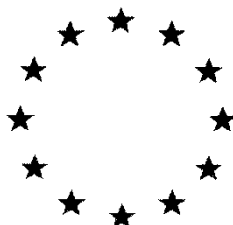


# *European Commission*



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

**LENACIL**

**Volume 3 – B.2 (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.  <i>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.</i>

*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.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE**

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.1. MELTING POINT AND BOILING POINT</b>						
<b>Melting, freezing or solidification point</b> B.2.1/01	EEC A.1, OECD 102 (capillary method – metal block) OPPTS Series 830.7200	Lenacil pure grade active ingredient, 066406003 (99%)	Melting point not determinable; decomposes >270°C	<b>Initial monograph:</b> Acceptable.  <b>Renewal:</b> The study remains acceptable for renewal.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon.
<b>Boiling point</b> B.2.1/02	EEC A.2, OECD 103 OPPTS Series 830.7220	Lenacil pure grade active ingredient, 066406003 (99%)	Test not performed since the test substance was observed to decompose prior to melting:  Boiling point not determinable; decomposes >270°C	<b>Initial monograph:</b> Acceptable.  <b>Renewal:</b> The study remains acceptable for renewal.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>Decomposition Sublimation temperature</b> B.2.1/03	EEC A.1 OECD 102 (heated block)	Lenacil pure grade active ingredient, 066406003 (99%)	Temperature of decomposition: >270°C	<b>Initial monograph:</b> Acceptable. Lenacil (pure grade) begins to decompose at approximately 270°C.  <b>Renewal:</b> The study remains acceptable for renewal.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon

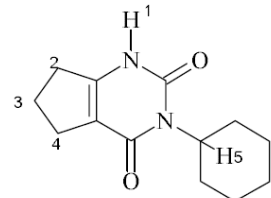
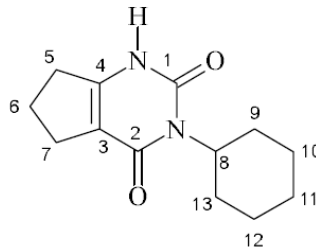
Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.2. VAPOUR PRESSURE, VOLATILITY</b>						
<b>Vapour pressure</b> <b>B.2.2/01</b>	OECD 104 EEC A.4. OPPTS Series 830.7950  (vapour pressure balance method)	Lenacil pure grade active ingredient, 066406003 (99%)	Measurements were done at temperatures in range 107.5 – 167.5°C Vapour pressure at 25°C (calculated by extrapolation) is $1.7 \times 10^{-9}$ Pa	<b>Initial monograph:</b> Acceptable. Lenacil is a very slightly volatile compound.  <b>Renewal:</b> The study remains acceptable for renewal. Lenacil is a very slightly volatile compound.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>Volatility (Henry's Law constant)</b> <b>B.2.2/02</b>	Calculation	n.a.	Henry's law constant $H = 1.3 \times 10^{-7}$ Pa m <sup>3</sup> mol <sup>-1</sup> Log H = -6.89  Calculated from the water solubility value of 3 mg/L (Study AMR 2435-92) and vapour pressure of $1.7 \times 10^{-9}$ Pa (study ACD 025/0141039) at 25°C.	<b>Initial monograph:</b> Acceptable. Lenacil is very slightly volatile from water.  <b>Renewal:</b> The study remains acceptable for renewal. Lenacil is a very slightly volatile compound. It is however noted that the value of 3 mg/L from study AMR 2435-92 considered not acceptable at the time of the first approval (because of the use of the flask method rather than the column elution method) was used to allow the determination of the volatility constant. Nevertheless, since the water solubility determined at pH 7 (distilled water) in study CEMS-2787 using column elution method and considered acceptable is of the same order of magnitude (2.9 mg/L), the value of 3	n.a. (calculation)	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
				mg/L is considered acceptable to perform the calculation of the volatility constant.		
<b>B.2.3. APPEARANCE (PHYSICAL STATE, COLOUR)</b>						
<b>Physical state and colour</b> <b>B.2.3/01</b>	OPPTS Series 830.6302 Visual assessment	Lenacil pure grade active ingredient, 066406003 (99%)	Colour and physical state: Light beige solid. Characteristic odour.	<b>Initial monograph:</b> Acceptable. <b>Renewal:</b> The study remains acceptable for renewal.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
	Visual assessment	Lenacil technical grade active ingredient, 141712003 (98.9%, reported in study by Hamroll 2003 but 98.6% reported in the CoA in study by Comb A. L. 2002)	Colour and physical state: Fine powder, light beige solid, slight characteristic odour	<b>Initial monograph:</b> Acceptable. <b>Renewal:</b> The study remains acceptable for renewal.	N	SHRM Report, Hamroll, 2003 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>B.2.4. SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY</b>						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference																
Ultraviolet/visible (UV/VIS) B.2.4/01	OECD 101 (UV-VIS) OPPTS Series 830.7050	Lenacil pure grade active ingredient, 066406003 (99%)	<p>The UV/Visible spectrum is shown in <b>Erreur ! Source du renvoi introuvable.</b> (neutral), <b>Erreur ! Source du renvoi introuvable.</b> (acidic) and <b>Erreur ! Source du renvoi introuvable.</b> (basic) of the study report.</p> <p>UV-VIS (scan range 220 – 800 nm, spectra recorded from 220 to 400 nm) :</p> <p>UV/VIS absorbance characteristics :</p> <table><tr><td></td><td><math>\lambda_{\text{max}}</math> (nm)</td><td><math>\epsilon</math> (L.mol<sup>-1</sup>.cm<sup>-1</sup>)</td></tr><tr><td>Neutral water/acetonitrile 3 : 1 v/v</td><td>271 at <math>\lambda</math> = 290 nm</td><td>7880 1760*</td></tr><tr><td>Acidic 0.133M HCl / acetonitrile 3 : 1 v/v</td><td>271 at <math>\lambda</math> = 290 nm</td><td>7990 1760*</td></tr><tr><td>Alkaline 0.133M NaOH / acetonitrile 3 : 1 v/v</td><td>227 291</td><td>7220 10100</td></tr></table> <p>*calculated estimation by RMS on the basis of the provided UV absorption spectra</p>		$\lambda_{\text{max}}$ (nm)	$\epsilon$ (L.mol <sup>-1</sup> .cm <sup>-1</sup> )	Neutral water/acetonitrile 3 : 1 v/v	271 at $\lambda$ = 290 nm	7880 1760*	Acidic 0.133M HCl / acetonitrile 3 : 1 v/v	271 at $\lambda$ = 290 nm	7990 1760*	Alkaline 0.133M NaOH / acetonitrile 3 : 1 v/v	227 291	7220 10100	<p><b>Initial monograph:</b> Acceptable All spectra were of good quality and were consistent with the assigned structure of lenacil.</p> <p>Significant UV-absorbance is observed at wavelengths above 290 nm. The UV-absorbance spectrum of lenacil at alkaline conditions is significantly different from that at neutral or acidic conditions, which is an indication of dissociation (see B.2.8/01).</p> <p><b>Renewal:</b> The study remains acceptable for renewal.</p>	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon				
	$\lambda_{\text{max}}$ (nm)	$\epsilon$ (L.mol <sup>-1</sup> .cm <sup>-1</sup> )																				
Neutral water/acetonitrile 3 : 1 v/v	271 at $\lambda$ = 290 nm	7880 1760*																				
Acidic 0.133M HCl / acetonitrile 3 : 1 v/v	271 at $\lambda$ = 290 nm	7990 1760*																				
Alkaline 0.133M NaOH / acetonitrile 3 : 1 v/v	227 291	7220 10100																				
Infrared (IR) B.2.4/02		Lenacil pure grade active ingredient, 066406003 (99%)	<p>The IR spectrum for lenacil is shown in <b>Erreur ! Source du renvoi introuvable.</b> of the study report and absorption bands and assignments are given here below.</p> <p>IR (KCl, scan range 4000 – 500 cm<sup>-1</sup>):</p> <table><tr><th>Frequency (cm<sup>-1</sup>)</th><th>Assignment</th><th>Intensity</th><th>Observation</th></tr><tr><td>3100-3350</td><td>N-H stretch (H-bonded)</td><td>Strong</td><td>Broad multiplet</td></tr><tr><td>2840-3000</td><td>C-H (alkyl) stretches</td><td>Variable</td><td>Sharp bands</td></tr><tr><td>1500-1750</td><td>Region includes:</td><td>Strong</td><td>Sharp bands</td></tr></table>	Frequency (cm <sup>-1</sup> )	Assignment	Intensity	Observation	3100-3350	N-H stretch (H-bonded)	Strong	Broad multiplet	2840-3000	C-H (alkyl) stretches	Variable	Sharp bands	1500-1750	Region includes:	Strong	Sharp bands	<p><b>Initial monograph:</b> Acceptable. Spectrum was consistent with the assigned structure of lenacil.</p> <p><b>Renewal:</b> Acceptable. Spectrum is consistent with the assigned structure of lenacil.</p>	Y	ACD 025/014039. Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
Frequency (cm <sup>-1</sup> )	Assignment	Intensity	Observation																			
3100-3350	N-H stretch (H-bonded)	Strong	Broad multiplet																			
2840-3000	C-H (alkyl) stretches	Variable	Sharp bands																			
1500-1750	Region includes:	Strong	Sharp bands																			

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings				Comments (Acceptable / Non acceptable)	GLP	Reference
				C=O (amide) stretches C=C stretch N-H deformation N-C=O symmetric stretch					
			1000-1500	Region includes: CH <sub>2</sub> deformations C-N stretch N-H in plane deformation	Medium/weak	Sharp bands			
			<1000	Region includes: N-H out of plane deformation Skeletal vibrations	Weak	Sharp bands			



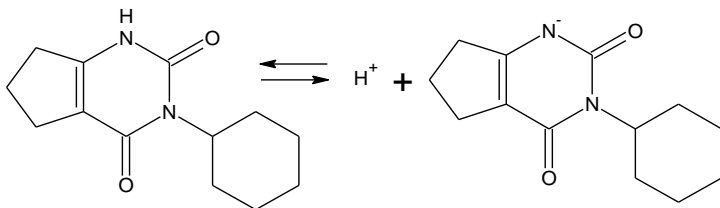
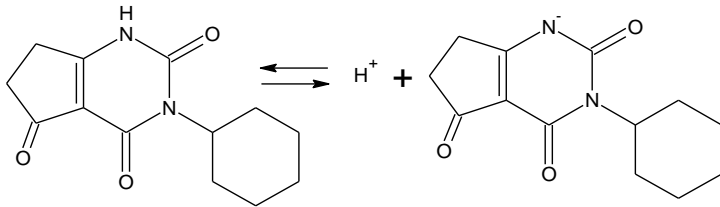
Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference																		
Nuclear magnetic resonance (NMR) B.2.4/03		Lenacil pure grade active ingredient, 066406003 (99%)	<p>The structure and the assignment of chemical shifts of proton and carbon atoms are given in <b>Erreur ! Source du renvoi introuvable.</b> and <b>Erreur ! Source du renvoi introuvable.</b> of the study report and chemical shifts are provided here below. The NMR spectra were consistent with the assigned structure of lenacil (pure grade):</p> <p><b><sup>1</sup>H-NMR</b> (DMSO-d<sub>6</sub>, 400 MHz)</p> <div></div> <table><thead><tr><th>Assignment</th><th>Chemical shift (ppm)</th></tr></thead><tbody><tr><td>H<sup>1</sup></td><td>11.0</td></tr><tr><td>H<sup>5</sup></td><td>4.6</td></tr><tr><td>Protons on Carbon 4</td><td>2.6</td></tr><tr><td>Protons on Carbon 2</td><td>2.4</td></tr><tr><td>Protons on Carbon 3</td><td>2.0</td></tr><tr><td>Protons on cyclohexane</td><td>1.2 – 1.8</td></tr></tbody></table> <p><b><sup>13</sup>C-NMR</b> (DMSO-d<sub>6</sub>, 100 MHz)</p> <div></div> <table><thead><tr><th>Assignment</th><th>Chemical shift (ppm)</th></tr></thead><tbody><tr><td>C<sup>1</sup></td><td>161</td></tr></tbody></table>	Assignment	Chemical shift (ppm)	H <sup>1</sup>	11.0	H <sup>5</sup>	4.6	Protons on Carbon 4	2.6	Protons on Carbon 2	2.4	Protons on Carbon 3	2.0	Protons on cyclohexane	1.2 – 1.8	Assignment	Chemical shift (ppm)	C <sup>1</sup>	161	<p><b>Initial monograph:</b> Acceptable. Spectrum was consistent with the assigned structure of lenacil.</p> <p><b>Renewal:</b> Acceptable. Spectra are consistent with the assigned structure of lenacil.</p>	Y	ACD 025/014039. Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
			Assignment	Chemical shift (ppm)																				
			H <sup>1</sup>	11.0																				
H <sup>5</sup>	4.6																							
Protons on Carbon 4	2.6																							
Protons on Carbon 2	2.4																							
Protons on Carbon 3	2.0																							
Protons on cyclohexane	1.2 – 1.8																							
Assignment	Chemical shift (ppm)																							
C <sup>1</sup>	161																							

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings		Comments (Acceptable / Non acceptable)	GLP	Reference
			C <sup>2</sup>	153			
			C <sup>4</sup>	152			
			C <sup>3</sup>	109			
			C <sup>8</sup>	52			
			C <sup>5</sup>	31			
			C <sup>9</sup> and C <sup>13</sup>	28			
			C <sup>11</sup>	27			
			C <sup>10</sup> and C <sup>12</sup>	26			
			C <sup>7</sup>	25			
			C <sup>6</sup>	20			
Mass spectra (MS) B.2.4/04		Lenacil pure grade active ingredient, 066406003 (99%)	The MS spectrum is provided in <b>Erreur ! Source du renvoi introuvable.</b> of the study report and peak assignments are provided here below. The mass spectrum was consistent with the assigned structure of lenacil (pure grade):  MS (EI, 70 eV) :		<b>Initial monograph:</b> Acceptable. Spectrum was consistent with the assigned structure of lenacil.  <b>Renewal:</b> Spectrum is consistent with the assigned structure of lenacil.	Y	ACD 025/014039. Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
		Peak – m/z	Assignment				
		234	Molecular ion				
		153	Loss of cyclohexyl ring from molecular ion				
		110	Loss of (OCNH) from m/z = 153				

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
Optical purity				Optical purity is not required since lenacil is not a resolved isomer.		
Spectra for impurities B.2.4/05			None of the impurities are considered to be of toxicological, ecotoxicological or environmental significance.	<b>Initial monograph:</b> no spectra of impurities are required. <b>Renewal:</b> no spectra of impurities are required.		
<b>B.2.5. SOLUBILITY IN WATER</b>						
Solubility in water B.2.5/01	German Guidelines for the Official Testing of Plant Protection Products I 1-2, US EPA 63-8	Lenacil technical B0634-88, (98.9%)	Water solubility at 20°C: pH 5 = 4 mg/L pH 7 = 3 mg/L pH 9 = 3 mg/L  Solubility in distilled water at 25°C: 3 mg/L	<b>Initial monograph:</b> Not acceptable. The method used in this study is considered to be inappropriate. For products with a solubility < 10 mg/L, the column elution method should be used. <b>Renewal:</b> The study was already considered not acceptable for first approval.	Y	AMR 2435-92 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
B.2.5/02	EEC method A6. Column elution method	Lenacil pure grade active ingredient 108906003 (99%)	Water solubility at 20°C (two test flow rates : ~12.5 and ~25 mL/h): pH 5 = 2.9 mg/L pH 7 = 2.9 mg/L pH 9 = 3.6 mg/L	<b>Initial monograph :</b> Acceptable Lenacil has a low water solubility, which is slightly increased at high pH (pH ≥ 9).	Y	CEMS-2787 Study summarised in Lenacil DAR,

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference																
			<p>Solubility increases slightly with pH.</p> <p>Concentrations were determined by HPLC-UV. For details on the method and validation, please refer to Vol.3 CA-B.5.1.2.7 – Study no. 1.</p>	<p><b>Renewal:</b> The study remains acceptable for renewal.</p>		Volume 3, B.2, 2007 and is relied upon																
B.2.6. SOLUBILITY IN ORGANIC SOLVENTS																						
<p>Solubility in organic solvents</p> <p>B.2.6/01</p>	EPA 63-8, German Guidelines for the Official Testing of Plant Protection Products I 1-2	Lenacil technical B0634-88, (98.9%)	<p>The method is based on the method EEC A6 (flask method):</p> <p>Solubility at 20°C:</p> <table><tr><th>Solvent</th><th>Solubility (mg/L)</th></tr><tr><td>Acetone</td><td>690</td></tr><tr><td>Acetonitrile</td><td>230</td></tr><tr><td>Dichloromethane</td><td>2000</td></tr><tr><td>Ethyl acetate</td><td>500</td></tr><tr><td>Hexane</td><td>1.3</td></tr><tr><td>Methanol</td><td>1500</td></tr><tr><td>Toluene</td><td>80</td></tr></table> <p>Concentrations were determined by reversed-phase HPLC-UV.</p> <p>The method validation was not provided. However, in the course of the assessment, the notifier provided limited validation data from AMR 2377-92 data records. The method was found to be linear in the ~ 0.1 – 0.96 mg/mL for the different solvents (except for hexane : 0 – 0.096 mg/mL) with <math>r^2 \geq 0.9981</math> (n = 3 or higher, with more than likely more than a single injection). Some summary of accuracy and RSD results for the lowest and highest concentration levels were provided showing results within the 70 -110 % range (except for toluene at the highest level with 119% ) and RSD in the 0.01 – 2.88 range (except for hexane for which a result of 17.9 was obtained). The notifier stated that chromatograms from all solvents demonstrated the absence of any background matrix peaks that eluted near lenacil. A typical chromatogram for the determination of the solubility in methanol has been provided.</p>	Solvent	Solubility (mg/L)	Acetone	690	Acetonitrile	230	Dichloromethane	2000	Ethyl acetate	500	Hexane	1.3	Methanol	1500	Toluene	80	<p><b>Initial monograph:</b> Acceptable. Lenacil is slightly soluble in hexane, moderately soluble in toluene, acetonitrile, ethylacetate and acetone and readily soluble in methanol and dichloromethane.</p> <p><b>Renewal:</b> The study remains acceptable for renewal.</p>	Y	AMR 2377-92 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
Solvent	Solubility (mg/L)																					
Acetone	690																					
Acetonitrile	230																					
Dichloromethane	2000																					
Ethyl acetate	500																					
Hexane	1.3																					
Methanol	1500																					
Toluene	80																					

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.7. PARTITION COEFFICIENT N-OCTANOL/WATER</b>						
Partition coefficient n-octanol/water B.2.7/01	EEC A.8./ OECD 117 (HPLC method) OPPTS Series 830.7550, 830.7560 or 830.7570	Lenacil pure active ingredient, 066406003 (99%)	At 25°C: pH 4: $\log_{10} P_{ow} = 1.70$ pH 7: $\log_{10} P_{ow} = 1.69$ pH 10: $\log_{10} P_{ow} = 1.25$	<b>Initial monograph:</b> Acceptable. The octanol/water partition coefficient (log Pow) of lenacil is below 3 and therefore, bioaccumulation of lenacil in the environment is considered to be unlikely. At higher pH, the log Pow is decreased due to dissociation of lenacil (see B.2.8).  <b>Renewal:</b> The study remains acceptable for renewal. Bioaccumulation of lenacil is considered to be unlikely.	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
	calculation KOWWIN (v1.68)	Metabolite IN-KE121	calculated value: $\log K_{ow} = 1.04^*$	The study has been submitted for the purpose of the renewal.  The Log Pow has been estimated by EPIWIN v.4.1 suite calculation (KOWWIN v.1.68).	N	DuPont-39162
	calculation KOWWIN (v1.68)	Metabolite IN-KF313	calculated value: $\log K_{ow} = 3.111^*$	The study has been submitted for the purpose of the renewal.  The Log Pow has been estimated by EPIWIN v.4.1 calculation (KOWWIN v.1.68).	N	DuPont-39162

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.8. DISSOCIATION IN WATER</b>						
<b>Dissociation constant</b> <b>B.2.8/01</b>	OECD 112 OPPTS Series 830.7370	Lenacil pure active ingredient, 066406003 (99%)	<p><math>pK_a = 10.7</math> at 25°C</p> 	<p><b>Initial monograph:</b> Lenacil is a weak acid with a <math>pK_a</math> of 10.7. This explains the difference between the neutral and basic UV spectra of the molecule (see B.2.1.9).</p> <p><b>Renewal:</b> The study remains acceptable for renewal.</p>	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>B.2.8/02</b>	OECD 112 (UV spectrophotometric method)	IN-KF313, technical metabolite KF313-1 (98.3%)	<p><math>pK_a = 7.5</math> at 20°C</p> 	<p><b>Initial monograph:</b> Study is considered acceptable, but is actually not required to address Annex Point IIA 2.9.4.</p> <p><b>Renewal:</b> The study remains acceptable for renewal.</p>	Y	AMR 2764-93 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>B.2.9. FLAMABILITY AND SHELF-HEATING</b>						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>Flammability</b> <b>B.2.9/01</b>	EEC A.10. OPPTS Series 830.6315  (Burning rate test)	Lenacil technical, 141712003 (98.6%)	Lenacil technical ignited and propagated a flame over 200 mm in 8 minutes and 26 seconds.  Lenacil is not highly flammable.	<b>Initial monograph:</b> Acceptable. Lenacil is not highly flammable.  <b>Renewal:</b> The study remains acceptable for renewal. Lenacil is not expected to be highly flammable (the propagation over 200 mm is more than 4 min as reported in EEC A 10 and more than 2 min. as recorded in Test N.1.).	Y	ACD 024/013898 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>Self heating</b> <b>B.2.9/02</b>	EEC A.16. OPPTS Series 830.6315	Lenacil technical, 141712003 (98.6%)	Lenacil is not self-igniting below 400°C.  A slight sample temperature fluctuation was observed around 300°C, which is consistent with the decomposition of the test substance.	<b>Initial monograph:</b> Acceptable. Lenacil is not self-igniting.  <b>Renewal:</b> The study remains acceptable for renewal. Lenacil is not expected to exhibit self-heating properties.	Y	ACD 024/013898
<b>B.2.10. FLASH POINT</b>						
<b>Flash point</b> <b>B.2.10/01</b>				Lenacil is a solid therefore flash point is not relevant. Additionally, melting point was not determinable; lenacil decomposes >270°C		
<b>B.2.11. EXPLOSIVE PROPERTIES</b>						

Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>Explosive properties</b> <b>B.2.11/01</b>	EEC A.14. OPPTS Series 830.6316	Lenacil technical, 141712003 (98.6%)	<p>No explosion occurred at the conditions of the thermal (Koenen test apparatus), shock (fall hammer test apparatus) and friction test, respectively.</p> <p>Hoenen test: yellow flame, tubes recovered intact, no explosion.</p> <p>Fall Hammer test: no evidence of explosion or decomposition.</p> <p>Friction test: no sign of ignition or explosion but slight decomposition indicated by dark mark on porcelain plate.</p> <p>Lenacil is not explosive.</p>	<p><b>Initial monograph:</b> Acceptable. Lenacil is not self-igniting.</p> <p><b>Renewal:</b> The study remains acceptable for renewal. Additionally, lenacil does not really contain chemical groups indicating explosive properties.</p> <p>The notifier also stated that lenacil's oxygen balance is &lt; - 200 (calculation) and that the thermal stability test via DSC (according to OECD 113) in ACD 025/014039 study only shows endothermic effects in traces at ~ 310°C.</p> <p>Lenacil does not exhibit explosive properties.</p>	Y	ACD 024/013898 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>B.2.12. SURFACE TENSION</b>						
<b>Surface tension</b> <b>B.2.12/01</b>	EEC A.5. OECD 115  (Harmonized ring method)	Lenacil pure active ingredient, 066406003 (99%)	62.5 mN/m (90% saturated aqueous solution) at 24°C	<p><b>Initial monograph:</b> Acceptable.</p> <p><b>Renewal:</b> The study remains acceptable for renewal. Lenacil is not considered to be surface active.</p>	Y	ACD 025/014039 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon



Test or Study Annex Point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non acceptable)	GLP	Reference
<b>B.2.13. OXIDISING PROPERTIES</b>						
<b>Oxidizing properties</b> <b>B.2.13/01</b>	EEC A.17.	Lenacil technical, 141712003 (98.6%)	<ul style="list-style-type: none"> <li>- Reference mixture (Barium nitrate/cellulose 3:2) burned vigorously to completion in 56 seconds;</li> <li>- Neither mixture of 2:1, 1:1 or 1:2 test substance/cellulose burned to completion.</li> </ul> <p>Lenacil is not oxidizing</p> <p>Additional statement of notifier: “[...] an examination of the structural formula in accordance with 1.1 of method A17 also establishes that lenacil is not likely to react exothermically with a combustible material. [...]”</p>	<p><b>Initial monograph:</b> Acceptable. Lenacil is not oxidizing.</p> <p><b>Renewal:</b> The study remains acceptable for renewal. However, it is noted that the test is not fully equivalent to the test required for CLP classification but based on the obtained results and the structure of Lenacil, it can be reasonably assumed that Lenacil does not exhibit oxidizing properties.</p>	Y	ACD 024/013898 Study summarised in Lenacil DAR, Volume 3, B.2, 2007 and is relied upon
<b>B.2.14. OTHER STUDIES</b>						
				None required		

Note 1 : the mass spectrometry, vapour pressure and thermal stability tests were performed at Huntingdon Research Centre, Huntingdon Cambridgeshire PE28 4HS. The NMR spectrometry was sub-contracted to Specialist Analysis and Technology Consultancy Service Ltd. (SATCO Ltd) c/o Institute of Food Research, Norwich Research Park, Colney, Norwich, NR4 7UA.

Note 2: Relative density was also determined for first approval in study ACD 025/014039. The method used the EEC A3 method (pycnometer solvent displacement method) and a relative density of 1.31 was found for lenacil (pure grade active ingredient) 066406003 (99%). The relative density is however no longer a requirement under Reg. (EU) 283/2013.

\* It is noted that in the study submitted, estimation of the log Pow for the six polar metabolites has also been done and is as follows : IPM1 (-3.2), PM1 (-1.06), PM2 (-1.18), PM3 (-0.26), PM4 (-1.62) and PM5 (-2.87).

### Conclusion:

The pure active substance lenacil is a light beige solid with a characteristic odour, which starts to decompose at  $\sim >270^{\circ}\text{C}$ . It is very slightly volatile (vapour pressure =  $1.7 \times 10^{-9}$  Pa and Henry's law constant =  $1.3 \times 10^{-7}$  Pa m<sup>3</sup> mol<sup>-1</sup>). Lenacil is not surface active. Lenacil is a weak acid with a pK<sub>a</sub> of 10.7, and has a low water solubility, which

does not vary considerably in the pH range 5 to 9 (3 to 4 mg/L at 20°C). The partition coefficient Log  $P_{ow}$  (1.7 at pH 4 and 1.69 at pH 7; 1.25 at pH 10; at 25°C) does not indicate any risk for bioaccumulation in the environment. Lenacil (as manufactured) is not self-igniting, not highly flammable, not explosive and does not exhibit oxidising properties and hence, it does not need to be classified for physical and chemical hazards.

**B.2.15. REFERENCES RELIED ON**

Peer reviewed open literature dealing with the side effects on health, environment, and non-target species for lenacil, and its metabolites is reported in the relevant sections. No peer reviewed open literature data were submitted for the physical and chemical properties.

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.1/01  (IIA 2.1.1-01, IIA2.1.2-01 and IIA2.1.3-01)  Vol.3 CA-B.2.1/01, B.2.1/02, b.2.1/03	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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.  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007
CA, 2.2/01  (IIA 2.3.1-01, IIA 2.3.2-01)  Vol.3 CA-B.2.2/01 and B.2.2/02	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.3/01  Vol.3 CA-B.2.3/01	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted.  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007
CA, 2.3/02  (IIA 2.4.1-01)  Vol.3 CA-B.2.3/02	Hamroll, C.K.	2003	Determination of the physical state, colour and odour of lenacil technical Schirm Ag Divison Hermania SHRM (Not given) GLP: No Published: No	N	N		FMC	Initial monograph November 20017

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.4/01 CA, 2.4/02 CA, 2.4/03 CA, 2.4/04  (IIA 2.5.1-01)  Vol.3 CA-B.2.4/01 – B.2.4/04	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.5/01  (IIA 2.6-01)  Vol.3 CA-B.2.5/02	Bell, A.	2005	Water solubility of lenacil CEM Analytical Services Ltd CEMS-2787 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.5/02 (IIA 2.6-01) Vol.3 CA-B.2.5/01	McQuage, J.D., Smyser B. P.	1992	Solubility of lenacil in water and in pH 5, 7 and 9 aqueous buffers DuPont Experimental Station AMR 2435-92 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection. Additionally the study was considered not acceptable and therefore not relied upon.	FMC	Initial monograph November 2007



<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.6/01  (IIA 2.7-01)  Vol.3 CA-B.2.6/01	McQuage, J.D., Smyser B. P.	1992	Solubility of lenacil in organic solvents DuPont Experimental Station AMR 2377-92 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection. Additionally the study was considered not acceptable and therefore not relied upon.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.7/01 (IIA 2.8-01)  Vol.3 CA-B.2.7/01	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007
CA, 2.7/02  (KCA 2.7/01, but also under KCA 5.8.1/02)  Vol.3 CA-B.2.7/02	Tier, G.J.and Serex, T.L	2014	A Non-Testing Approach to evaluate the relevance of specific groundwater metabolites of Lenacil E.I du Pont de Nemours and Company DuPont-39162 GLP: No Published: No	N	N	-	FMC	No, submitted for the purpose of renewal

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.8/01 (IIA 2.9-04)  Vol.3 CA-B.2.8/01	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007
CA, 2.8/02	Smyser, B.P., Beaver, E.E.	1995	Dissociation constant of IN-KF313 DuPont Experimental Station AMR 2764-93 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 submitted	FMC	

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.9/01 and CA, 2.9/02  (IIA 2.11.1-01 and IIA 2.11.1-02)  Vol.3 CA-B.2.9/01 and B.2.9/02	Comb, A.L.	2002	Lenacil Technical Physico-Chemical Properties Huntingdon Life Sciences Ltd ACD 024/013898 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.11/01 (IIA 2.13-01)  Vol.3 CA-B.2.11/01	Comb, A.L.	2002	Lenacil Technical Physico-Chemical Properties Huntingdon Life Sciences Ltd ACD 024/013898 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.12/01 (IIA 2.14-01)  Vol.3 CA-B.2.12/01	Comb, A.L.	2002	Lenacil (pure grade) physico-chemical properties Huntingdon Life Sciences Ltd ACD025/014039 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

<b>Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP Status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data Protection Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>
CA, 2.13/01 (IIA 2.15-01)  Vol.3 CA-B.2.13/01	Comb, A.L.	2002	Lenacil Technical Physico-Chemical Properties Huntingdon ACD 024/013898 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 submitted  RMS: the study was already considered for the first approval and more than likely out of protection.	FMC	Initial monograph November 2007

No vertebrate studies submitted in this section.

Note:

- Several of the above mentioned studies were owned by DuPont and Schirm GmbH. DuPont confirmed (letter dated from 20.06.2016) that for all lenacil active substance and lenacil product data sponsored by Schirm GmbH or by both companies, E.I. Du Pont de Nemours and Company (DuPont) and Schirm GmbH, which were submitted or referred to for the renewal of approval of lenacil, DuPont is the sole data owner.
- Following of a transfer of the responsibility of EU approval activities of certain active substances owned by E.I. duPont de Nemours and Company, the data applicant for lenacil is FMC Agricultural Solution A/S and the data owner is FMC International Switzerland Sarl (FISSarl) (letter from FMC dated from 05 December 2018).