

European Commission



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

INDOXACARB

**Volume 3 – B.2 (PPP) – INDOXACARB 150 g/L
EC**

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

Version History

When	What
2016-12	Initial RAR

Table of contents

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT NAME	4
B.2.1. APPEARANCE.....	4
B.2.2. EXPLOSIVE AND OXIDISING PROPERTIES	4
B.2.3. FLAMABILITY AND AUTO-FLAMABILITY	5
B.2.4. ACIDITY/ALKALINITY AND PH VALUE	6
B.2.5. VISCOSITY AND SURFACE TENSION.....	6
B.2.6. RELATIVE DENSITY AND BULK DENSITY.....	7
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT	7
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT	15
B.2.8.1. Wettability	15
B.2.8.2. Persistence foaming.....	15
B.2.8.3. Suspensibility	15
B.2.8.4. Degree of dissolution and dilution stability	16
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability	16
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability	17
B.2.8.7. Flowability, pourability and dustability.....	18
B.2.9. PHYSICAL COMPATIBILITY WITH OTHER PRODUCT INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED.....	18
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS	18
B.2.11. OTHER STUDIES.....	19
B.2.12. REFERENCES RELIED ON.....	20

B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT INDOXACARB 150 EC

Use concentrations: min 0.025% w/v and max 0.25% w/v

Commercial packaging: Indoxacarb 150 g/L EC formulation will be packed in (50 mL, 100 mL, 200 mL, 300 mL, 1 L, 3 L, 5 L) bottles made on HDPE/EVOH (High Density Polyethylene with Ethylene Vinyl Alcohol layer) and in 500 mL bottles made on HDPE/F (High Density Polyethylene with Fluorination).

The formulation contains hydrocarbons or co-formulant H304 < 10%

Plant production product Indoxacarb 150 g/L EC submitted for the renewal does not have the same composition as that originally submitted in the DAR (2000).

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour B.2.1/01	Visual and olfactory assessment	Indoxacarb 150 g/L EC (DPX-KN128-206) and (DPX-KN128-311)	Indoxacarb 150 g/L EC is a liquid; it is straw yellow to straw brown in colour, with a pungent sweet pear odour.	Acceptable Studies submitted to the EU for the first time in this submission.	Y	DuPont-20351
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties B.2.2/01	EEC A.14	Indoxacarb 150 g/L EC (DPX-KN128-206)	Indoxacarb 150 g/L EC did not react explosively to thermal stress or to mechanical stress. On the basis of these test results, the product was determined to be non-explosive. Thermal sensitivity — Indoxacarb 150 g/L EC was subject to conditions of intense heat and confinement. No explosions were observed. Mechanical sensitivity — Indoxacarb 150 g/L EC with respect to shock was negative; no positive results were obtained in 6-drop impact	Acceptable Study submitted to the EU for the first time in this submission. Plant production product is not explosive according to EECA.14. However, test should be performed according to CLP criteria (Part I Test series Section 11 of manual UN RTDG).	Y	DuPont-20351

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			tests with a 10 kg weight dropped from 0.4 meters. Mechanical sensitivity with respect to friction is not applicable to liquids. Conclusion: Indoxacarb 150 g/L EC is not explosive.			
Oxidizing properties B.2.2/02	O.2 of manual UN RTDG	Indoxacarb 150 g/L EC (DPX-KN128-206)	As directed by UN Test O.2, "Test for Oxidizing Liquids", Reference 6.2, the product was mixed with dry cellulose and heated in a pressure vessel until the bursting disc ruptured or the test time had elapsed. The pressure profile was compared with that of a reference standard and classified, in accordance with the guidance found in the UN Recommendations on the Transport of Dangerous Goods. Conclusion: Indoxacarb 150 g/L EC does not have oxidising properties.	Acceptable Study submitted to the EU for the first time in this submission. The preparation has no oxidizing properties according to DSD system. However test should be performed according to CLP criteria (method O.2 of manual UN RTDG)	Y	DuPont-20351
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations B.2.3/01	EEC A.9	Indoxacarb 150 g/L EC (DPX-KN128-206)	The flash point (closed cup) of Indoxacarb 150 g/L EC is $69 \pm 3^{\circ}\text{C}$. The flash point was determined using ASTM D93-06, employing a Pensky-Martins closed cup Flash Point Tester.	Acceptable Study submitted to the EU for the first time in this submission Plant production product is not highly flammable. However test should be performed according to CLP criteria (manual UN RTDG)	Y	DuPont-20351
Flammability of solid formulations B.2.3/02			Not applicable to liquid preparations.			
Self-heating of formulation B.2.3/03	EEC A.15	Indoxacarb 150 g/L EC (DPX-KN128-206)	The self-ignition temperature of Indoxacarb 150 g/L EC is determined to be $255 \pm 5^{\circ}\text{C}$.	Acceptable Study submitted to the EU for the first time in this	Y	DuPont-20351

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
				submission. Plant production product is not is not auto-flammable at ambient temperature. However test should be performed according to CLP criteria (manual UN RTDG)		
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation B.2.4/01						
pH of a 1 % dilution of the solid or non aqueous formulation B.2.4/02	CIPAC MT 75.3	Indoxacarb 150 g/L EC (DPX-KN128-206) and (DPX-KN128-311)	The pH of Indoxacarb 150 g/L EC in a 1% aqueous dispersion at 25°C was determined to between 5.0 and 5.4.	Acceptable Study submitted to the EU for the first time in this submission		DuPont-20351 and DuPont-20352
Acidity / Alkalinity B.2.4/03			Not applicable as pH of a 1% dilution in water is not lower than 4 or greater than 10.			
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation B.2.5/01	OECD 114	Indoxacarb 150 g/L EC (DPX-KN128-206)	The viscosity standard at 20°C was determined to be 4.29mm ² /s. The kinematic viscosity was measured at 20°C and 40°C employing a U-Tube Capillary viscometer. Kinematic viscosity: 2.95 mm ² /s at 40°C 4.68 mm ² /s at 20°C This preparation contains no aliphatic, alicyclic, or aromatic hydrocarbon components.	Acceptable Study submitted to the EU for the first time in this submission	Y	DuPont-20351

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference												
Surface tension of the formulation B.2.5/02	EEC A.5 OECD 115	Indoxacarb 150 g/L EC (DPX-KN128-206)	The surface tension of Indoxacarb 150 g/L EC was measured for “neat” and in a tank mix at maximum recommended use rate. All measurements were made at a temperature of 25 ± 0.5°C. Results are as follows: Neat formulation: 28.9 mN/m Maximum use rate (0.25%): 39.3 mN/m	Acceptable Study submitted to the EU for the first time in this submission	Y	DuPont-20351												
B.2.6. RELATIVE DENSITY AND BULK DENSITY																		
Relative density of the liquid formulation B.2.6/01	EEC A.3 OECD 109 (1995)	Indoxacarb 150 g/L EC (DPX-KN128-206)	25 mL pycnometers were used to measure the density of Indoxacarb 150 g/L EC at a temperature of 20°C The relative density was recorded as 0.9494.	Acceptable Study submitted to the EU for the first time in this submission	Y	DuPont-20351												
Bulk density (pour and tap) of powder or granules B.2.6/02			Not applicable to liquid preparations.															
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT																		
Stability after accelerated storage (54°C during 14 days) B.2.7/01	CIPAC MT 46.3 (accelerated storage)	Indoxacarb 150 g/L EC (DPX-KN128-206)	Indoxacarb 150 g/L EC was stored in a 1 litre fluorinated High Density Polyethylene (HDPE/F) commercial package at a temperature of 54°C for a period of 2 weeks. <table><tr><td>Test</td><td>T₀</td><td>T_{2 weeks at 54°C}</td></tr><tr><td>Appearance</td><td>Straw yellow free flowing liquid Pungent sweet pear</td><td>Straw brown free flowing liquid Pungent sweet pear</td></tr><tr><td>Packaging</td><td colspan="2">Packaging remained intact and unaffected by the storage.</td></tr><tr><td>DPX KN128 content Method N°1191B¹</td><td>149.9g/L</td><td>150.1g/L</td></tr></table>	Test	T ₀	T _{2 weeks at 54°C}	Appearance	Straw yellow free flowing liquid Pungent sweet pear	Straw brown free flowing liquid Pungent sweet pear	Packaging	Packaging remained intact and unaffected by the storage.		DPX KN128 content Method N°1191B ¹	149.9g/L	150.1g/L	Acceptable This study submitted to the EU for the first time in this submission. Indoxacarb 150 EC is stable in terms of physical characteristics of the emulsion concentrate formulation and active ingredient when stored in commercial packaging made on HDPE/F. ¹ Method N°1191B is fully described and validated in this report. Method N° KN128.220.01 described in B.5 was slightly adapted then fully validated with respect to specificity, linearity (range 50 to 150%, 7 solutions tested, R ² = 0.999), Accuracy (mean recovery: 99.8%, CV: 0.4%) and repeatability (8 solutions tested at 150g/L, SD: 0.3%) ² Method N°1191A is fully described and validated	Y	DuPont-20351
Test	T ₀	T _{2 weeks at 54°C}																
Appearance	Straw yellow free flowing liquid Pungent sweet pear	Straw brown free flowing liquid Pungent sweet pear																
Packaging	Packaging remained intact and unaffected by the storage.																	
DPX KN128 content Method N°1191B ¹	149.9g/L	150.1g/L																

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
		Indoxacarb 150 g/L EC (DPX-KN128-206)	Inactive isomer Method N°1191A ²	Not detected	Not detected	in this report. Method N° KN128.220.ST (first version) was validated with respect of linearity (ranged from 10.1 to 40.5 µg/mL, R ² = 0.999), specificity (chromatograms are presented and no interferences were showed), accuracy and precision (mean recovery 98.3% for 10 µ/ml and 96.8% for 40µg/ml) LoQ was set to be 10µg/ml The inactive Enantiomeric content in the formulation before and after storage was < 10µg/mL (LoQ) The relevant impurities contents should be determined before and after acerbated storage. DuPont response The relevant impurities will now be kept at below the limit of detection (LOD) for both the technical and the formulated product. Since the relevant impurities will be kept below LOD, DuPont does not believe it is necessary to analyze for the relevant impurities after aging. ➔ The justification/explanation provided by notifier cannot be accepted. The relevant impurities contents should be determined before and after acerbated storage or a justification for "non-formation" of these impurities during the formulation or the storage is required. Study shows that there are no significant physical or chemical changes of the test item or the packaging when stored at 54°C during 2 weeks in commercial packaging made on PE/EVOH. As the formulation is EC, the HDPE/EVOH packaging can be considered as acceptable as the stability was performed on PE/EVOH packaging-	Y	DuPont-33102
			pH 1% CIPAC MT75.3	5.40	5.40			
			Emulsion characteristics in at maximum rate of product (0.2%) CIPAC water A and D after 24H CIPAC MT36.3	No cream or oil	No cream or oil			
			Emulsion characteristics Re-emulsion in CIPAC water A and D CIPAC MT 36.3	No cream or oil	No cream or oil			
			Indoxacarb 150 g/L EC was stored in 1L Polyethylene/Ethyl Vinyl Alcohol (PE/EVOH) commercial package at a temperature of 54°C for a period of 2 weeks.					
			Test	T ⁰	T 2 weeks at 54°C			
			Appearance	Light yellow, mild solvent liquid	Light yellow, mild solvent liquid			
			Packaging	No perforation darkening, leakage or rust at the seam of the packaging: packaging remained intact and unaffected by the storage.				
			DPX KN128	144.3+1.6 g/l	146.4+1.3 g/l			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			content Method N° KN128.220.01 ¹					
			Inactive isomer Method N°1191A ²	Not detected	Not detected			
			pH 1% CIPAC MT75.3	5.0	5.2			
			Emulsion characteristics <u>at a low dose</u> (0.021%) in CIPAC water D and A (CIPAC MT36.3) <u>After 30 sec:</u> Emulsification Forth, ml	Homogenous Nil	Homogenous 0.5			
			<u>After 30 min:</u> Forth, mL Free oi/cream, mL	Nil Nil	Nil Nil			
			<u>After 24h:</u> Forth, ml Free oil/cream, mL	Nil Nil	Nil Nil			
			<u>Re-emulsification after 24h</u> Emulsification Forth, ml Oil free, ml	Homogenous Nil Nil	Homogenous 0.5 Nil			
			<u>After 30 min</u> Forth, ml Free oil/cream,	Nil Nil	Nil Nil			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			mL					
			Emulsion characteristics at a higher dose (0.25%) in CIPAC water A (CIPAC MT36.3)					
			After 30 sec: Emulsification	Homogenous Nil	Homogenous 1.4			
			Forth, ml					
			After 30 min: Fort, mL	Nil Nil	0.5 Nil			
			Free oi/cream, mL					
			After 24h: Fort, ml	Nil	Nil			
			Free oil/cream, mL	Nil	Nil			
			Re-emulsification after 24h Emulsification	Homogenous Nil	Homogenous 1.4			
			Forth, ml		Nil			
			Oil free, ml	Nil				
			After 30 min Fort, ml	Nil	Nil			
			Free oil/cream, mL	Nil	Nil			
			Persistent foaming at 0.25% w/v CIPAC MT 47.2, ml					
			1 min.	9±1	11±1			
			3 min.	7±1	9±1			
			12 min.	5±1	5±1			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference																		
Effect of low temperature on stability of liquid formulation B.2.7/02	CIPAC MT 39.3	Indoxacarb 150 g/L EC (DPX-KN128-206)	Indoxacarb 150 g/L EC was stored in a 1 litre fluorinated High Density Polyethylene commercial package at a temperature of 0 ± 2°C for a period of 7 days. After storage, the test substance was held at room temperature for 24 hours and then inverted, examined visually, and the volume and nature of any separated material reported. Sediment: <i>ca.</i> 0.05 mL	Acceptable, formulation is stable after storage 7 days at 0°C. Study submitted to the EU for the first time in this submission	Y																			
Shelf life following storage at ambient temperature B.2.7/03	GIFAP Monograph No 17	Indoxacarb 150 g/L EC (DPX-KN128-206)	<div>A sample of Indoxacarb 150 g/L EC, stored in a 1-L sealed, Polyethylene/Ethyl Vinyl Alcohol, PE/EVOH container, was placed in a commercial warehouse for 2 years. The test results are reported below:</div> <table><tr><th>Test</th><th>T⁰</th><th>T 2 years 20°C</th></tr><tr><td>Appearance</td><td>light yellow, mild solvent liquid</td><td>Light yellow, mild solvent liquid</td></tr><tr><td>Packaging</td><td colspan="2">No perforation darkening, leakage or rust at the seam of the packaging: packaging remained intact and unaffected by the storage.</td></tr><tr><td>DPX KN128 content Method N° KN128.220.01</td><td>144.3±1.6 g/l</td><td>146.6±1.7 g/l</td></tr><tr><td>pH 1% CIPAC MT75.3</td><td>5.0</td><td>5.1</td></tr><tr><td>Emulsion characteristics at a low dose (0.021%) in CIPAC water D and A (CIPAC MT36.3) <u>After 30 sec:</u> Emulsification</td><td>Homogenous</td><td>Homogenous</td></tr></table>	Test	T ⁰	T 2 years 20°C	Appearance	light yellow, mild solvent liquid	Light yellow, mild solvent liquid	Packaging	No perforation darkening, leakage or rust at the seam of the packaging: packaging remained intact and unaffected by the storage.		DPX KN128 content Method N° KN128.220.01	144.3±1.6 g/l	146.6±1.7 g/l	pH 1% CIPAC MT75.3	5.0	5.1	Emulsion characteristics at a low dose (0.021%) in CIPAC water D and A (CIPAC MT36.3) <u>After 30 sec:</u> Emulsification	Homogenous	Homogenous	<div>Acceptable.</div> <div>Studies were submitted to the EU for the first time.</div> <div>The physico-chemical testing and active ingredient content shows that formulation is stable when stored in room temperature during 2 years in commercial packaging made on PE/EVOH and HDPE-f bottles.</div> <div>Method N°1191B is fully described and validated in this report. Method N° KN128.220.01 described in B.5 was slightly adapted then fully validated with respect to specificity, linearity (range 50 to 150%, 7 solutions tested, R² = 0.999), Accuracy (mean recovery: 99.8%, CV: 0.4%) and repeatability (8 solutions tested at 150g/L, SD: 0.3%)</div> <div>Method N°1191A is fully described and validated in this report. Method N° KN128.220.ST (first version) was validated with respect of linearity (ranged from 10.12 to 40.48 µg/mL, R² = 0.999), specificity (chromatograms are presented and no interferences were showed), accuracy and precision (mean recovery 98.3% for 10 µ/ml and 96.8% for 40µg/ml) LoQ was set to be 10µg/ml</div> <div>The inactive Enantiomeric content in the formulation before and after storage was < 10µg/mL (LoQ)</div>	Y	DuPont-33103
Test	T ⁰	T 2 years 20°C																						
Appearance	light yellow, mild solvent liquid	Light yellow, mild solvent liquid																						
Packaging	No perforation darkening, leakage or rust at the seam of the packaging: packaging remained intact and unaffected by the storage.																							
DPX KN128 content Method N° KN128.220.01	144.3±1.6 g/l	146.6±1.7 g/l																						
pH 1% CIPAC MT75.3	5.0	5.1																						
Emulsion characteristics at a low dose (0.021%) in CIPAC water D and A (CIPAC MT36.3) <u>After 30 sec:</u> Emulsification	Homogenous	Homogenous																						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			Forth, ml	Nil	Nil	<p>The relevant impurities contents should be determined before and after acerbated storage.</p> <p>DuPont response</p> <p>Per your request to an earlier point above, the relevant impurities will now be kept at below the limit of detection (LOD) for both the technical and the formulated product. Since the relevant impurities will be kept below LOD, DuPont does not believe it is necessary to analyze for the relevant impurities after aging.</p> <p>➔ The justification/explanation provided by notifier cannot be accepted, the relevant impurities contents should be determined before and after acerbated storage or a justification for "non-formation" of these impurities during the formulation or the storage is required.</p>		
			<u>After 30 min:</u> Forth, mL	Nil	Nil			
			Free oi/cream, mL	Nil	Nil			
			<u>After 24h:</u> Forth, ml	Nil	Nil			
			Free oil/cream, mL	Nil	Nil			
			<u>Re-emulsification after 24h</u> Emulsification Forth, ml	Homogenous	Homogenous 0.5ml			
			Oil free, ml	Nil	Nil			
			<u>After 30 min</u> Forth, ml	Nil	Nil			
			Free oil/cream, mL	Nil	Nil			
			Emulsion characteristics at a higher dose (0.25%) in CIPAC water A (CIPAC MT36.3)					
			<u>After 30 sec:</u> Emulsification Forth, ml	Homogenous 1.4 ml	Homogenous 0.5ml			
			<u>After 30 min:</u> Forth, mL	Nil	0.5ml			
			Free oi/cream, mL	Nil	Nil			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference								
			<div><div><div>After 24h: Forth, ml Free oil/crem, mL</div><div>Re-emulsification after 24h Emulsification Forth, ml Oil free, ml</div><div>After 30 min Forth, ml Free oil/crem, mL</div></div><div><div>Persistent foaming at 0.25% w/v CIPAC MT 47.2, ml 1 min. 3 min. 12 min.</div><div>9±1 7±1 5±1</div><div>11±1 9±1 5±1</div></div></div>	<div><div>Nil Nil</div><div>Homogenous Nil Nil</div><div>Nil Nil Nil</div></div>	<div><div>Nil</div><div>Homogenous 1.4 Nil</div><div>Nil Nil Nil</div></div>											
		Indoxacarb 150 g/L EC (DPX-KN128-206)	<div><div>A sample of Indoxacarb 150 g/L EC, stored in a 1-L sealed, fluorinated HDPE bottle, was placed in a commercial warehouse for 2 years in room temperature. The test results are reported below:</div><table><tr><td>Test</td><td>T₀</td><td>T₂ years at 20°C</td></tr><tr><td>Appearance</td><td>Straw yellow free flowing liquid Pungent sweet pear</td><td>Straw brown free flowing liquid Pungent sweet pear</td></tr><tr><td>Packaging</td><td colspan="2">Container remains intact. No evidence of interaction with contents</td></tr></table></div>	Test	T ₀	T ₂ years at 20°C	Appearance	Straw yellow free flowing liquid Pungent sweet pear	Straw brown free flowing liquid Pungent sweet pear	Packaging	Container remains intact. No evidence of interaction with contents		<div><div>Acceptable</div></div>		Y	DuPont-20352
Test	T ₀	T ₂ years at 20°C														
Appearance	Straw yellow free flowing liquid Pungent sweet pear	Straw brown free flowing liquid Pungent sweet pear														
Packaging	Container remains intact. No evidence of interaction with contents															

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results			Comments (Acceptable / Non acceptable)	GLP	Reference
			DPX KN128 content Method N°1191B	149.9g/L	154.3g/L			
			Inactive isomer Method N°1191A	Not detected	Not detected			
			pH 1% CIPAC MT75.3	5.40	5.85			
			Emulsion characteristics in at maximum rate of product (0.2%) CIPAC water A and D after 24H CIPAC MT36.3	No cream or oil	No cream or oil			
			Emulsion characteristics Re-emulsion in CIPAC water A and D CIPAC MT 36.3	No cream or oil	No cream or oil			
			Persistent foaming after 3- years storage in a HDPE/F container at ambient temperature After 10 sec 10 mL 1 min 5 mL 3 min 4 mL 12 min 2 mL			After 3 years storage, plant production product forms foam in acceptable limits.	Y	DuPont-38318

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation B.2.8.1/01			Not applicable to liquid formulations.			
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	Indoxacarb 150 g/L EC (DPX-KN128-206) (DPX-KN128-311)	<p>The volume of the foam was recorded after 10-second, 1-minute, 3-minute, and 12-minute time for Indoxacarb 150g/L EC (at its highest recommended use rate (0.25% in CIPAC water D))</p> <p>Prior to stability testing:</p> <p>10 sec 18 ± 2 mL 1 min 9 ± 1 mL 3 min 7 ± 1 mL 12 min 5 ± 1 mL</p> <p>After stability testing (3yares at room temperature)</p> <p>10 sec 18 ± 2 mL 1 min 9 ± 1 mL 3 min 7 ± 1 mL 12 min 5 ± 1 mL</p>	<p>Acceptable, plant production product forms foam in acceptable limits before and after storage.</p> <p>Studies submitted to the EU for the first time in this submission and listed under "Documents Submitted"</p>	Y	DuPont-33102
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01			Not applicable to Emulsifiable Concentrate preparations.			
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02			Not applicable to Emulsifiable Concentrate preparations.			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Dispersion stability of SE, OD or EG formulation B.2.8.3/03			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01			Not applicable to Emulsifiable Concentrate preparations.			
Dilution stability of water soluble formulation B.2.8.4/02			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation B.2.8.5.1/01			Not applicable to Emulsifiable Concentrate preparations.			
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02			Not applicable to Emulsifiable Concentrate preparations.			
Nominal size range of granule B.2.8.5.1/03			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.5.2. Dust content						
Dust content of granular formulation B.2.8.5.2/01			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.5.4. Hardness and integrity						

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Hardness of tablets B.2.8.5.4/01			Not applicable to Emulsifiable Concentrate preparations.			
Integrity of tablets B.2.8.5.4/02			Not applicable to Emulsifiable Concentrate preparations.			
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01	CIPAC MT 36.3	Indoxacarb 150 g/L EC	<p>CIPAC Std. Water A AND d at the highest (0.25%) and lowest (0.021%) recommended use rate.</p> <p><u>Emulsion Stability:</u></p> <p>Before stability testing (2 years at room temperature) 30 seconds: Homogenous emulsion 30 minutes: No formation of oil or cream 2 hours: No formation of oil or cream 24 hours: No formation of oil or cream Re-emulsification: Homogeneous</p> <p>After stability testing (2 years at room temperature) 30 seconds: Homogenous emulsion 30 minutes: No formation of oil or cream 2 hours: No formation of oil or cream 24 hours: No formation of oil or cream <u>Re-emulsification:</u> Homogeneous</p> <p><u>Emulsion Stability:</u> CIPAC Std. Water D at the highest (0.25%) and lowest (0.021%) recommended use rate. 2 hours: No formation of oil or cream 24 hours: No formation of oil or cream <u>Re-emulsification:</u> Homogeneous</p>	Acceptable Study submitted to the EU for the first time in this submission	Y	DuPont-33102 And DuPont-20352
Stability of dilute emulsions	CIPAC	Indoxacarb 150 g/L EC	Indoxacarb 150 g/L EC was added to CIPAC standard water "D" and to distilled water at the			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
	MT 20 (EO, EW)	(DPX-KN128-206)	highest (0.25%) and lowest (0.021%) recommended use rate. There was no evidence of phase separation in either the CIPAC “D” or the distilled water.			
Stability of emulsions	CIPAC MT 20	Indoxacarb 150 g/L EC (DPX-KN128-206)	The emulsion was determined to be completely stable in both hard and soft water with no indication of phase separation.			
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01			Not applicable to Emulsifiable Concentrate preparations.			
Pourability of suspensions B.2.8.7/02			Not applicable to Emulsifiable Concentrate preparations.			
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not applicable to Emulsifiable Concentrate preparations.			
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures B.2.9/01			Where relevant please refer to local recommendations			
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds B.2.9.10/01			No study provided since this is only required for seed treatment formulations			

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.11. OTHER STUDIES						

The formulation Indoxacarb 150 g/L EC is an Emulsifiable Concentrate. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of straw yellow to brown, with pungent sweet pear odour. It is not explosive and has no oxidizing properties. The product is not flammable and has a flash point of $69 \pm 3^\circ\text{C}$. It has a self-ignition temperature of $255 \pm 5^\circ\text{C}$. Since the CLP tests became effective for formulations and there was no correspondence between the tests, the new studies according to the CLP criteria (manual UN RTDG) are required.

In aqueous solution (1%), it has a pH value between 5.0 and 5.4 at 25°C . There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C , neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in (fluorinated High Density Polyethylene (HDPE/F) and Polyethylene/Ethyl Vinyl Alcohol (PE/EVOH)).

As the stability studies were performed on PE/EVOH and on HDPE/F bottle, packaging made on PE/EVOH and on HDPE/F can be considered as acceptable.

Its technical characteristics are acceptable for Emulsifiable Concentrate formulation.

The formulation is not classified for the physical-chemical part.

Data still required:

- Relevant impurities content in the formulation should be determined before and after storage study or a justification for "non-formation" of these impurities during the formulation or the storage is required.
- Explosive properties, oxidizing properties, flash point and self-heating: tests should be performed according to CLP criteria (manual UN RTDG).

B.2.12. REFERENCES RELIED ON

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
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. ^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
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.

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
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.

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
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.

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
CP, 2.4/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical and 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.

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
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.

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
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.

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
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.

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
CP, 2.7/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical and 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.

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
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.

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
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.

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
CP, 2.7/04	Shanthaveera ppa, 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.

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
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.

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
CP, 2.8.2/01	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical and 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.

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
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.

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
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.

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
CP, 2.8.6/02	Anand, H.S.	2011	Indoxacarb 150 g/L EC (DPX-KN128) emulsifiable concentrate formulation: Laboratory study of physical and 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.

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
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.

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
CP, 2.8.6/04	Shanthaveera ppa, 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.

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
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.

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
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.

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