European Commission

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

LENACIL

Volume 3 – B.1 (AS)

Rapporteur Member State : Belgium
Co-Rapporteur Member State : Austria

Version History

When	What
November 2007 – July 2009	Draft Assessment Report (DAR) – prepared by RMS BE in the context of the inclusion of the a.s. in Annex I to Council Directive 91/414/EEC. Updated versions of the initial DAR, as well as addenda to the initial DAR, were issued in the period February 2009 – May 2009 (before and after experts' meetings) and were compiled by EFSA in a final 'addendum' dated July 2009.
December 2012 – March 2013	Addenda to DAR Vol.3, B.8 and B.7 (Environmental Fate & Behaviour and Residues), respectively – prepared by RMS BE in the context of the evaluation of confirmatory information requested by Commission Directive 2010/39/EU.
May 2016	Update of DAR Vol.3, B.6 (Toxicology and metabolism) – prepared by RMS BE in the context of the evaluation of confirmatory data on the relevance of ground water metabolites (following classification of lenacil according to Reg. (EC) No 1272/2008).
May 2019	Draft Renewal Assessment Report (DRAR) – prepared by RMS BE in the context of the application for renewal of approval of the a.s. according to Reg. (EU) No 844/2012. *Note: The DRAR is a stand-alone document containing the evaluations already displayed in the initial DAR (incl. its addenda and updated versions), as well as the new assessments. The revision of the initial DAR has been done in accordance with SANCO/10180/2013 rev.1 (March 2013), with changes to the original text – resulting from assessment of new studies (or reconsideration of old studies or studies that were not yet previously peer-reviewed) – being highlighted by means of yellow shading. Changes to the original conclusions have been highlighted in level 2 of Vol.1.*

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS.

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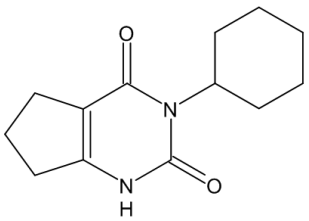
B.1. IDENTITY

B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE

B.1.1.1. Common name proposed or ISO-accepted and synonyms	Lenacil
B.1.1.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	3-cyclohexyl-1,5,6,7-tetrahydrocyclopentapyrimidine-2,4(*3H*)-dione
CA	3-cyclohexyl-6,7-dihydro-1H-cyclopentapyrimidine-2,4(*3H,5H*)-dione
B.1.1.3. Producer's development code number	DPX-B0634 (synonym : B10048563)
B.1.1.4. CAS, EEC and CIPAC numbers	
CAS	2164-08-1
EEC	218-499-0 (EINECS)
CIPAC	163
B.1.1.5. Molecular and structural formula, molecular mass	
Molecular formula	$C_{13}H_{18}N_2O_2$
Structural formula	
Molecular mass	234.3 g/mol
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	Confidential information, for details please refer to the confidential Vol.4.
B.1.1.7. Specification of purity of the active substance in g/kg	The minimum purity is 975 g/kg. For details please refer to the confidential Vol.4.
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	
B.1.1.8.1. *Additives*	Confidential information, for details please refer to the confidential Vol.4.
B.1.1.8.2. *Significant impurities*	Confidential information, for details please refer to the confidential Vol.4.
B.1.1.8.3. *Relevant impurities*	Impurities potentially relevant have been identified. For details, please refer to the confidential Vol.4.
B.1.1.9. Analytical profile of batches	Confidential information, for details please refer to the confidential Vol.4.

B.1.2. REFERENCES RELIED ON

None.