

# *European Commission*



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

**INDOXACARB**

**Volume 3 – B.1 (AS)**

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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## B.1. IDENTITY

### B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE

<b>B.1.1.1. Common name proposed or ISO-accepted and synonyms</b>	Indoxacarb
<b>B.1.1.2. Chemical name (IUPAC and CA nomenclature)</b>	
IUPAC	methyl (S)-N-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)indeno[1,2-e][1,3,4]oxadiazin-2-ylcarbonyl]-4'-(trifluoromethoxy)carbanilate
CA	methyl (4aS)-7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate
<b>B.1.1.3. Producer's development code number</b>	<p>The following development codes are used in the EU renewal dossier for indoxacarb:</p> <ul style="list-style-type: none"> <li>• DPX-KN128: The pure insecticidal active isomer (S-isomer) and the technical material for this active substance renewal dossier</li> <li>• DPX-MP062 is the development code for the technical material containing approximately 75% DPX KN128 and 25% IN-KN127 (insecticidally inactive enantiomer), used as reference material in Indoxacarb DAR and review report (Indoxacarb SANCO/1408/2001 Rev.3) from 2005.</li> <li>• DPX-JW062 is the development code for the racemic mixture of DPX-KN128 and IN-KN127.</li> </ul>
<b>B.1.1.4. CAS, EEC and CIPAC numbers</b>	
CAS	173584-44-6
EEC	None
CIPAC	612
<b>B.1.1.5. Molecular and structural formula, molecular mass</b>	
Molecular formula	$C_{22}H_{17}ClF_3N_3O_7$
Structural formula	<p>Structure of indoxacarb (DPX-KN128):</p>
Molecular mass	527.84 g/mole

<b>B.1.1.6. Method of manufacture (synthesis pathway) of the active substance</b>	CONFIDENTIAL information – see Volume 4
<b>B.1.1.7. Specification of purity of the active substance in g/kg</b>	<p><b>Minimum purity is 930 g/kg</b></p> <p>The technical material considered for indoxacarb active substance approval in 2006 (entry 119 in Regulation EU 540/2011) was DPX-MP062 which is an isomeric mixture of DPX-KN128 (the insecticidal active (S) indoxacarb) and IN-KN127 (insecticidal inactive (R)-indoxacarb) in a 75:25 ratio with a minimum purity of 628 g/kg.</p> <p>Since then DuPont has been able to move from DPX-MP062 to DPX-KN128 technical material (single enantiomeric form) which has increased the minimum purity to 930 g/kg.</p> <p>Today, DuPont is in a transition phase moving all formulated product registrations to DPX-KN128 technical material.</p>
<b>B.1.1.8. Identity and content of additives (such as stabilisers) and impurities</b>	
<b><i>B.1.1.8.1. Additives</i></b>	CONFIDENTIAL information – see Volume 4
<b><i>B.1.1.8.2. Significant impurities</i></b>	CONFIDENTIAL information – see Volume 4
<b><i>B.1.1.8.3. Relevant impurities</i></b>	<p>Impurity IN-06439 corresponds to “tetraethyl base”</p> <p>Impurity IN-R1T94 corresponds to “tetraethyl hydrol”</p> <p>Impurity IN-J1063 corresponds to “tetraethyl ketone”</p> <p>IN-C0800 corresponds to “Ethyl violet”</p> <p>Toluene</p>
<b>B.1.1.9. Analytical profile of batches</b>	CONFIDENTIAL information – see Volume 4

**B.1.2. REFERENCES RELIED ON**

No study provided.