

European Commission



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

INDOXACARB

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

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

Version History

When	What
2016-12	Initial RAR

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B.3. DATA ON APPLICATION AND EFFICACY

B.3.1. FIELD OF USE ENVISAGED

Plant protection products containing indoxacarb (DPX-KN128) are to be used in agriculture situations under field and greenhouse conditions, as an insecticide for control of a broad spectrum of lepidopteran in a large range of crops and of some pests belonging to other orders such as homopteran pests (leafhoppers and planthoppers).

More specifically, the claimed representative uses for indoxacarb (DPX-KN128) concern the control of lepidopteran insect pests in the representative crops; lettuce, maize (grain and silage) and sweet corn and for the control of the coleopteran insect pest *Diabrotica virgifera* in maize and sweet corn.

Application is by tractor-mounted hydraulic field sprayers with ground-directed booms. For maize (grain and silage) and sweet corn the application must be made from above the crop.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

Indoxacarb (=DPX-KN128) is active as a larvicide by stomach and contact routes of entry into the insect. The importance of stomach versus contact action varies with the species and the crop situation. Data from laboratory and field indicates that the product is active on all larval stages of Lepidoptera, together with some activity on some other orders. For certain species the active has ovicidal effect. Paralysis occurs within a few hours of exposure and results in cessation of movement and feeding. Final control takes 1-3 days. The metabolite IN-JT333 also shows insecticidal effects.

Study about the lack of insecticidal activity of R enantiomer (IN-KN127), Study submitted to the EU for the first time in this submission and listed under reference lists “Documents Submitted”.

The active substance indoxacarb (DPX-KN128) was discovered by DuPont in 1991 as a racemic mixture (DPX-JW062), where the S-enantiomer is the active insecticidal enantiomer (DPX-KN128) and the R-enantiomer is the non-active insecticidal enantiomer (IN-KN127). The lack of insecticidal activity of IN-KN127 was investigated in DuPont-21517.

Report: Andaloro, J.T., (2006); Insecticidal activity of technical grade DPX-KN128 and DPX-KN127

DuPont Report No.: DuPont-21517

Guidelines: None cited **Deviations:** None

Test Facility: DuPont Stine-Haskell Research Center, Newark, Delaware, USA

Test Facility Report No.: DuPont-21517

GLP: No

Certifying Authority: Not applicable.

Summary

The level of biological activity of DPX-KN128 and IN-KN127 on key Lepidopteran pests was investigated. Larval mortality and feeding damage was investigated and the following laboratory reared species were tested: diamondback moth, *Plutella xylostella*, cabbage looper, *Trichoplusia ni*, cotton bollworm, *Helicoverpa zea*, and cotton budworm, *Heliothis virescens*, beet armyworm, *Spodoptera exigua*, and fall armyworm, *Spodoptera frugiperda*. Technical DPX-KN128 and IN-KN127 were applied at 1, 5, 10 and 50 ppm.

DPX-KN128 showed high activity on all species tested. IN-K127 only showed a side effect when used at 50 ppm on diamondback moth (*Plutella xylostella*) and beet armyworm (*Spodoptera exigua*) larvae, but no noticeable effect on cotton budworm (*Heliothis virescens*), cotton bollworm (*Helicoverpa zea*), cabbage looper (*Trichoplusia ni*) and fall armyworm (*Spodoptera frugiperda*) was observed in terms of mortality.

The level of insecticidal activity expected from IN-KN127 would be negligible.

Efficacy of KN127 and KN128 technical on 2nd instar of *Plutella xylostella* and *Trichoplusia ni* on collards in the laboratory

Treatment	Rate ppm ai	% Mortality 96 h after exposure		% Feeding damage 96 h after exposure (% reduction vs UNT)	
		<i>P. xylostella</i>	<i>T. ni</i>	<i>P. xylostella</i>	<i>T. ni</i>
KN127	1	8	0	50 (0)	90 (0)
	5	0	8	50 (0)	80 (0)
	10	26	0	50 (0)	80 (0)
	20	34	0	40 (20)	90 (0)
	50	26	6	30 (40)	70 (13)
KN128	1	66	100	10 (80)	10 (88)
	5	84	100	10 (80)	10 (88)
	10	100	100	0 (100)	10 (88)
	20	100	100	10 (80)	10 (88)
	50	100	100	0 (100)	10 (88)
X-77 alone (non-ionic surfactant)	500	8	0	50	100
Untreated	----	8	0	50	80

Efficacy of KN127 and KN128 technical on 2nd instar of *Helicoverpa zea* and *Heliothis virescens* on cotton in the laboratory

Treatment	Rate ppm ai	% Mortality 96 h after exposure		% Feeding damage 96 h after exposure (% reduction vs UNT)	
		<i>H. zea</i>	<i>H. virescens</i>	<i>H. zea</i>	<i>H. virescens</i>
KN127	1	0	0	100 (0)	100 (0)
	5	0	0	100 (0)	90 (10)
	10	0	---	100 (0)	---
	20	0	0	100 (0)	90 (10)
	50	0	0	100 (0)	80 (20)
KN128	1	8	4	60 (40)	50 (50)
	5	92	46	30 (70)	30 (70)
	10	100	---	30 (70)	---
	20	100	88	20 (80)	20 (80)
	50	100	96	10 (90)	10 (90)
X-77 alone (non-ionic surfactant)	500	0	0	100	100
Untreated	----	0	0	100	100

Efficacy of KN127 and KN128 technical on 2nd instar of *Spodoptera exigua* and *Spodoptera frugiperda* on soybeans in the laboratory

Treatment	Rate ppm ai	% Mortality 96 h after exposure		% Feeding damage 96 h after exposure (% reduction vs UNT)	
		<i>S. exigua</i>	<i>S. frugiperda</i>	<i>S. exigua</i>	<i>S. frugiperda</i>
KN127	1	---	4	---	70 (30)
	5	0	4	70 (22)	80 (20)
	20	0	0	70 (22)	80 (20)
	50	21	0	50 (44)	70 (30)
	1	---	25	---	30 (70)
KN128	5	54	100	20 (78)	20 (80)
	20	79	96	10 (89)	10 (90)
	50	100	100	10 (89)	10 (90)
	500	0	0	90	100
Untreated	----	0	0	90	100

B.3.3. DETAILS OF INTENDED USE

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	mL product/ ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ max		
1	EU	Maize, Sweet Corn	F	<i>Ostrinia nubilalis</i> <i>Diabrotica virgifera</i>	hydraulic ground directed boom <u>Note:</u> application must be made from above the crop	BBCH 34-77	a) 2 (20 days) b) 2 (20 days)	a) 250 b) 500	a) 37.5 b) 75	100-1000	BBCH 77	EU CRITICAL GAP
2	South Zone	Maize (grain and silage)	F	<i>Ostrinia nubilalis</i> <i>Diabrotica virgifera</i>	hydraulic ground directed boom <u>Note:</u> application must be made from above the crop	BBCH 34-77	a) 2 (20 days) b) 2 (20 days)	a) 250 b) 500	a) 37.5 b) 75	100-1000	BBCH 77	
3	Central Zone Northern Zone	Maize (grain and silage)	F	<i>Ostrinia nubilalis</i> <i>Diabrotica virgifera</i>	hydraulic ground directed boom <u>Note:</u> application must be made from above the crop	BBCH 34-77	a) 2 (20 days) b) 2 (20 days)	a) 250 b) 500	a) 37.5 b) 75	200-700	BBCH 77	

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	mL product/ ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ max		
4	South Zone	Sweet corn	F	<i>Ostrinia nubilalis</i> <i>Diabrotica virgifera</i>	hydraulic ground directed boom <u>Note</u> application must be made from above the crop	BBCH 34-77	a) 2 (20 days) b) 2 (20 days)	a) 250 b) 500	a) 37.5 b) 75	100-1000	3	
5	Central Zone Northern Zone	Sweet corn	F	<i>Ostrinia nubilalis</i> <i>Diabrotica virgifera</i>	hydraulic ground directed boom <u>Note</u> application must be made from above the crop	BBCH 34-77	a) 2 (20 days) b) 2 (20 days)	a) 250 b) 500	a) 37.5 b) 75	200-700	3	
6	EU	Lettuce	F	<i>Autographa gamma</i> <i>Chrysodeixis chalcites</i> <i>Helicoverpa armigera</i> <i>Mythimna unipuncta</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i>	hydraulic ground directed boom	BBCH 13-49 Seed crops BBCH 13-59	a) 4 (7 days) b) 4 (7 days)	a) 250 b) 1000	a) 37.5 b) 150	200-1000	1	EU CRITICAL GAP
7	South Zone except for France	Lettuce	F	<i>Autographa gamma</i> <i>Chrysodeixis chalcites</i> <i>Helicoverpa armigera</i> <i>Mythimna unipuncta</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i>	hydraulic ground directed boom	BBCH 13-49 Seed crops BBCH 13-59	a) 4 (7 days) b) 4 (7 days)	a) 250 b) 1000	a) 37.5 b) 150	200-1000	1	

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Cf B3.3.

B.3.5. METHOD OF APPLICATION

The representative crops, lettuce, maize (grain and silage), and sweet corn, are treated with tractor-mounted hydraulic field sprayers with ground-directed booms. For maize (grain and silage) and sweet corn the application must be made from above the crop.

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION**Maximum number of applications and their timing**

Indoxacarb 150 g/L EC will be applied at an interval of 7-20 days with a maximum of 2-4 applications per crop / season depending on crop and pest pressure. The PHI varies by crop and an overview is presented in Table 1.

Table 1
Number and timing of applications of Indoxacarb 150 g/L EC

Crop	Maximum number of treatments	Timing
Lettuce	4 (7 days)	BBCH 13-49 Seed crops: BBCH 13-59
Maize (grain and silage) & Sweet corn	2 (20 days)	BBCH 34-77

For each application, growth stages of the crop or plants to be protected

Applications of Indoxacarb 150 g/L EC is based on pest development.

Application to lettuce can be made from 3rd leaf unfolded until lettuce head fully developed (BBCH 13-49). In lettuce for seed production application can be made from 3rd leaf unfolded until first flower petals are visible (BBCH 13-59).

Application to maize (grain and silage) and sweet corn can be made from 4th node detectable until 70% of kernels have reached full size (BBCH 34-77)

For each application, development stage of the harmful organisms concerned

Application of Indoxacarb 150 g/L EC should be made just before egg hatch or at young larvae to achieve maximum activity.

Duration of protection afforded by each application

Duration of control of Indoxacarb 150 g/L EC is 7-20 days depending on pest, crop, and pest pressure.

Duration of protection afforded by the maximum number of applications

Season-long protection can be achieved with the maximum proposed applications per crop. However, Indoxacarb 150 g/L EC is recommended to be a part of a plant protection programme to support resistance management.

B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS**Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops**

Use of Indoxacarb 150 g/L EC according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling.

Limitations on choice of succeeding crops

Use of Indoxacarb 150 g/L EC according to the proposed GAP does not limit choice of rotational crops and does not justify a specific labelling.

Description of damage to rotational crops

None observed.

B.3.8. PROPOSED INSTRUCTIONS FOR USE

Please refer to B.3.3, table of uses.

B.3.9. EFFECTIVENESS

More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

Please refer to Volume 3 CA B.3 (active substance), paragraph B.3.7.

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

B.3.13. 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, 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	N.A. ^a
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 EU GLP: No Published: No	N	N		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.

