method for the determination of DPX-MP062 75% DPX-KN128 (indoxacarb) and 25% IN-KN127 in cloth by LC/MS/MS DuPont Stine-Haskell Research Center DuPont-15035 GLP: No Published: No	N	N		DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/06	Henze, R.M.	1997	Analytical method (HPLC/column switching/UV) for the determination of residues of DPX-KN128/DPX-KN127 and IN-JT333 in whole fish DuPont Experimental Station AMR 4304-97 GLP: No Published: No	N	N		DuPont	N.A.
KCA, 4.1.2/07	Henze, R.M., Stry, J.J.	2012	Analytical method for the determination of indoxacarb and metabolites in water using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-35303 GLP: No Published: No	N	N		DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/08	Lakaschus, S., Gizler, A.	2010	Adaptation and validation of a method for the determination of DPX-KN128 (indoxacarb) in honey Eurofins / Dr. Specht Laboratorien GmbH DuPont-Specht DUP-0801V GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
KCA, 4.1.2/09	Stry, J.J.	2004	Analytical method for the determination of DPX-MP062 and metabolites IN-KB687, IN-KG433, IN-KT319, IN-JU873, and IN-JT333 in poultry skin, liver, muscle, fat, and eggs DuPont Stine-Haskell Research Center, Dr. Specht & Partner Chemische Laboratorien GmbH DuPont-12739, Revision No. 1 GLP: No Published: No	N	N		DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.1.2/10	Stry, J.J.	2014	Analytical method for the determination of DPX-MP062 (75% DPX-KN128 and 25% IN-KN127) and metabolites IN-JT333 and IN-KT413 in ground, surface, and drinking waters using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-7898, Supplement No. 1 GLP: No Published: No	N	N		DuPont	N.A.
CA, 4.2	Class, T.	2000	Independent laboratory validation (ILV) of the analytical residue method AMR 4271-96 for the determination of residues of DPX-KN128 and IN-KN127 in plant material which might be treated with DPX-MP062 PTRL Europe DuPont-3295 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 4.2	Class, T.	2001a	Independent laboratory validation (ILV) of the analytical residue method DuPont-2338 for the determination of residues of DPX-KN128, IN-KN127, and the metabolite IN-JT333 in foodstuffs of animal origin PTRL Europe DuPont-3520, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.2	Class, T.	2001b	Validation of the analytical residue method DuPont-2338 for the determination of residues of DPX-KN128, IN-KN127, and the metabolite IN-JT333 in edible offal PTRL Europe DuPont-6224 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.
CA, 4.2	Hill, S.J., Pentz, A.M., Stry, J.J.	2003	Analytical method for the determination of DPX-MP062 [75% DPX-KN128 (indoxacarb) and 25% IN-KN127] and metabolites IN-JT333, IN-MP819, IN-JU873, and IN-KG433 in ground, surface, and drinking waters using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-9605, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.
CA, 4.2	Linkerhagner, M., Guinivan, R.A.	2001	Testing of DFG method S 19 for the determination of DPX-MP062 and its metabolite IN-JT333 in foodstuffs of animal origin Dr. Specht & Partner Chemische Laboratorien GmbH DuPont-2338, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CA, 4.2	Mol, J.G.J.	2003	Independent laboratory validation of DuPont-9605 rev1 analytical method for the determination of DPX-MP062 (75% DPX-KN128 (indoxacarb) and 25% DPX-KN127) and metabolites IN-MS775, IN-JT333, IN-MP819, IN-JU873 and IN-KG433 in groundwater surface water and TNO Nutrition and Food Research DuPont-12182 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 DAR.
CA, 4.2	Schmidt, F.	1997	Testing of DFG method S 19 for the determination of residues of KN128 along with KN127 in crops which might be treated with DPX-MP062 Dr. Specht & Partner Chemische Laboratorien GmbH AMR 4271-96 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/01	Cermak, J.	2013	Validation of multi-residue method DFG S19 for the determination of residues of DPX-MP062 (DPX-KN128 (indoxacarb) and IN-KN127) in grapes, tomato, oilseed rape and maize using LC/MS/MS Vyzkumny ustav organickych syntez a.s. (VUOS) DuPont-37894, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
KCA, 4.2/02	Henze, R.M., Stry, J. J.	2012	Analytical method for the determination of indoxacarb and metabolites in soil using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-35025 GLP: No Published: No	N	N		DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/03	Lakaschus, S., Klimmek, A.	2006	Validation of multi-residue method DFG S19 (L 00.00-34) for the determination of residues of DPX-MP062 (DPX-KN128 (indoxacarb) and IN-KN127) in grass Eurofins Analytik GmbH DUP-0602V GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/04	Richter, S.	2013	Validation of the multi-residue method DFG S19 for the determination of residues of indoxacarb and its metabolite IN-JT333 in animal matrices, using LC-MS/MS PTRL Europe DuPont-39006 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.
KCA, 4.2/05	Stry, J.J.	2014	Analytical method for the determination of DPX-MP062 [75% DPX-KN128 (indoxacarb) and 25% IN-KN127] and metabolites IN-JT333, IN-MP819, IN-JU873, and IN-KG433 in ground, surface, and drinking waters using LC/MS/MS DuPont Stine-Haskell Research Center DuPont-9605, Supplement No. 1 GLP: No Published: No	N	N		DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/06	Stry, J.J.	2008	Analytical method for the analysis of indoxacarb and metabolite IN-JT333 in plasma, mik, and fat DuPont Stine-Haskell Research Center DuPont-24760 GLP: No Published: No	N	N		DuPont	N.A.
KCA, 4.2/07	van Schaik, F.	2006	Development confirmation air method for DPX-MP062 using LC-MS/MS TNO Quality of Life DuPont-18596 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/08	Stanislowski, T.	2015	Independent laboratory validation (ILV) of the multi-residue method DFG S19 for the determination of residues of indoxacarb in crop matrices, using LC-MS/MS PTRL Europe DuPont-44627 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/09	Aitken, A.	2014	Determination of the decline of residues of DPX-KN128 (indoxacarb) along with IN-KN127 in maize forage following applications of DPX-MP062 30WG - Southern Europe – 2012 Charles River Laboratories (UK) DuPont-35172 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/10	[REDACTED]	2006	Oral (gavage) developmental neurotoxicity study of DPX-KN128 (Indoxacarb) technical in CrI:CD (SD)IGS BR VAF/Plus rats [REDACTED] DuPont-15150 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/11	Berg, C.	2015	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany 2014 Eurofins Agrosience Services GmbH DuPont-37489, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/12	[REDACTED]	2003	Indoxacarb (DPX-KN128) technical: Mouse bone marrow micronucleus test [REDACTED] DuPont-13021 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/13	Giammarrusti, L., De Paoli, M.	2003	Decline of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in sweet corn following application of DPX-MP062 30WG - Italy, season 2003 ERSA DuPont-13320 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.



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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/14	Gudi, R., Rao, M.	2004	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> mammalian chromosome aberration study in human peripheral blood lymphocytes BioReliance DuPont-13022, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/15	Guinivan, R.A., Daussin, S.	2008	Recovery of DPX-MP062 and five metabolites from hen-derived matrices (whole eggs, muscle, fat and liver) after frozen storage Dupont Stine-Haskell Research Center DuPont-19901 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/16	[REDACTED]	2011	Indoxacarb (DPX-KN128) technical: 28-Day immunotoxicity feeding study in mice [REDACTED] DuPont-29280 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/17	Klank, C.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Honey bee ( <i>Apis mellifera</i> L.) larval toxicity test (single feeding exposure) Eurofins Agrosience Services EcoChem GmbH DuPont-34817 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/18	Klein, O.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the bumble bee ( <i>Bombus terrestris</i> L; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany in 2013 Eurofins Agrosience Services GmbH DuPont-38419 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/19	Kleinhenz, M.	2011a	Indoxacarb (DPX-KN128) 150 g/L EC: A study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ) in the field in <i>Brassica napus</i> L. in eastern Germany in 2009 Eurofins Agrosience Services GmbH DuPont-26946 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/20	Kleinhenz, M.	2011b	Indoxacarb (DPX-KN128) 150 g/L EC: A study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ) in the field in Brassica napus L. in northern Germany in 2009 Eurofins Agrosience Services GmbH DuPont-26947 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/21	Lakaschus, S., Amann, S.	2012a	Determination of magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in protected tomato following applications of DPX-MP062 30WG and DPX-KN128 30WG- Europe, 2011 Eurofins Agrosience Services GmbH DuPont-32128 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.



<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/22	Lakaschus, S., Amann, S.	2012b	Determination of magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in lettuce following applications of DPX-MP062 30WG and DPX-KN128 30WG - Europe, 2011 Eurofins Agrosience Services Chem GmbH DuPont-33518 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/23	Markell, L.K.	2015	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> 3T3 NRU phototoxicity test DuPont Haskell Laboratory DuPont-43522 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/24		2003	Magnitude of residues of indoxacarb (as DPX-MP062) in laying hen tissue and eggs: a feeding study conducted to EPA guidelines  DuPont-8305 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

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	Data Protection Y/N	Justification if data protection is claimed	Owner	Previous Evaluation
KCA, 4.2/25	[REDACTED]	2004	Indoxacarb (DPX-KN128) technical: Developmental toxicity study in rats [REDACTED] DuPont-12748 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/26	Rentschler, S.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany 2014 Eurofins Agrosience Services EcoChem GmbH DuPont-41668 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
KCA, 4.2/27	San, R.H.C., Clarke, J.	2003	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT test) BioReliance DuPont-13023 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal.

**For preparation**

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 5.1.1	Kahler, T.W.	2006	Technical grade active ingredient indoxacarb (DPX-KN128) analysis and certification of product ingredients in support of registration of DuPont KN128 technical Exygen Research DuPont-16774 and DuPont-16774, Confidential attachment Published: No	N	Y	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study summarised in evaluation report on the equivalence of the technical material for the active substance Indoxacarb, 2009
CP, 5.1.1/01	Gravelle, W.D.	2015	Description and validation of the analytical methods for the determination of IN-J1063, IN-C0800, IN-06439, and IN-R1T94 impurities in indoxacarb (DPX-KN128) technical and indoxacarb (DPX-KN128) 150 g/L EC formulation Product Safety Labs DuPont-38062, Revision No. 1 and DuPont-38062, Revision No. 1, Confidential attachment GLP: Yes Published: No	N	Y	Conducted to meet guideline requirement. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>

<b>Data Requirement No., Reference No.</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source Company Report No. GLP or GEP Status (where relevant) Published or Not</b>	<b>Vertebrate Study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if Data Protection Is Claimed</b>	<b>Owner</b>	<b>Previous Evaluation</b>
CP, 5.1.1/02	Hansen, S.W.	2004	Technical grade indoxacarb (DPX-KN128) analysis and certification of product ingredients in support of registration of DuPont KN128 technical and DuPont Claridox C technical DuPont Stine-Haskell Research Center DuPont-13126 and DuPont-13126, Confidential attachment GLP: Yes Published: No	N	Y	Representative formulation supporting renewal different from PPP supporting initial inclusion. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 5.1.1/03	Kennedy, A.P.	2014	Description and validation of the analytical method for determination of ethyl violet (IN-J1063) in Indoxacarb (DPX-KN128) 150 g/L EC formulation DuPont Stine-Haskell Research Center DuPont-40620, Revision No. 1 and DuPont-40620, Revision No. 1, Confidential attachment GLP: Yes Published: No	N	Y	Conducted to meet guideline requirement. The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal.



**A.6. TOXICOLOGY AND METABOLISM DATA**

For the active substance

<b>Data Point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
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CA, 5.1.1		1997a	<sup>14</sup> C-DPX-MP062 (a 3:1 mixture of DPX-KN128 and IN-KN127): Metabolism in the rat HL-1997-00439 Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.1.1		1997b	<sup>14</sup> C-DPX-JW062 (a racemic mixture of DPX-KN128 and IN-KN127): Metabolism in the rat HLR 283-96 Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.1.1/01		2000	<sup>14</sup> C-DPX-JW062 (a racemix mixture of DPX-KN128 and IN-KN127): Metabolism in the rat HLR 283-96, Supplement No. 1 GLP: No Published: No	Y	Y <u>Comment from RMS:</u> this study is a supplemental of the previous one 1997b. Moreover, this is not a GLP study. So, it cannot grant any data protection.	The study is necessary for the regulatory decision, and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>
CA, 5.2.1		1997	IN-JU874-2: Oral approximate lethal dose (ALD) in mice HL-1997-00368,	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

			Revision No. 1 Published: No					
CA, 5.2.1		2005	: Oral approximate lethal dose (ALD) in mice HL-1997-00432, Revision No. 1 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.2.1/01		1997	Acute oral toxicity study with DPX-KN128 technical in male and female rats HLO-1997-00055 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.2.1		1996a	Acute oral toxicity study with DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127) in male and female rats HLR 910-96 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

CA, 5.2.2/01		2003	Indoxacarb (DPX-KN128) technical: Acute dermal toxicity study in rats DuPont-13019 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.2.2		1996b	Acute dermal toxicity study with DPX-MP062 technical (approximately 75% DPX- KN128, 25% DPX-KN127) in rats HLR 798-96 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

CA, 5.2.3		1995	Inhalation median lethal concentration (LC <sub>50</sub> ) study with DPX-JW062-112 in rats HLR 70-95. Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR
CA, 5.2.4/01		2003	Indoxacarb (DPX-KN128) technical: Acute dermal irritation study in rabbits DuPont-13164 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.2.4		1997a	Primary dermal irritation study with DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127) in rabbits HLR 589-96 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

CA, 5.2.5/01		2003	Indoxacarb (DPX-KN128) technical: Acute eye irritation study in rabbits DuPont-13020 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.2.5		1997b	Primary eye irritation study with DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127) in rabbits HLR 588-96 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

CA, 5.2.6/01		2003	Indoxacarb (DPX-KN128) technical: Dermal sensitization - Magnusson- Kligman maximization method [REDACTED] DuPont-13018 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.2.6/02		2006	Indoxacarb (DPX-KN128) technical: Dermal sensitization test - Buehler method [REDACTED] DuPont-18915 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.2.6		1996	Guinea pig dermal sensitization - Magnusson- Kligman maximization test with DPX- MP062 technical (approximately 75% DPX- KN128, 25% DPX-KN127). [REDACTED] HLO 388-96 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

CA, 5.2.7/01	Markell, L.K.	2015	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> 3T3 NRU phototoxicity test DuPont Haskell Laboratory DuPont-43522 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.3.1	[REDACTED]	1993a	Repeated dose oral toxicity: 28-day feeding study with DPX-JW062-34 in male and female rats [REDACTED] HLR 403-93 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.1	[REDACTED]	1993b	Repeated dose oral toxicity: 28-Day feeding study with DPX-JW062-34 in male and female mice [REDACTED] HLR 406-93, Revision No. 1 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.







CA, 5.3.2		1997	Subchronic oral toxicity: 90-Day study with DPX-JW062-34 (50% DPX-KN128, 50% DPX-KN127) feeding study in mice HLR 750-93, Revision No. 1 Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.2		1998	DPX-JW062 technical: Subchronic toxicity; 90-day feeding study in rats HL-1998-01200 Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.2/01		1997	Subchronic oral toxicity: 90-Day study with DPX-MP062 (approximately 75% DPX-KN128, 25% DPX-KN127) feeding study in rats HL-1997-00056, Revision No. 1 GLP: Yes Published: No	Y	Y <u>Comment from RMS:</u> No new experimental results are available in the Revision No 1 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <u>Comment from RMS:</u> Study HL-1997-00056 previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.2/02		1997a	Subchronic oral toxicity: 90-Day study with DPX-JW062-69 (99.7% DPX-KN128) feeding study in rats	Y	Y <u>Comment from RMS:</u> No new experimental results are available in the Revision No 2 of this	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously	DuPont	N.A. <u>Comment from RMS:</u> Study HLR 301-94 Revision No. 1 previously reviewed for EU approval in the 2000

			HLR 301-94, Revision No. 2 GLP: Yes Published: No		previously submitted study. So it cannot grant any new data protection.	protected the period of data protection has not expired at the time of submission of this dossier.		DAR.
CA, 5.3.2/03		1997b	Subchronic oral toxicity: 90-Day study with DPX-JW062-34 (50% DPX-KN128, 50% DPX-KN127) feeding study in rats HLR 751-93, Revision No. 2 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 2 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR 751-93 Revision No. 1 previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.2/04		1997a	Subchronic oral toxicity: 90-Day study with DPX-JW062-106 (50% DPX-KN128, 50% DPX-KN127) feeding study in dogs HLO 494-95, Revision No. 3 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 3 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLO 494-95 previously reviewed for EU approval in the 2000 DAR.
CA, 5.3.2/05		1997b	Chronic toxicity study with DPX-JW062-106 (50% DPX-KN128, 50% DPX-KN127) one year feeding study in dogs HLO 885-96, Revision No. 1 GLP: Yes	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 1 of this previously submitted study. So it cannot grant any	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR 885-96 previously reviewed for EU approval in the 2000 DAR.

			Published: No		new data protection.	submission of this dossier.		
CA, 5.3.2/06		1995	Six-week palatability and toxicity study with DPX-JW062-106 feeding study in dogs HLO 162-95 GLP: Yes Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <u>Comment from RMS:</u> Study previously reviewed for EU approval in the 2001 Addendum to DAR.
CA, 5.3.3		1999	DPX-MP062 technical: Repeated -dose dermal toxicity 28-day study in rats DuPont-2813 Published: No	Y	Y <u>Comment from RMS:</u> Study from the original submission (Addendum to the DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study submitted in the EU Dossier in 2001 and included in the first EU approval review (2001 Addendum to DAR).
CA, 5.4.1	Gladnick, N.L.	1998	IN-JU874-2: Mutagenicity testing in the <i>Salmonella typhimurium</i> plate incorporation assay DuPont Haskell Laboratory HL-1997-00251 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.4.1	Donner E.M.	2005	: mutagenicity testing in the <i>Salmonella typhimurium</i> plate incorporation assay DuPont Haskell Laboratory	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

			HL-1997-00253, Revision No. 1 Published: No					
CA, 5.4.1	San, R.H.C., Sly, J.E.	1997b	DPX-MP062 (approximately 75% DPX-KN128, 25% DPX-KN127): Unscheduled DNA synthesis in mammalian cells <i>in vitro</i> with an independent repeat assay Microbiological Associates, Inc. HLO-1997-00033 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.4.1/01	Gudi, R., Rao, M.	2004	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> mammalian chromosome aberration study in human peripheral blood lymphocytes BioReliance DuPont-13022, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.4.1/02	San, R.H.C., Clarke, J.	2003	Indoxacarb (DPX-KN128) technical: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT test) BioReliance DuPont-13023 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

CA, 5.4.1/03	Wagner, V.O., Klug, M.L.	2004	Indoxacarb (DPX-KN128) technical: bacterial reverse mutation test BioReliance DuPont-14332 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.4.1	Mathison, B.H.	1997	DPX-MP062 (approximately 75% DPX-KN128, 25% DPX-KN127): Mutagenicity testing in the <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> plate incorporation assay DuPont Haskell Laboratory HLR 831-96 Superseded by DuPont-14332 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.4.1	Gudi, R., Schadley, E.	1996	DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127): <i>In vitro</i> mammalian cytogenetic test using human peripheral lymphocytes Microbiological Associates, Inc. HLO 979-96 Superseded by DuPont-13022,	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

			Revision No. 1 Published: No					
CA, 5.4.1	San, R.H.C., Clarke, J.J.	1997	DPX-MP062 (approximately 75% DPX-KN128, 25% DPX- KN127): <i>In vitro</i> mammalian cell gene mutation test with an independent repeat assay Microbiologica l Associates, Inc. HLO-1997- 00030 Superseded by DuPont-13022, Revision No. 1 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.4.2/01		2003	Indoxacarb (DPX-KN128) technical: Mouse bone marrow micronucleus test  DuPont-13021 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.4.2		1997	DPX-MP062 (approximately 75% DPX-KN128, 25% DPX- KN127): Mouse bone marrow micronucleus assay  HLR 1046-96, Revision No. 1 Superseded by DuPont-13021	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.

			Published: No					
CA, 5.5		1997	Oncogenicity study with DPX-JW062-106 (50% DPX-KN128, 50% DPX-KN127) eighteen-month feeding study in mice [REDACTED] HLR 799-96 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.5/01		1997	Chronic toxicity study with DPX-JW062-106 (50% DPX-KN128, 50% DPX-KN127) one year feeding study in dogs [REDACTED] HLR 1174-96, Revision No. 1 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 1 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR 1174-96 previously reviewed for EU approval in the 2000 DAR.
CA, 5.6.1/01		2005	Two generation reproduction/fertility study with DPX-JW062-106 in rats [REDACTED] HLO 115-96, Revision No. 2 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 2 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR HLO 115-96 previously reviewed for EU approval in the 2000 DAR.
CA, 5.6.2		1997	DPX-JW062-112 (50% DPX-KN128, 50% DPX-KN127): Developmental toxicity study	Y	Y  <u>Comment from RMS:</u> Study from the original submission	Data protection is on a country by country basis as the status of data protection	DuPont	Study previously reviewed for EU approval in the 2000 DAR.



			in rats [REDACTED] HL-1997-00049 Published: No		(DAR), so this study is not protected anymore	may vary depending on the MS		
CA, 5.6.2	[REDACTED]	1995	Developmental toxicity study of DPX-JW062-112 in rabbits [REDACTED] HLR 587-95 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.6.2/01	[REDACTED]	2005	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Developmental toxicity study in rats [REDACTED] HL-1997-00202, Revision No. 2 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 2 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR HL-1997-00202 previously reviewed for EU approval in the 2000 DAR.
CA, 5.6.2/02	[REDACTED]	2004	Indoxacarb (DPX-KN128) technical: Developmental toxicity study in rats [REDACTED] DuPont-12748 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.6.2/03	[REDACTED]	1997a	DPX-JW062-112: Pilot developmental toxicity study	Y	N		DuPont	N.A.  <u>Comment from RMS:</u>





			(no. 2) in rats [REDACTED] HL-1997-01050 GLP: No Published: No					Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.6.2/04	[REDACTED]	1997b	DPX-MP062 technical: Pilot developmental toxicity study (no. 2) in rats [REDACTED] HL-1997-01051 GLP: No Published: No	Y	N		DuPont	N.A.  <u>Comment from RMS:</u> Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.7.1	[REDACTED]	1997	Subchronic oral neurotoxicity study of DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127) in rats [REDACTED] HLR 1116-96, Revision No. 1 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.7.1/01	[REDACTED]	2001	Acute oral neurotoxicity study of DPX-MP062 (approximately 75% DPX-KN128; 25% DPX-KN127) in rats [REDACTED] HLR 1117-96, Revision No. 2 GLP: Yes Published: No	Y	Y  <u>Comment from RMS:</u> No new experimental results are available in the Revision No 2 of this previously submitted study. So it cannot grant any new data protection.	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.  <u>Comment from RMS:</u> Study HLR 1117-96 previously reviewed for EU approval in the 2000 DAR.
CA, 5.7.2/01	[REDACTED]	2006a	Oral (gavage) developmental neurotoxicity study of DPX-	Y	Y	The study is necessary for the regulatory decision,	DuPont	N.A.

			KN128 (Indoxacarb) technical in CrI:CD (SD)IGS BR VAF/Plus rats [REDACTED] DuPont-15150 GLP: Yes Published: No			conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 5.7.2/02	[REDACTED]	2006b	Oral (gavage) developmental neurotoxicity study of DPX- KN128 (Indoxacarb) technical in CrI:CD (SD)IGS BR VAF/Plus rats [REDACTED] DuPont-15150, Supplement No. 1 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CA, 5.8.1	Gudi, R., Schadley, E.	1996	IN-JT333-20: <i>In vitro</i> evaluation for chromosome abberations in human peripheral blood lymphocytes Microbiologica l Associates, Inc. HLO 951-96 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1	Kemper, R.A.	2002	In vitro hemolytic potential of IN- MT713 in erythrocytes from normal and glucose-6-phos phate dehydrogenase -deficient humans	N	N		DuPont	Study previously reviewed for EU approval in the 2005 Addendum to DAR.

			DuPont Haskell Laboratory DuPont-11842 FR Published: No					
CA, 5.8.1	Kemper, R.A.	2004	In vitro hemolytic potential of N- hydroxy-4- (trifluoromethoxy)aniline (IN- MT713) in rats, dogs, and humans DuPont Haskell Laboratory DuPont-12062, Revision No. 1 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2005 Addendum to DAR.
CA, 5.8.1		1997	Acute oral toxicity study with IN- KG433 technical in male and female rats  Inc. (USA) HLO-1997- 00469 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1		1992	Repeated dose oral toxicity: 14-Day feeding study with in JT333-1 in male and female rats  HLR 475-91 Published: No	Y	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1	Mathison, B.H.	1996	IN-JT333-20: Mutagenicity testing in the <i>Salmonella</i> <i>typhimurium</i> and <i>Escherichia</i> <i>coli</i> plate incorporation assay DuPont Haskell Laboratory	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.

			HLR 830-96 Published: No					
CA, 5.8.1	San, R., Clarke, J.J	1997	IN-JT333-20: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT ) with an independent repeat assay Microbiologica l Associates, Inc. HLO 925-96 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPon t	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1	San, R.H.C., Clarke, J.J.	1997	IN-KG433 technical: <i>In vitro</i> mammalian cell gene mutation test (CHO/HGPRT ) with an independent repeat assay Microbiologica l Associates, Inc. HLO-1997- 00405 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPon t	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1	San, R.H.C., Sly, J.E.	1997	IN-KG433 technical: Unscheduled DNA synthesis in mammalian cells <i>in vitro</i> with an independent repeat assay Microbiologica l Associates, Inc. HLO-1997- 00406 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPon t	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.1		1996	Acute oral toxicity study with IN-JT333- 20 in male and female rats  HLR 927-96 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPon t	Study previously reviewed for EU approval in the 2000 DAR

CA, 5.8.1	Wagner, V.O., Reece, J.D.	1997	IN-KG433 technical: Mutagenicity testing in the <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> plate incorporation assay Microbiological Associates, Inc. HLO-1997-00254 Published: No	N	Y  <u>Comment from RMS:</u> Study from the original submission (DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CA, 5.8.2		1999	<sup>14</sup> C-DPX-JW062 (a racemic mixture of DPX-KN128 and IN-KN127): Distribution of erythrocytes of rats  DuPont-1952 Published: No	Y	Y  <u>Comment from RMS:</u> Study from the original submission (Addendum to the DAR), so this study is not protected anymore	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Study previously reviewed for EU approval in the 2001 Addendum to DAR.
CA, 5.8.2/01	Green, J.W.	1999	DPX-MP062, DPX-JW062, and DPX-KN128: Regression analysis of changes in red cell mass parameters following subchronic dietary exposure DuPont Haskell Laboratory DuPont-2780 GLP: No Published: No	N	N		DuPont	N.A.
CA, 5.8.2/02	Green, J.W.	2002	A statistical analysis of indoxacarb-induced hematologic changes in rats and dogs using historical	N	N		DuPont	N.A.

			control data DuPont Haskell Laboratory DuPont-6122, Revision No. 1 GLP: No Published: No					
CA, 5.8.2/03		2011	Indoxacarb (DPX-KN128) technical: 28-Day immunotoxicit y feeding study in mice DuPont-29280 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPon t	N.A.
CA, 5.8.3/01	Orton, F., Rosivatz, E., Scholze, M., Kortenkam p, A.	2011	Widely used pesticides with previously unknown endocrine activity revealed as <i>in vitro</i> antiandrogens Envir Health Persp Vol 119(6), 794- 600 (2011) GLP: No Published: Yes	N	N		Author s	N.A.
CA, 5.8.3/02	Sipes, N.S., Martin, M.T., Kothiya, P., Reif, D.M., Judson, R.S., Richard, A.M., Houck, K. A., Dix, D.J., Kavlock, R.J., Knudsen, T.B.	2013	Profiling 976 toxcast chemicals across 331 enzymatic and receptor signaling assays 'Chem Res Tox, Vol 26, 878-895 (2013) GLP: No Published: Yes	N	N		Author s	N.A.

CA, 5.9.2/01	Jin, K.	2012	Rhabdomyolysis, methemoglobinemia and acute kidney injury after indoxacarb poisoning Clin Toxicol, Vol 50, 227 (2012) GLP: No Published: Yes	N	N		Author s	N.A.
CA, 5.9.2/02	Park, J.S., Hoon, K., Lee, S.W., Min, J.H.	2011	Successful treatment of methemoglobinemia and acute renal failure after indoxacarb poisoning. Clin Toxicol, Vol 49, 744-746 (2011) GLP: No Published: Yes	N	N		Author s	N.A.
CA, 5.9.2/03	Prasanda, L., Rao, S.M., Singh, V., Kujur, R., and Gowrishankar	2008	An unusual Presentation as Methemoglobinemia Indian J Crit Care Med, Vol 12(4), 198-200 (2008). GLP: No Published: Yes	N	N		Author s	N.A.
CA, 5.9.2/04	Wu, Y-J., Lin, Y-Li, Huang, H-Y, and Hsu, B-G	2010	Methemoglobinemia induced by indoxacarb intoxication Clin Toxicol, Vol 48, 766-767 (2010) GLP: No Published: Yes	N	N		Author s	N.A.
CA, 5.9.2/05	Shih, P-C., Tsai, T-H.	2011	Methemoglobinemia following ingestion of Indoxacarb: A case report J Acute Med, Vol 1, 55-57 (2011) GLP: No Published: Yes	N	N		Author s	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal



## For the preparation

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	[REDACTED]	2004	Indoxacarb (DPX- KN128)150 g/L EC: Acute oral toxicity in rodents - up- and-down procedure [REDACTED] DuPont-13455 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A. <sup>a</sup>
CP, 7.1.2/01	[REDACTED]	2003	Indoxacarb (DPX-KN128) 150 g/L EC: Acute dermal toxicity study in rats [REDACTED] DuPont-13456 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 7.1.3/01	[REDACTED]	2004	Indoxacarb (DPX-KN128) 150 g/L EC: Inhalation median lethal concentration (LC <sub>50</sub> ) study in rats [REDACTED]	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been	DuPont	N.A.



			<p>██████████</p> <p>DuPont-13460 GLP: Yes Published: No</p>			protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CP, 7.1.4/01	██████████	2003	<p>Indoxacarb (DPX-KN128) 150 g/L EC: Acute dermal irritation study in rabbits</p> <p>██████████</p> <p>DuPont-13457 GLP: Yes Published: No</p>	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 7.1.5/01	██████████	2003	<p>Indoxacarb (DPX-KN128) 150 g/L EC: Acute eye irritation study in rabbits</p> <p>██████████</p> <p>DuPont-13459 GLP: Yes Published: No</p>	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 7.1.6/01	██████████	2003	<p>Indoxacarb (DPX-KN128) 150 g/L EC: Dermal sensitization - Magnusson-Kligman maximization method</p> <p>██████████</p> <p>DuPont-13458 GLP: Yes Published: No</p>	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has	DuPont	N.A.

						not expired at the time of submission of this dossier.		
CP, 7.1.7/01		2012a	Indoxacarb (DPX-KN128) 150 g/L EC (pure active substance indoxacarb) Repeated-dose oral toxicity 28-day feeding study in rats [REDACTED] DuPont-33601 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 7.1.7/02		2012b	Indoxacarb (DPX-KN128) 150 g/L EC (pure active substance indoxacarb): Subchronic toxicity 90-day feeding study in rats [REDACTED] DuPont-33600 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

CP 7.2.3.2	Guinivan, R.A., Enriquez, M.A., Schelling- Schiavo, M.	1997	Magnitude and decline pattern of KN128 together with KN127 foliar dislodgeable residues in/on apple leaves from crops grown in Europe following applications of DPX-JW062 WG - season 1995 (analysis by GC/MSD) Battelle Europe-Centre de Recherche de Geneve AMR 3394-95 Published: No	N	N		DuPont	Study previously reviewed for EU approval in the 2000 DAR.
CP, 7.3/01	Mingoia, R.T.	2014a	Indoxacarb (DPX-KN128) 150 g/L EC: <i>In vitro</i> percutaneous absorption of indoxacarb in rat and human skin DuPont Haskell Laboratory DuPont-38096 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.
CP, 7.3/02		2014b	Indoxacarb (DPX-KN128) 150 g/L EC: <i>In vivo</i> dermal absorption of indoxacarb in the rat  DuPont-38097 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	N.A.

<sup>a</sup> N.A. = not applicable, as this is a new study submitted for the first time at EU level for the purpose of renewal.

## A.7. RESIDUE DATA

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	Desmond, P.J.	1997	A study of the recovery of residues of DPX-KN128/DPX-KN127 (formulated as either DPX-JW062 or DPX-MP062) after frozen storage on: Grapes, grape wet pomace, wine, apples, lettuce, tomatoes, apple juice, and soil; and incurred residue studies on tomatoes, DuPont Experimental Station AMR 3778-96 Study previously reviewed for EU approval in the 2000 DAR. Published: No	N	N		DuPont	Y
CA, 6.3.1/03	Guinivan, R., Kennedy, C.M., Enriquez, M.A.	2003a	Combined decline and magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in maize (green plant and grain) following applications of DPX-MP062 30WG – Europe, season	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	

			2001 Battelle Europe-Centre de Recherche de Geneve DuPont-6006 GLP: Yes Published: No					
CA, 6.3.1/04	Guinivan, R.A., Kennedy, C.M., Enriquez, M.A.	2003b	Combined decline and magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in maize (green plant and grain) following applications of DPX-MP062 30WG and DPX-MP062 150SC – Europe, season 2002 Battelle Europe-Centre de Recherche de Geneve DuPont-9777 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	
CA, 6.1/01	Guinivan, R.A., Daussin, S.	2008	Recovery of DPX-MP062 and five metabolites from hen- derived matrices (whole eggs, muscle, fat and liver) after frozen storage Dupont Stine- Haskell Research Center DuPont-19901 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	
CA, 6.2.1	Scott, M.T., Guseman, J.C.	1997	Metabolism of <sup>14</sup> C-DPX- JW062, a racemic mixture of DPX-KN128 and IN-KN127,	N	N		DuPont	Y

			in cotton DuPont Experimental Station AMR 2691-93 Study previously reviewed for EU approval in the 2000 DAR. Published: No					
CA, 6.2.1	Gaddamidi , V., Hashinger, B.M.	1997a	Metabolism of [ <sup>14</sup> C]DPX- JW062, a racemic mixture of DPX-KN128 and IN-KN127 in lettuce DuPont Experimental Station AMR 2730-93 Study previously reviewed for EU approval in the 2000 DAR. Published: No	N	N		DuPont	Y
CA, 6.2.1	Gaddamidi , V., Hashinger, B.M.,	1997b	Metabolism of [ <sup>14</sup> C]DPX- JW062, a racemic mixture of DPX-KN128 and IN-KN127, in grapes DuPont Experimental Station AMR 2729-93 Study previously reviewed for EU approval in the 2000 DAR. Published: No	N	N		DuPont	Y
CA, 6.2.1	Brown, A.M., Young, G.A.	1997	Metabolism of [TMP(U)- <sup>14</sup> C]DPX- JW062, a racemic mixture of DPX-KN128 and IN-KN127, insecticide in tomatoes DuPont Experimental	N	N		DuPont	Y

			Station AMR 3561-95 Study previously reviewed for EU approval in the 2000 DAR. Published: No					
CA, 6.2.2		1997	Metabolism of <sup>14</sup> C-DPX- JW062 (racemic mixture of DPX-KN128 and IN- KN127) in laying hens     AMR 3187-94 Study previously reviewed for EU approval in the 2000 DAR. Published: No	Y	N		DuPont	Y
CA, 6.2.3		1997b	Metabolism of <sup>14</sup> C-DPX- JW062, a racemic mixture of DPX-KN128 and IN-KN127, in the lactating cow    AMR 2979-94, Supplement No. 1 Study submitted in the EU Dossier in 2001 and included in the first EU approval review. Published: No	N	N		DuPont	Y
CA, 6.3.1/01	Aitken, A.	2014a	Determination of the Decline of Residues of DPX-KN128 (Indoxacarb)	N	Y	The study is necessary for the regulatory decision, conducted according to GLP	DuPont	


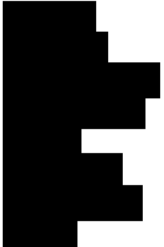




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			along with IN-KN127 in Maize Forage Following Applications of DPX-MP062 30WG - Southern Europe – 2012 Charles River Laboratories (UK) DuPont-35172 GLP: Yes Published: No			and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier		
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CA, 6.3.2/01	Giammarusti, L., De Paoli, M.	2003	Decline of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in sweet corn following application of DPX-MP062 30WG - Italy, season 2003 ERSA DuPont-13320 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	
CA, 6.3.3	Kennedy, C.M., Enriquez, M.A., Gasser, F., Larcinese, J.P., Belgaid, R.	2000	Combined decline and magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in leaf vegetables (field lettuce) following applications of DPX-MP062 30WG - southern Europe, season 1999 Battelle Europe-Centre de Recherche de Geneve DuPont-2577 Study previously reviewed for EU approval in the 2005 DAR. Published: No	N	N		DuPont	Y
CA, 6.3.3	Kennedy, C.M., Enriquez, M.A., Larcinese, J.P., Mattou, H.	1999	Combined decline and magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in leaf vegetables (lettuce) following applications of DPX-MP062 30WG southern	N	N		DuPont	

			Europe - season 1998 Battelle Europe-Centre de Recherche de Geneve AMR 5006-98 Does not support a crop not in the representative GAP Published: No					
CA, 6.3.3/01, Bridging	Lakaschus, S., Amann, S.	2012	Determination of magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in lettuce following applications of DPX-MP062 30WG and DPX-KN128 30WG - Europe, 2011 Eurofins Agroscience Services Chem GmbH DuPont-33518 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	
CA, 6.3.3/02, Bridging	Old, J., Hansford, R.J., Ward, L.	2007	Determination of magnitude of residues of DPX-KN128 (indoxacarb) together with IN-KN127 in lettuce and broccoli/caulifl ower following applications of DPX-MP062- 30WG and DPX-KN128- 15EC - Europe 2006 Charles River Laboratories (UK) DuPont-19688 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	
CA, 6.3.3/03	Spence, C.	2014	Determination of magnitude	N	Y	The study is necessary for the regulatory	DuPont	

			and decline of residues of DPX-KN128 (indoxacarb) along with IN-KN127 in lettuce following applications of DPX-KN128 30WG - Europe - initiated 2012 Charles River Laboratories (UK) DuPont-35819 GLP: Yes Published: No			decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier		
CA, 6.4.1/01		2003	Magnitude of residues of indoxacarb (as DPX-MP062) in laying hen tissue and eggs: a feeding study conducted to EPA guidelines  DuPont-8305 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	
CA, 6.4.2		1997	Magnitude of residues of DPX-KN128/IN-KN127 and IN-JT333 in edible tissues and milk of lactating dairy cows following dosing with DPX-MP062 experimental insecticide  AMR 3820-96 Study	Y	N		DuPont	Y

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			previously reviewed for EU approval in the 2000 DAR. Published: No					
CA, 6.6.1	Freeman, C.J., Terranova, A.J.	1997	Accumulation of residues in confined rotational crops (carrots, lettuce, wheat, and soybeans) using field aged soil after treatment with [ <sup>14</sup> C]DPX-JW062, a racemic mixture of DPX-KN128 and IN-KN127 DuPont Experimental Station AMR 4029-96 Study previously reviewed for EU approval in the 2000 DAR. Published: No	N	N		DuPont	Y

## A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

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	Spare, W.C.	1997	Aerobic soil metabolism of DPX-MP062, an ~3:1 mixture of DPX-KN128 and IN-KN127 Agrisearch, Inc. AMR 3633-95 Published: No	N	N	Data protection is on a country by country basis as the status of data protection may vary depending on the MS	DuPont	Yes, in the DAR (2000).
CA, 7.1.1.1	Singles S.K.	1997	Aerobic soil metabolism of DPX-MP062, an ~3:1 mixture of DPX-KN128 and IN-KN127 Agrisearch, Inc. AMR 3633-95, Supplement No. 1 Published: No	N	N		DuPont	Yes, in the DAR (2000).
CA, 7.1.1.1	Mellor, S.J.	2003	<sup>14</sup> C-DPX-MP062 (a 3:1 mixture of DPX-KN128 and IN-KN127): Aerobic soil metabolism Huntingdon Life Sciences Ltd. DuPont-8516 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.1.1	Singles, S.K.	2002	Aerobic soil metabolism of <sup>14</sup> C-DPX-JW062 DuPont Experimental Station AMR 2803-93, Revision No. 1 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005).
CA, 7.1.1.1	Singles, S.K.	2003	Measurement of the enantiomeric ratio of IN-JT333 in soil DuPont Stine-Haskell Research Center DuPont-12971 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.1.2 /01	Allan, J.	2015	<sup>14</sup> C-Indoxacarb (DPX-KN128): Anaerobic degradation in soil ABC Laboratories, Inc. (Missouri) DuPont-35049 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time	DuPont	No, submitted for the purpose of renewal

						of submission of this dossier.		
CA, 7.1.1.3	Berg, D.S.	1997	Photodegradation of radiolabeled DPX-JW062, a racemic mixture of DPX-KN128 and IN-KN127, on soil under simulated sunlight DuPont Experimental Station AMR 2818-93 Published: No	N	N		DuPont	Yes, in the DAR (2000).
CA, 7.1.2/0 1	Partsch, S., Khanijo, I., Price, K., Ball, M.	2015	Degradation of indoxacarb and its metabolites IN-JT333 (IN-KN125), IN-JU873, IN-KB687, IN- KG433, IN-KT413, IN- MK638, IN-MK643, IN-ML438, IN-MP819, IN- MS775, IN-UYG24, IN- U8E24, and IN-U8F52 in soil and water/sediment systems - kinetic calculations following Focus kinetics Dr. Knoell Consult GmbH DuPont-34821 EU GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.1 .1	Rhodes, B.C.	1997	Degradation rates of DPX- MP062 in soil DuPont Experimental Station AMR 4251-96 Published: No	N	N		DuPont	Yes, in the DAR (2000).
CA, 7.1.2.1 .1	Smyser, B.P.	2002	Degradation rates of DPX- MP062 in soil DuPont Experimental Station AMR 4251-96, Supplement No. 1 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1 .1	Mellor, S.J.	2003	<sup>14</sup> C-DPX-MP062 (a 3:1 mixture of DPX-KN128 and IN-KN127): Aerobic soil metabolism Huntingdon Life Sciences Ltd. DuPont-8516 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1 .1	Singles, S.K.	2002	Aerobic soil metabolism of <sup>14</sup> C-DPX-JW062 DuPont Experimental Station AMR 2803-93, Revision No. 1 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA,	Spare,	1997	Aerobic soil metabolism of	N	N	Data	DuPont	Yes, in the

7.1.2.1.1	W.C.		DPX-MP062, an ~3:1 mixture of DPX-KN128 and IN-KN127 Agriseach, Inc. AMR 3633-95 Published: No				t	DAR addendum 3 (2005).
CA, 7.1.2.1.2	Aikens, P.J.	2002	Degradation rates of [ <sup>14</sup> C]IN-KG433 in five soils Huntingdon Life Sciences Ltd. DuPont-8117 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005).
CA, 7.1.2.1.2	Caldwell, E.	2002	Degradation rates of [ <sup>14</sup> C]IN-MK643 in five soils Huntingdon Life Sciences Ltd. DuPont-9783 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1.2	Hatzenbeler, C.J.	2002	Rates of degradation of [ <sup>14</sup> C]IN-MK638 in five soils Ricerca Biosciences, LLC DuPont-10278 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1.2	Lentz, N.R.	2003	Rates of degradation of [ <sup>14</sup> C]IN-KT413 in three soils Ricerca Biosciences DuPont-10499 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1.2	Mellor, S.J.	2002	Degradation rates of [ <sup>14</sup> C]IN-JU873 in five soils Huntingdon Life Sciences Ltd. DuPont-8137 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1.2	Singles, S.K.	2002	Rate of degradation and estimated K <sub>oc</sub> of IN-ML438 in soil DuPont Stine-Haskell Research Center DuPont-11433 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005).
CA, 7.1.2.1.2	Singles, S.K.	2003	Measurement of the enantiomeric ratio of IN-JT333 in soil DuPont Stine-Haskell Research Center DuPont-12971 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.2.1.2/01	Allan, J.	2012	<sup>14</sup> C-IN-KB687: Rate of degradation in five aerobic soils ABC Laboratories, Inc. (Missouri) DuPont-31717 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been	DuPont	No, submitted for the purpose of renewal



			Published: No			protected or if previously protected the period of data protection has not expired at the time of submission of this dossier		
CA, 7.1.2.1 .2/02	Allan, J.	2014	Rate of degradation of <sup>14</sup> C-IN-ML438 in five aerobic soils ABC Laboratories, Inc. (Missouri) DuPont-36691 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.1 .2/03	Clark, B.	2014	<sup>14</sup> C-IN-JT333: Rate of degradation in five aerobic soils ABC Laboratories, Inc. (Missouri) DuPont-35168 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.1 .3/01	Allan, J.	2015	<sup>14</sup> C-Indoxacarb (DPX-KN128): Anaerobic degradation in soil ABC Laboratories, Inc. (Missouri) DuPont-35049 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.1 .4/01	Allan, J.	2015	<sup>14</sup> C-Indoxacarb (DPX-KN128): Anaerobic degradation in soil ABC Laboratories, Inc. (Missouri) DuPont-35049	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not	DuPont	No, submitted for the purpose of renewal

			GLP: Yes Published: No			previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier		
CA, 7.1.2.2.1/01	Doig, A.	2015a	The field soil dissipation of indoxacarb (DPX-KN128) following a single application to bare ground - Italy - 2012 Charles River Laboratories (UK) DuPont-34346 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.2.1/02	Doig, A.	2015b	The field soil dissipation of indoxacarb (DPX-KN128) following a single application to bare ground - northern Germany - 2012 Charles River Laboratories (UK) DuPont-34892 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.2.1/03	Doig, A.	2015c	The field soil dissipation of indoxacarb (DPX-KN128) following a single application to bare ground - north Spain - 2012 Charles River Laboratories (UK) DuPont-34324 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.2.2.1/04	Doig, A.	2015d	The field soil dissipation of indoxacarb (DPX-KN128) following a single application to bare ground - north France - 2012	N	Y	The study is necessary for the regulatory decision, conducted according to GLP	DuPont	No, submitted for the purpose of renewal

			Charles River Laboratories (UK) DuPont-34323 GLP: Yes Published: No			and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier		
CA, 7.1.2.2.1/05	Woodmansey, L.	2014	Freezer storage stability of indoxacarb (DPX-KN128) and metabolites (IN-MK643, IN-MK638, IN-KB687, IN-KT413, IN-KG433, IN-JU873 and IN-JT333) in soils Charles River Laboratories (UK), Charles River (France), Charles River Laboratories (Spain) DuPont-35167 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.3.1.1	Smyser, B.P.	2002	Batch equilibrium study of DPX-JW062 (a racemic mixture of DPX-KN128 and IN-KN127) and IN-JT333 DuPont Experimental Station, Harris Laboratories Inc. AMR 3489-95, Revision No. 1 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.3.1.2	Caldwell, E.	2002	Adsorption/desorption of [ <sup>14</sup> C]IN-MK643, a metabolite of indoxacarb, in five soils Huntingdon Life Sciences Ltd. DuPont-9784 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.3.1.2	Hatzenberger, C.J.	2002	Adsorption/desorption of [ <sup>14</sup> C]IN-KG433, a metabolite of indoxacarb, in five soils Ricerca LLC DuPont-6408, Revision No. 2. Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.3.1.2	Hatzenberger, C.J.	2002	Adsorption/desorption of [ <sup>14</sup> C]IN-JU873, a metabolite of indoxacarb, in five soils Ricerca Inc. (USA) DuPont-6407 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)

CA, 7.1.3.1.2	Herczog, K.J.S.	2002	Adsorption/desorption of [ <sup>14</sup> C]IN-MK638, a metabolite of indoxacarb, in five soils Ricerca Biosciences, LLC DuPont-10279 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.3.1.2	Walsh, K.J.	2003	Adsorption/desorption of [ <sup>14</sup> C]IN-KT413, a metabolite of indoxacarb, in four soils Ricerca Biosciences, LLC DuPont-10500 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.1.3.1.2/01	Allan, J.	2012	<sup>14</sup> C-IN-KB687: Batch equilibrium (adsorption/desorption) in five soils ABC Laboratories, Inc. (Missouri) DuPont-31718 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.1.3.1.2/02	Allan, J.	2015	[ <sup>14</sup> C]IN-ML438: Batch equilibrium (adsorption/desorption) in five soils ABC Laboratories, Inc. (Missouri) DuPont-36692 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.2.1.1/01	Clark, B.	2015	Hydrolysis of <sup>14</sup> C-Indoxacarb (DPX-KN128) in buffer solutions at pH 4, 7, and 9 ABC Laboratories, Inc. (Missouri) DuPont-35853, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal

CA, 7.2.1.2 /01	Singles, S.K.	2003	Photodegradation of DPX-KN128 in pH 5 buffer and natural water by simulated sunlight DuPont Stine-Haskell Research Center DuPont-12943 GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal
CA, 7.2.2.1 /01	Tunink, A.	2014	DPX-KN128: Determination of ready biodegradability using the CO <sub>2</sub> evolution method ABC Laboratories, Inc. (Missouri) DuPont-36501 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.2.2.2 /01	Allan, J.	2014	DPX-KN128: Aerobic mineralization in surface water ABC Laboratories, Inc. (Missouri) DuPont-34820 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier	DuPont	No, submitted for the purpose of renewal
CA, 7.2.2.3	Shaw, D.	2002	<sup>14</sup> C-DPX-MP062 (a 3:1 mixture of DPX-KN128 and IN-KN127): Degradability and fate in the water/sediment system Huntingdon Life Sciences Ltd. DuPont-8417 Published: No	N	N		DuPont	Yes, in the DAR addendum 3 (2005)
CA, 7.2.2.3 /01	Allan, J.	2014	Aerobic aquatic metabolism of [ <sup>14</sup> C]DPX-KN128 (indoxacarb) in two water-sediment systems ABC Laboratories, Inc. (Missouri) DuPont-39061 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data	DuPont	No, submitted for the purpose of renewal

						protection has not expired at the time of submission of this dossier		
CA, 7.2.2.3/02	Partsch, S., Khanijo, I., Price, K., Ball, M.	2015	Degradation of indoxacarb and its metabolites IN-JT333 (IN-KN125), IN-JU873, IN-KB687, IN-KG433, IN-KT413, IN-MK638, IN-MK643, IN-ML438, IN-MP819, IN-MS775, IN-UYG24, IN-U8E24, and IN-U8F52 in soil and water/sediment systems - kinetic calculations following Focus kinetics Dr. Knoell Consult GmbH DuPont-34821 EU GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal
CP, 9.1.3/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its major soil metabolites in soil after application to various crops in the European Union Dr. Knoell Consult GmbH DuPont-36914 EU, Revision No. 1 GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal
CP, 9.2.4/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its metabolites in groundwater following the application to various crops - a modelling assessment for Europe using the focus groundwater scenarios Dr. Knoell Consult GmbH DuPont-36912 EU GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal
CP, 9.2.5/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its metabolites in surface water and sediment following application to various crops in Europe: A modeling study conducted with focus surface water scenarios Dr. Knoell Consult GmbH DuPont-36913 EU GLP: No Published: No	N	N		DuPont	No, submitted for the purpose of renewal



## A.9. ECOTOXICOLOGY DATA

Active substance : indoxacarb

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	[REDACTED]	1996	IN-JT333-20: An acute oral toxicity study with the northern bobwhite [REDACTED] AMR 3890-96 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In</i> <i>DAR</i> (2000)
CA, 8.1.1.1	[REDACTED]	1997	DPX-MP062 technical (approximately 75% DPX- KN128, 25% DPX-KN127): An acute oral toxicity study with the northern bobwhite [REDACTED] AMR 3940-96, Revision No. 2 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In</i> <i>DAR</i> (2000)
CA, 8.1.1.2	[REDACTED]	1997a	DPX-MP062 technical (approximately 75% DPX- KN128, 25% DPX-KN127): A dietary LC <sub>50</sub> study with the northern bobwhite [REDACTED] AMR 4094-96 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In</i> <i>DAR</i> (2000)
CA,	[REDACTED]	1997b	DPX-MP062	Y	✗	<u>Comment</u>	DuPont	<i>In</i> <i>DAR</i>



8.1.1.2			technical (approximately 75% DPX-KN128, 25% DPX-KN127): A dietary LC <sub>50</sub> study with the mallard AMR 4093-96 Published: No		N	<u>from RMS:</u> Study from the original submission	t	(2000)
CA, 8.1.1.3		1997a	DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127): A reproduction study with the mallard ( <i>Anas platyrhynchos</i> ) AMR 4095-96 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	In DAR (2000)
CA, 8.1.1.3		1997b	DPX-MP062 technical (approximately 75% DPX-KN128, 25% DPX-KN127): A reproduction study with the northern bobwhite ( <i>Colinus virginianus</i> ) AMR 4096-96 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	In DAR (2000)
CA, 8.1.2/01	Brugger, K.E., Malley, L., Carro, T. O'Neill, B.	2015	Indoxacarb (DPX-KN128): Refinement of mammal chronic endpoint according to EFSA (2009) risk assessment for birds and mammals guidance document DuPont Stine-	N	N	-	DuPont	Submitted for the purpose of renewal

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			Haskell Research Center DuPont-37411 EU, Revision No. 2 GLP: No Published: No					
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CA, 8.2.1		1999	IN-KT413, a metabolite of DPX-MP062: Acute, static, 96-hour toxicity test to rainbow trout, <i>Oncorhynchus mykiss</i> DuPont-1311 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2001)</i>
CA, 8.2.1		1996	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Flow-through, acute, 96-hour LC <sub>50</sub> to rainbow trout, <i>Oncorhynchus mykiss</i> HLR 911-96 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2001)</i>
CA, 8.2.1		1997a	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Flow-through, acute, 96-hour LC <sub>50</sub> to bluegill sunfish, <i>Lepomis macrochirus</i> HLR 912-96, Revision No. 2 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>
CA, 8.2.1		1997b	IN-JT333-20: Flow-through, acute, 96-hour LC <sub>50</sub> to rainbow trout, <i>Oncorhynchus mykiss</i>	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>

			HL-1997-00180 Published: No					
CA, 8.2.1		2003a	IN-MP819: Flow-through, acute, 96-hour LC <sub>50</sub> to rainbow trout, <i>Oncorhynchus mykiss</i> [REDACTED] DuPont-11492 Published: No	Y	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.1		2003b	IN-MS775: Static, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> [REDACTED] DuPont-12091 Published: No	Y	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.1/01		2013	IN-MK643: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static test conditions [REDACTED] DuPont-36162 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.1/02		1997	Flow-through acute toxicity of DPX-MP062 to the sheepshead minnow, <i>Cyprinodon variegatus</i> [REDACTED] HLO-1997-00090,	Y	¥ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has	DuPont	<i>Submitted for the purpose of renewal</i>




			Revision No. 1 GLP: Yes Published: No			not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on		
CA, 8.2.1/03		2013	IN-KB687: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static test conditions DuPont-35828 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.2.1/04		2010	Indoxacarb (DPX-KN128) technical: A 96-hour flow-through acute toxicity test with the rainbow trout ( <i>Oncorhynchus mykiss</i> ) DuPont-29541 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.2.1/05		1997	IN-KG433 technical: Flow-through, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> HL-1997-00412 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at	DuPont	Submitted for the purpose of renewal


						the time of submission of this dossier.		
CA, 8.2.1/06		2013	IN-MK638: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static test conditions DuPont-35827 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.2.1/07		1998	IN-JU874: A 96-hour static-renewal toxicity test with the rainbow trout ( <i>Oncorhynchus mykiss</i> ) AMR 4951-98 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.2.1/08		2014	IN-JU873: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static-renewal test conditions DuPont-35826 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal

CA, 8.2.1/09		2015	IN-U8E24: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static test conditions DuPont-43485 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.1/10		2015a	IN-KN124: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static- renewal test conditions DuPont-43113 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.1/11		2015b	IN UYG24: Acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , determined under static test conditions DuPont-43422 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.1/12		2015	IN-KN125: Acute toxicity to the rainbow trout, <i>Oncorhynchus</i>	Y	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>

			mykiss, determined under static- renewal test conditions [REDACTED] DuPont-43104 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.2.1	[REDACTED]	1997	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Early life-stage toxicity to rainbow trout, <i>Oncorhynchus mykiss</i> [REDACTED] HLR 598-96, Revision No. 1 Published: No	Y	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	In DAR (2000)
CA, 8.2.2.1/0 1	[REDACTED]	1997	Early life stage toxicity of DPX-MP062 to the sheepshead minnow, <i>Cyprinodon variegatus</i> [REDACTED] HLO-1997- 00091, Revision No. 1 GLP: Yes Published: No	Y	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on	DuPont	Submitted for the purpose of renewal
CA, 8.2.2.1/0 2	[REDACTED]	2014	IN-JT333: Early life-stage toxicity test with the fathead minnow, <i>Pimephales</i>	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has	DuPont	Submitted for the purpose of renewal



			<i>promelas</i> , under flow-through conditions  DuPont-41669 GLP: Yes Published: No			not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.2.1/0 3		2014	Indoxacarb (DPX-KN128): Early life-stage toxicity test with the fathead minnow, <i>Pimephales promelas</i> , under flow-through conditions  DuPont-41426 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

CA, 8.2.2.3		2002	Bioconcentration and metabolism of [indanone-1- <sup>14</sup> C]DPX-JW062 and [trifluoromethoxyphenyl(U)- <sup>14</sup> C]DPX-JW062 in fish (a racemic mixture of DPX-KN128 and IN-KN127)  AMR 3663-95, Revision No. 1 Published: No	Y	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.4.1	Boeri, R.L., Magazu, J.P., Ward, T.J.	1999	IN-KT413, a metabolite of DPX-MP062: Acute, static, 48-hour toxicity (EC <sub>50</sub> ) test to <i>Daphnia magna</i> T.R. Wilbury Laboratories, Inc. DuPont-1309 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2001)</i>
CA, 8.2.4.1	Hoke, R.A.	1996	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Static acute, 48-hour EC <sub>50</sub> to <i>Daphnia magna</i> DuPont Haskell Laboratory HLR 603-96 Published: No	N	¥ N	Data protection is on a country by country basis as the status of data protection may vary depending on the MS <u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2001)</i>
CA, 8.2.4.1	Hoke, R.A.	1997	IN-JT333-20: Static-renewal, acute, 48-hour EC <sub>50</sub> to <i>Daphnia magna</i> DuPont	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>

			Haskell Laboratory HL-1997-00006 Published: No					
CA, 8.2.4.1	Samel, A.	2003a	IN-MP819: Flow-through, acute, 48-hour EC <sub>50</sub> to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-11491 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.4.1	Samel, A.	2003b	IN-MS775: Static, acute, 48-hour EC <sub>50</sub> to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-12090 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.4.1/01	Bergfield, A.	2013	IN-MK643: 48-Hour static, acute toxicity test with the Cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-36163 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/02	Gaertner, K.	2013	IN-KB687: 48-Hour static, acute toxicity test with the Cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-35831 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at	DuPont	<i>Submitted for the purpose of renewal</i>

						the time of submission of this dossier.		
CA, 8.2.4.1/03	Gallagher, S.P., Kendall, T.Z., Krueger, H.O.	2010	Indoxacarb (DPX-KN128) technical: A 48-hour flow-through acute toxicity test with the Cladoceran ( <i>Daphnia magna</i> ) Wildlife International, Ltd. DuPont-29542 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/04	Hoke, R.A.	1997	IN-KG433 technical: Static-renewal, acute, 48-hour limit test to <i>Daphnia magna</i> DuPont Haskell Laboratory HLO-1997-00363 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/05	Holou, M.	2013	IN-MK638: 48-Hour static, acute toxicity test with the Cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-35830 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/0	Palmer, S.J.,	1998	IN-JU874: A 48-hour static-	Y	Y	The study is necessary for	DuPont	<i>Submitted for the purpose</i>

6	Krueger, H.O.		renewal acute toxicity test with the Cladoceran ( <i>Daphnia magna</i> ) Wildlife International, Ltd. AMR 4950-98 GLP: Yes Published: No			the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		<i>of renewal</i>
CA, 8.2.4.1/0 7	Rebstock, M.	2014	IN-JU873: 48- Hour static- renewal, acute toxicity test with the Cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-35829 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

CA, 8.2.4.1/0 8	Bradbury, N.	2015a	IN-U8E24: 48-hour static, acute toxicity test with the cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-43486 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/0 9	Bradbury, N.	2015b	IN-UYG24: 48-Hour static, acute toxicity test with the cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-43423 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/1 0	Goudie, O.J.	2015	IN-KN124: 48-hour static- renewal, acute toxicity test with the cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-43106 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.1/1 1	Mays, C.	2015	IN-KN125: 48-Hour static- renewal, acute toxicity test with the	N	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>

			cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-43105 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.4.2/01	Brougher, D.S., Martin, K.H., Gallagher, S.P., Bodle, E.S.	2014	IN-KT413: A 96-hour static acute toxicity test with the saltwater mysid ( <i>Americamysis bahia</i> ) Wildlife International Ltd. (USA) DuPont-38347 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/02	Dinehart, S.	2013a	IN-MK643: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static test conditions ABC Laboratories, Inc. (Missouri) DuPont-36476 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/03	Dinehart, S.	2013b	IN-MK638: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static test conditions ABC	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if	DuPont	<i>Submitted for the purpose of renewal</i>

			Laboratories, Inc. (Missouri) DuPont-36475 GLP: Yes Published: No			previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.4.2/0 4	Dinehart, S.	2013c	IN-KB687: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static- renewal test conditions ABC Laboratories, Inc. (Missouri) DuPont-36477 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/0 5	Dinehart, S.	2013d	IN-JT333: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static- renewal conditions ABC Laboratories, Inc. (Missouri) DuPont-36489 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/0 6	Dinehart, S.	2013e	IN-JU873: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static- renewal conditions ABC Laboratories, Inc. (Missouri) DuPont-36474 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at	DuPont	<i>Submitted for the purpose of renewal</i>



			Published: No			the time of submission of this dossier.		
CA, 8.2.4.2/07	Dinehart, S.	2014a	Indoxacarb (DPX-KN128): Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under flow-through test conditions ABC Laboratories, Inc. (Missouri) DuPont-38440 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/08	Dinehart, S.	2014b	IN-KG433: Acute toxicity with the mysid shrimp, <i>Americamysis bahia</i> , determined under static-renewal test conditions ABC Laboratories, Inc. (Missouri) DuPont-36478 GLP: Yes Published: No	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.4.2/09	Ward, T.J., Magazu, J.P., Boeri, R.L.	1997	Flow-through acute toxicity of DPX-MP062 to the mysid, <i>Mysidopsis bahia</i> T.R. Wilbury Laboratories, Inc. HLO-1997-00205, Revision No. 1 GLP: Yes Published: No	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of	DuPont	<i>Submitted for the purpose of renewal</i>

						submission of this dossier. <u>Comment from RMS:</u> Study not relied on		
CA, 8.2.5.1	Hoke, R.A.	1997a	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Chronic toxicity to <i>Daphnia magna</i> DuPont Haskell Laboratory HLR 597-96, Revision No. 1 Published: No	N	✗ N	Data protection is on a country by country basis as the status of data protection may vary depending on the MS <u>Comment from RMS:</u> Study not relied on	DuPont	<i>In DAR (2000)</i>
CA, 8.2.5.1	Hoke, R.A.	1997b	DPX-MP062 (approximately 75% DPX-KN128, 25% IN-KN127): Chronic toxicity to <i>Daphnia magna</i> DuPont Haskell Laboratory HL-1997-00912 Published: No	N	✗ N	Data protection is on a country by country basis as the status of data protection may vary depending on the MS <u>Comment from RMS:</u> Study not relied on	DuPont	<i>In DAR (2000)</i>
CA, 8.2.5.1/01	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2003	IN-KT413: Chronic, static-renewal toxicity to the daphnid, <i>Daphnia magna</i> T.R. Wilbury Laboratories, Inc. DuPont-12041 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.5.1/02	Lamichhanne, K.	2014	Indoxacarb (DPX-KN128): Static renewal,	N	Y	The study is necessary for the regulatory	DuPont	<i>Submitted for the purpose of renewal</i>

			chronic toxicity test with the cladoceran, <i>Daphnia magna</i> ABC Laboratories, Inc. (Missouri) DuPont-41661 GLP: Yes Published: No			decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.5.2/01	Boeri, R.L., Magazu, J.P., Ward, T.J.	1997	Chronic toxicity of DPX-MP062 to the mysid, <i>Mysidopsis bahia</i> T.R. Wilbury Laboratories, Inc. HLO-1997-00206, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.2.5.3	Radford, K.	2000	DPX-MP062: To assess the toxicity to the sediments dwelling phase of the midge <i>Chironomus riparius</i> Huntingdon Life Sciences Ltd. DuPont-4055 Published: No	N	✗ N	<u>Comment from RMS:</u> Study not relied on	DuPont	In addendum to DAR (2005)
CA, 8.2.5.3/01	Thomas, S.T., Kendall, T.Z., Martin, K.H., Gallagher, S.P., Krueger, H.O.	2014	IN-KT413: A prolonged sediment toxicity test with <i>Chironomus riparius</i> using spiked water Wildlife International Ltd. (USA) DuPont-36116 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data	DuPont	Submitted for the purpose of renewal

			Published: No			protection has not expired at the time of submission of this dossier.		
CA, 8.2.5.3/02	Thomas, S.T., Martin, K.H., Gallagher, S.P., Bodle, E.S.	2014	<sup>14</sup> C DPX-KN128: A prolonged sediment toxicity test with <i>Chironomus riparius</i> using spiked water Wildlife International Ltd. (USA) DuPont-35832, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.5.3/03	Thomas, S.T., Siddiqui, A.I., Gallagher, S.P., Krueger, H.O.	2015	<sup>14</sup> C-Indoxacarb (DPX-KN128) technical: A prolonged sediment toxicity test with the midge ( <i>Chironomus riparius</i> ) using spiked water Wildlife International Ltd. (USA) DuPont-41246 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

CA, 8.2.5.4	Aufderheid e, J.	2004a	IN-MP819: Chronic toxicity test with midge larvae ( <i>Chironomus riparius</i> ) using spiked sediment ABC Laboratories, Inc. DuPont-13231 Published: No	N	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.5.4	Aufderheid e, J.	2004b	IN-MS775: Chronic toxicity test with midge larvae ( <i>Chironomus riparius</i> ) using spiked sediment ABC Laboratories, Inc. DuPont-13232 Published: No	N	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.5.4	Radford, K.	2001	IN-JT333: To assess the toxicity to the sediment dwelling phase of the midge <i>Chironomus riparius</i> Huntingdon Life Sciences Ltd. DuPont-4054 Published: No	N	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.5.4/0 1	Thomas, S.T., Kendall, T.Z., Martin, K.H., Gallagher, S.P., Krueger, H.O.	2013	IN-KT413: A prolonged sediment toxicity test with <i>Chironomus riparius</i> using spiked sediment Wildlife International Ltd. (USA) DuPont-35824 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

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CA, 8.2.5.4/0 2	Thomas, S.T., Martin, K.H., Gallagher, S.P., Krueger, H.O.	2014	IN-KG433: A prolonged sediment toxicity test with <i>Chironomus riparius</i> using spiked sediment Wildlife International Ltd. (USA) DuPont-35825 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
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CA, 8.2.6.1	Boeri, R.L., Ward, T.J.	2000	IN-KT413: Influence on growth and growth rate of the alga, <i>Selenastrum capricornutum</i> T.R. Wilbury Laboratories, Inc. DuPont-3935 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.6.1	Sloman, T.L., Leva, S.E.	1997a	DPX-MP062 (consisting of 75% DPX-KN128 and 25% IN- KN127): Influence on growth and growth rate of the green alga <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i> ) DuPont Stine- Haskell Research Center AMR 4273-96 Published: No	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In DAR (2000)</i>
CA, 8.2.6.1	Sloman, T.L., Leva, S.E.	1997b	IN-JT333 (metabolite of DPX-MP062): Influence on growth and growth rate of the green alga <i>Pseudokirchneriella subcapitata</i> (formerly called <i>Selenastrum capricornutum</i> ) DuPont Stine- Haskell Research Center AMR 4259-96 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>
CA, 8.2.6.1	Brugger, K.E.	2001	IN-KT413: Extrapolation of a NOAEC from toxicity data with	N	N		DuPont	<i>In addendum to DAR (2005)</i>

			<i>Selenastrum capricornutum</i> DuPont Stine-Haskell Research Center DuPont-6620 Published: No					
CA, 8.2.6.1	Sloman, T.L.	2003a	IN-MP819: Influence on growth and growth rate of the green alga <i>Selenastrum capricornutum</i> DuPont Haskell Laboratory DuPont-11493 Published: No	N	✖ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.6.1	Sloman, T.L.	2003b	IN-MS775: Influence on growth and growth rate of the green alga <i>Selenastrum capricornutum</i> DuPont Haskell Laboratory DuPont-12092 Published: No	N	✖ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.2.6.1/01	Aufderheide, J.	2014	Indoxacarb (DPX-KN128): Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-38349 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/02	Bergfield, A.	2013	IN-MK643: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i>	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been	DuPont	<i>Submitted for the purpose of renewal</i>



			ABC Laboratories, Inc. (Missouri) DuPont-36161 GLP: Yes Published: No			protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.6.1/03	Gaertner, K.	2013	IN-KB687: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-35822 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/04	Holou, M.	2013	IN-MK638: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-35821 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/05	Rebstock, M.	2014	IN-JU873: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-35820 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has	DuPont	<i>Submitted for the purpose of renewal</i>

			Published: No			not expired at the time of submission of this dossier.		
CA, 8.2.6.1/06	Sloman, T.L., Leva, S.E.	1997	IN-KG433 (metabolite of DPX-MP062): Influence on growth and growth rate of the green alga <i>Selenastrum capricornutum</i> DuPont Haskell Laboratory AMR 4280-97 GLP: Yes Published: No	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <b><u>Comment from RMS:</u></b> study not relied on	DuPont	<i>Submitted for the purpose of renewal</i>

CA, 8.2.6.1/0 7	Amoroso, T.	2015	IN-KN125: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-43103, Revision No. 1 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/0 8	Goudie, O.J.	2015a	IN-UYG24: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-43421 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/0 9	Goudie, O.J.	2015b	IN-U8E24: Growth inhibition test with the unicellular green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-43484 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.2.6.1/1 0	Mays, C.	2015	IN-KN124: Growth inhibition test with the unicellular	N	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>

			green alga, <i>Pseudokirchneriella subcapitata</i> ABC Laboratories, Inc. (Missouri) DuPont-43112 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.2.7/01	Sloman, T.L., Leva, S.E.	1997	DPX-MP062 (consisting of 75% DPX-KN128 and 25% DPX- KN127): Influence on growth and reproduction of <i>Lemma gibba</i> G3 DuPont Stine- Haskell Research Center AMR 3602-95, Revision No. 1 GLP: Yes Published: No	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <b><u>Comment from RMS:</u></b> study not relied on	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.3.1.1.1	Kling, A.	2000	DPX-MP062: Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. GAB Biotechnologie , GmbH DuPont-3995 Published: No	N	✗ N	<b><u>Comment from RMS:</u></b> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.3.1.1.1/ 01	Haupt, S.	2014	Indoxacarb (DPX-KN128) technical: Acute oral and contact toxicity to the bumblebee, <i>Bombus terrestris</i> L. (Hymenoptera) IBACON DuPont-38350 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data	DuPont	<i>Submitted for the purpose of renewal</i>

			Published: No			protection has not expired at the time of submission of this dossier.		
CA, 8.3.1.1.1/02	Kling, A.	2014	Indoxacarb (DPX-KN128) technical: Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. under laboratory conditions Eurofins Agrosience Services EcoChem GmbH DuPont-36500 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.3.1.1.2	Kling, A.	2000	Indoxacarb (DPX-KN128) technical: Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. under laboratory conditions GAB Biotechnologie GmbH DuPont-3995 Published: No	N	✗ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.3.1.1.2/01	Haupt, S.	2014	Indoxacarb (DPX-KN128) technical: Acute oral and contact toxicity to the bumblebee, <i>Bombus terrestris</i> L. (Hymenoptera) IBACON DuPont-38350 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA,	Kling, A.	2014	Indoxacarb	N	Y	The study is	DuPont	<i>Submitted for</i>

8.3.1.1.2/02			(DPX-KN128) technical: Acute oral and contact toxicity to the honeybee, <i>Apis mellifera</i> L. under laboratory conditions Eurofins Agrosience Services EcoChem GmbH DuPont-36500 GLP: Yes Published: No			necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	t	<i>the purpose of renewal</i>
CA, 8.3.1.2/01	Kling, A.	2014	Indoxacarb (DPX-KN128) technical: Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding test Eurofins Agrosience Services EcoChem GmbH DuPont-36490 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.3.1.3/01	Kleinhenz, M.	2014	Indoxacarb (DPX-KN128) technical: A feeding study to evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in Germany 2013 Eurofins Agrosience Services EcoChem GmbH DuPont-36493 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA,	Berg, C.	2015	Indoxacarb	N	Y	The study is	DuPont	<i>Submitted for</i>

8.3.1.3/02			(DPX-KN128) technical: A feeding study to evaluate effects on the brood of honey bees ( <i>Apis Mellifera</i> , Hymenoptera, Apidae) in Germany 2015 Eurofins Agrosience Services EcoChem GmbH DuPont-43111 GLP: Yes Published: No			necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	t	<i>the purpose of renewal</i>
CA, 8.4.1	Luhrs, U.	2002a	IN-KG433: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON DuPont-10067 Published: No	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.4.1	Luhrs, U.	2002b	IN-JU873: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON DuPont-10068 Published: No	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.4.1	Luhrs, U.	2002c	IN-MK638: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON DuPont-10070 Published: No	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.4.1	Luhrs, U.	2002d	IN-MK643: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON DuPont-10072 Published: No	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.4.1	Luhrs, U.	2002e	IN-KT413: Acute toxicity to the earthworm,	N	¥ N	<u>Comment from RMS:</u> Study not relied on	DuPont	<i>In addendum to DAR (2005)</i>

			<i>Eisenia fetida</i> in artificial soil IBACON DuPont-11050 Published: No					
CA, 8.4.1	Wachter, S.	1996a	Acute toxicity of IN-JT333 technical on earthworms, <i>Eisenia foetida</i> using an artificial soil test GAB Biotechnologie, GmbH, AMR 3826-96 Published: No	N	✗ N	<u>Comment from RMS:</u> Study not relied on	DuPont	In DAR (2000)
CA, 8.4.1	Wachter, S.	1996b	Acute toxicity of DPX-MP062 technical on earthworms, <i>Eisenia foetida</i> using an artificial soil test GAB Biotechnologie, GmbH, AMR 3968-96 Published: No	N	✗ N	<u>Comment from RMS:</u> Study not relied on	DuPont	In DAR (2000)
CA, 8.4.1/01	Lührs, U.	2013a	IN-KG433: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36496 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.1/02	Lührs, U.	2013b	IN-JU873: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been	DuPont	Submitted for the purpose of renewal



			DuPont-36497 GLP: Yes Published: No			protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.4.1/03	Lühns, U.	2013c	IN-JT333: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36494 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.1/04	Lühns, U.	2013d	IN-MK638: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36498 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.1/05	Lühns, U.	2013e	IN-MK643: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36499 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has	DuPont	<i>Submitted for the purpose of renewal</i>

						not expired at the time of submission of this dossier.		
CA, 8.4.1/06	Lühns, U.	2014a	IN-KT413: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36495 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.1/07	Lühns, U.	2014b	IN-JT333: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil, 2014 IBACON DuPont-39714 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.1/08	Pavic, B.	2013	Indoxacarb (DPX-KN128) technical: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat IBACON DuPont-36101 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA,	Shanmugas	2011	IN-KB687:	N	Y	The study is	DuPont	<i>Submitted for</i>

8.4.1/09	un-daram, R.		Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil with 5% peat International Institute of Biotechnology and Toxicology (IIBAT) DuPont-31720 GLP: Yes Published: No			necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	t	<i>the purpose of renewal</i>
CA, 8.4.2.1/01	Luhrs, U.	2005	IN-JU873: Effects on the collembola, <i>Folsomia candida</i> in artificial soil IBACON DuPont-16461 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.2.1/02	Luhrs, U.	2006	IN-MK643: Effects on the collembola, <i>Folsomia candida</i> in artificial soil IBACON DuPont-16462 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.4.2.1/03	Luhrs, U.	2011	IN-KB687: Effects on the collembola <i>Folsomia candida</i> in artificial soil	N	Y	The study is necessary for the regulatory decision, conducted according to	DuPont	<i>Submitted for the purpose of renewal</i>

			with 5% peat IBACON DuPont-31721, Revision No. 1 GLP: Yes Published: No			GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.4.2.1/04	Pavić, B.	2013a	IN-JU873: Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35308 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/05	Pavić, B.	2013b	IN-KT413: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35306 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/06	Pavić, B.	2013c	Indoxacarb (DPX-KN128) technical: Effects on the collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-35311	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously	DuPont	Submitted for the purpose of renewal

			GLP: Yes Published: No			protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.4.2.1/07	Pavić, B.	2013d	Indoxacarb (DPX-KN128) technical: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35304 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/08	Pavić, B.	2013e	IN-JT333: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-35312 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/09	Pavić, B.	2013f	IN-JT333: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35305 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of	DuPont	Submitted for the purpose of renewal

						submission of this dossier.		
CA, 8.4.2.1/10	Pavić, B.	2013g	IN-KT413: Effects on the collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-35313 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/11	Pavić, B.	2013h	IN-KG433: Effects on the Collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-35314 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/12	Pavić, B.	2013i	IN-KG433: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35307 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/13	Pavić, B.	2013j	IN-MK638: Effects on the collembola	N	Y	The study is necessary for the regulatory	DuPont	Submitted for the purpose of renewal

			<i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-35315 GLP: Yes Published: No			decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.4.2.1/14	Pavić, B.	2013k	IN-MK638: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35309 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/15	Pavić, B.	2013l	IN-MK643: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-35310 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CA, 8.4.2.1/16	Pavić, B.	2013m	IN-KB687: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously	DuPont	Submitted for the purpose of renewal

			IBACON DuPont-35364 GLP: Yes Published: No			been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CA, 8.5	Carter, J.N.	1997	DPX-MP062 (a racemic mixture of 75% DPX-KN128 and 25% IN- KN127): Effects on soil non-target micro-organisms Huntingdon Life Sciences Ltd. AMR 4134-96 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>
CA, 8.5	Carter, J.N.	1996	IN-JT333 effects on soil non-target micro- organisms Huntingdon Life Sciences Ltd. AMR 3910-96 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In DAR (2000)</i>
CA, 8.5	Kolzer, U.	2002a	IN-JU873: Assessment of the effects on soil microflora GAB Biotechnologie , GmbH DuPont-10069 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.5	Kolzer, U.	2002b	IN-MK638: Assessment of the effects on soil microflora GAB Biotechnologie , GmbH DuPont-10071 Published: No	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.5	Kolzer, U.	2002c	IN-MK643: Assessment of the effects on soil microflora GAB Biotechnologie	N	¥ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>



			, GmbH DuPont-10073 Published: No					
CA, 8.5	Kolzer, U.	2002d	IN-KT413: Assessment of the effects on soil microflora GAB Biotechnologie , GmbH DuPont-11051 Published: No	N	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>
CA, 8.5/01	Carter, J.N.	1997	IN-KG433 technical: Effects on soil non-target micro- organisms Huntingdon Life Sciences Ltd. AMR 4436-97 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.5/02	Feil, N.	2011	IN-KB687: Assessment of the effects on soil microflora IBACON DuPont-31719 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CA, 8.8	Lebertz, H.	1999	Indoxacarb: Activated sludge, respiration inhibition test Institut Fresenius Chemische und Biologische/G mbH DuPont-2533	N	✗ N	<u>Comment from RMS:</u> Study from the original submission	DuPont	<i>In addendum to DAR (2005)</i>

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			Published: No					
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Preparation : INDOXACARB 150 G/L EC

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
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CP, 10.1.1.1/ 01	<b>F</b>	2006	Indoxacarb (DPX-KN128) 150 g/L EC: An acute oral toxicity study with the northern bobwhite <b>[REDACTED]</b> DuPont-18923 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.2.1/01	<b>[REDACTED]</b>	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Static, acute, 96-hour toxicity test to rainbow trout, <i>Oncorhynchus mykiss</i> <b>[REDACTED]</b> DuPont-18927 GLP: Yes Published: No	Y	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.2.1/02	Dinehart, S.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Acute toxicity with the Mysid shrimp, <i>Americamysis bahia</i> , determined under static test conditions ABC Laboratories, Inc. (Missouri) DuPont-38348 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.2.1/03	Sloman, T.L.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Static, 72-hour growth	N	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>

			inhibition toxicity test to the green alga, <i>Pseudokirchneriella subcapitata</i> DuPont Haskell Laboratory DuPont-18926 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CP, 10.2.1/04	Turner, J.T.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Static, acute, 48-hour toxicity test with <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-18928 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CP, 10.3.1.1.1/01	Haupt, S.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Acute oral and contact toxicity to the bumblebee, <i>Bombus terrestris</i> L. (Hymenoptera) IBACON DuPont-38351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CP, 10.3.1.1.1/02	Schmitzer, S.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Acute oral and contact toxicity to the honey bee, <i>Apis mellifera</i> L. IBACON	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if	DuPont	Submitted for the purpose of renewal

			DuPont-18924 GLP: Yes Published: No			previously protected the period of data protection has not expired at the time of submission of this dossier.		
CP, 10.3.1.1.2 /01	Haupt, S.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Acute oral and contact toxicity to the bumblebee, <i>Bombus terrestris</i> L. (Hymenoptera) IBACON DuPont-38351 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.1.2 /02	Schmitzer, S.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Acute oral and contact toxicity to the honey bee, <i>Apis mellifera</i> L. IBACON DuPont-18924 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.2/ 01	Kling, A.	2014	Indoxacarb 150 g/L EC: Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding test Eurofins Agrosience Services EcoChem	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at	DuPont	<i>Submitted for the purpose of renewal</i>

			GmbH DuPont-36492 GLP: Yes Published: No			the time of submission of this dossier.		
CP, 10.3.1.3/ 01	Klank, C.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Honey bee ( <i>Apis mellifera</i> L.) larval toxicity test (single feeding exposure) Eurofins Agroscience Services EcoChem GmbH DuPont-34817 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.3/ 02	Kleinhenz, M.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A feeding study to evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, apidae) in Germany 2013 Eurofins Agroscience Services EcoChem GmbH DuPont-37488 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.3/ 03	Giffard, H.	2006	Evaluation des effets sur l'abeille domestique d'une application de Steward et de DPX KN128 150 EC (indoxacarbe) sur culture de phacélie. (Evaluation of the effects on domestic bees from one application of	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of	DuPont	<i>Submitted for the purpose of renewal</i>

			Steward and of DPX-KN128 150 EC (indoxacarb) on a blue tansy (Phacelia) crop) Testapi à Sarré, Etude No. 92- 2006 GLP: Yes Published: No			this dossier.		
CP, 10.3.1.6/ 01	Berg, C.	2013	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in maize ( <i>Zea mays</i> ) in Germany 2013 Eurofins Agroscience Services GmbH DuPont-37487 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 02	Berg, C.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany 2014 Eurofins Agroscience Services GmbH DuPont-38405 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 03	Berg, C.	2015	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to	N	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>

			evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany 2014 Eurofins Agrosience Services GmbH DuPont-37489, Revision No. 1 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CP, 10.3.1.6/04	Bocksch. S.	2011	Indoxacarb (DPX-KN128) 150 g/L EC: A study to evaluate effects on the honeybee ( <i>Apis mellifera</i> ) in the field in maize in Germany in 2010 Eurofins Agrosience Services GmbH DuPont-30106 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/05	Giffard, H.	2008	DPX-KN128 150EC [150 g a.s./L (w/v)]: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera mellifera</i> ; Hymenoptera, Apidae) on phacelia in France 2007 Testapi DuPont-19453 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/06	Gonsior, G.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to	N	Y	The study is necessary for the regulatory decision, conducted	DuPont	<i>Submitted for the purpose of renewal</i>



			evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) in Phacelia in Germany 2006 GAB Biotechnologie, GmbH DuPont-19449 GLP: Yes Published: No			according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		
CP, 10.3.1.6/07	Gonsior, G.	2007a	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) in Phacelia tanacetifolia in France 2007 GAB Biotechnologie, GmbH DuPont-19450 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/08	Gonsior, G.	2007b	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) in Phacelia tanacetifolia in Germany 2007 GAB Biotechnologie, GmbH DuPont-19451 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/	Gonsior, G.	2008a	Indoxacarb (DPX-KN128)	N	Y	The study is necessary for	DuPont	<i>Submitted for the purpose</i>

09			150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Alsace, France 2007 eurofins-GAB GmbH DuPont-21945 GLP: Yes Published: No			the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.		<i>of renewal</i>
CP, 10.3.1.6/10	Gonsior, G.	2008b	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ; Hymenoptera, Apidae) on wheat treated with artificial honeydew in Northern France 2007 eurofins-GAB GmbH DuPont-21944 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/11	Klein, O.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the bumble bee ( <i>Bombus terrestris</i> L; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany in 2013 Eurofins Agrosience Services	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

			GmbH DuPont-38419 GLP: Yes Published: No			<u>Comment from RMS:</u> Study not relied on		
CP, 10.3.1.6/ 12	Kleinhenz, M.	2011a	Indoxacarb (DPX-KN128) 150 g/L EC: A study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ) in the field in <i>Brassica napus</i> L. in eastern Germany in 2009 Eurofins Agrosience Services GmbH DuPont-26946 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 13	Kleinhenz, M.	2011b	Indoxacarb (DPX-KN128) 150 g/L EC: A study to evaluate effects on the honey bee ( <i>Apis mellifera carnica</i> ) in the field in <i>Brassica napus</i> L. in northern Germany in 2009 Eurofins Agrosience Services GmbH DuPont-26947 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 14	Kleinhenz, M.	2014a	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the brood of honey bees ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data	DuPont	<i>Submitted for the purpose of renewal</i>

			Germany 2012 Eurofins Agroscience Services GmbH DuPont-34108 GLP: Yes Published: No			protection has not expired at the time of submission of this dossier.		
CP, 10.3.1.6/ 15	Kleinhenz, M.	2014b	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera</i> ; Hymenoptera, apidae) in <i>Phacelia tanacetifolia</i> in Germany 2013 Eurofins Agroscience Services EcoChem GmbH DuPont-36482 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 16	Mamet, O.	2008a	DPX-KN128 150EC [150 g a.s./L (w/v)]: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera mellifera</i> ; Hymenoptera, Apidae) on wheat treated with artificial honeydew in France 2007 Testapi DuPont-19454 GLP: Yes Published: No	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.1.6/ 17	Mamet, O.	2008b	DPX-KN128 150EC [150 g a.s./L (w/v)]: A semi-field study to evaluate effects on the honey	N	✗ N	The study is necessary for the regulatory decision, conducted according to GLP and has	DuPont	<i>Submitted for the purpose of renewal</i>

			bee ( <i>Apis mellifera mellifera</i> ; Hymenoptera, Apidae) on wheat treated with artificial honeydew in France 2007 Testapi DuPont-19455 GLP: Yes Published: No			not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on		
CP, 10.3.1.6/18	Rentschler, S.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: A semi-field study to evaluate effects on the honey bee ( <i>Apis mellifera</i> ; Hymenoptera, Apidae) in <i>Phacelia tanacetifolia</i> in Germany 2014 Eurofins Agrosience Services EcoChem GmbH DuPont-41668 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CP, 10.3.1.6/19	van der Steen, J.J.M., Dinter, A.	2006	A monitoring study to assess the acute mortality effects of indoxacarb on honey bees ( <i>Apis mellifera</i> L.) in flowering apple orchards PPO Bijen, DuPont de Nemours (Deutschland) GmbH Pest Manag Sci 63 1095-1099 (2007) GLP: No Published: Yes	N	N		Authors	Submitted for the purpose of renewal
CP,	Warmers,	2006a	Indoxacarb	N	Y	The study is	DuPont	Submitted for

10.3.2.1/ 01	C.		(DPX-KN128) 150 g/L EC: A laboratory rate response test to study the effects on the parasitoid <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) GAB Biotechnologie, GmbH DuPont-19443 GLP: Yes Published: No			necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	t	<i>the purpose of renewal</i>
CP, 10.3.2.1/ 02	Warmers, C.	2006b	Indoxacarb (DPX-KN128) 150 g/L EC: A laboratory rate response test to study the effects on the predatory mite <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) GAB Biotechnologie, GmbH DuPont-19444 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.2.2/ 01	Adelberger, I.	2007	Indoxacarb (DPX-KN128) 150 g/L EC: An extended laboratory test with field-aged spray deposits to study the effects on the aphid parasitoid, <i>Aphidius rhopalosiphii</i> de Stefani Perez (Hymenoptera, Braconidae) GAB Biotechnologie, GmbH DuPont-21947 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP,	Klug, T	2007	Indoxacarb	N	Y	The study is	DuPont	<i>Submitted for</i>

10.3.2.2/ 02			(DPX-KN128) 150 g/L EC: An extended laboratory test with field-aged spray deposits to study the effects on the green lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) GAB Biotechnologie , GmbH DuPont-21946 GLP: Yes Published: No			necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	t	<i>the purpose of renewal</i>
CP, 10.3.2.2/ 03	Warmers, C.	2007a	Indoxacarb (DPX-KN128) 150 g/L EC: An extended laboratory rate response test to study the effects on the aphid parasitoid, <i>Aphidius rhopalosiphii</i> de Stefani Perez (Hymenoptera, Braconidae) GAB Biotechnologie , GmbH DuPont-19445 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.3.2.2/ 04	Warmers, C.	2007b	Indoxacarb (DPX-KN128) 150 g/L EC: An extended laboratory rate response test to study the effects on the green lacewing <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) GAB Biotechnologie , GmbH DuPont-19446 GLP: Yes	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

			Published: No					
CP, 10.3.2.2/ 05	Warmers, C.	2007c	Indoxacarb (DPX-KN128) 150 g/L EC: An extended laboratory test with field-aged spray deposits to study the effects on the predatory bug <i>Orius laevigatus</i> Fieber (Heteroptera, Anthocoridae) GAB Biotechnologie , GmbH DuPont-22391 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.4.1/01	Lühns, U.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Acute toxicity to the earthworm, <i>Eisenia fetida</i> in artificial soil IBACON DuPont-18929 GLP: Yes Published: No	N	Y N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.4.1/02	Lühns, U.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Acute toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil IBACON DuPont-38832 GLP: Yes Published: No	N	Y N	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at	DuPont	<i>Submitted for the purpose of renewal</i>



						the time of submission of this dossier. <u>Comment from RMS:</u> Study not relied on		
CP, 10.4.1.1.1/01	Pavic, B.	2014	Indoxacarb (DPX-KN128) 150 g/L EC: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> , in artificial soil IBACON DuPont-37891 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CP, 10.4.2.1/01	Pavic, B.	2014a	Indoxacarb (DPX-KN128) 150 g/L EC: Effects on the collembola <i>Folsomia candida</i> in artificial soil with 5% peat IBACON DuPont-37892 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	Submitted for the purpose of renewal
CP, 10.4.2.1/02	Pavic, B.	2014b	Indoxacarb (DPX-KN128) 150 g/L EC: Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil with 5% peat IBACON DuPont-37893 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of	DuPont	Submitted for the purpose of renewal

						submission of this dossier.		
CP, 10.5/01	Reis, K.-H.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: Assessment of the effects on soil microflora IBACON DuPont-18925 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.6.2/01	Porch, J.R., Martin, K.H.	2006	Indoxacarb (DPX-KN128) 150 g/L EC: A greenhouse study to investigate the effects on vegetative vigor of ten sensitive terrestrial plants following foliar exposure Wildlife International Ltd. (USA) DuPont-19456 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>
CP, 10.6.2/02	Porch, J.R., Keller, K.	2015	Indoxacarb (DPX-KN128) 150 g/L EC: A greenhouse study to investigate the effects on vegetative vigor of ten terrestrial plants following foliar exposure Wildlife International Ltd. (USA) DuPont-42153 GLP: Yes Published: No	N	Y	The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or if previously protected the period of data protection has not expired at the time of submission of this dossier.	DuPont	<i>Submitted for the purpose of renewal</i>

