Renewal Assessment Report

under Regulation (EC) 1107/2009

Zoxamide

Volume 3

Active substance
B1. Identity

Rapporteur Member State: Latvia
Co-Rapporteur Member State: France

Version history

Date	Subject
2001	Initial DAR Draft Assessment Report (DAR) – prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC. + 1st addendum Jun 2002 + 2nd addendum July 2002 + 3nd addendum April 2003
2016	RAR

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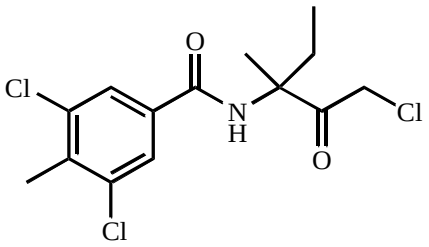
B.1. IDENTITY

B.1.1. Identity of the active substance (IIA 1, 3.1)

B.1.1.1 Common name proposed or ISO-accepted and synonyms (IIA 1.3)	Zoxamide
B.1.1.2 Chemical name (IUPAC and CA nomenclature) (IIA 1.4)	
IUPAC	3,5-Dichloro-N-(3-chloro-1-ethyl-1-methylacetonyl)-p-toluamide
CA	3,5-Dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methylbenzamide
B.1.1.3 Producer's development code numbers	Development codes: RH-117,281 and RH-7281
B.1.1.4 CAS, EEC and CIPAC numbers	
CAS	156052-68-5
EEC	Not assigned
CIPAC	640
B.1.1.5 Molecular and structural formulae, molecular mass	
Molecular formula	$C_{14}H_{16}NO_2Cl_3$
Structural formula	 The technical active ingredient consists of a single racemic compound containing one chiral center. Both enantiomers are present in equal quantities.
Molecular mass	336.65 g/mol

B.1.1.6 Method of manufacture (synthesis pathway) of the active substance	Refer to confidential volume 4
B.1.1.7 Specification of purity of the active substance in g/kg	Minimum purity of active substance: 950 g/kg
B.1.1.8 Identity and content of additives (such as stabilisers) and impurities	
B.1.1.8.1. *Additives*	Refer to confidential volume 4
B.1.1.8.2. *Significant impurities*	Refer to confidential volume 4
B.1.1.8.3. *Relevant impurities*	Not contain relevant impurities
B.1.1.9 Analytical profile of batches	Refer to confidential volume 4

B.1.2. References relied on

Identity of the active substance (Annex IIA 1, 3.1 to 3.4)
Refer to confidential volume 4