

European Commission



**Combined Draft Renewal Assessment Report prepared according to
Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report)
according to Regulation (EC) N° 1272/2008**

LENACIL

Volume 2

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.</i> |

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A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED

A.1. IDENTITY

References presented in the table below relates to the confidential section.

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|--------------------|------|--|-------------------------|------------------------|---|-------|--|
| CA, 1.8.1/01 (KCA 1.8.1) Vol.4 C.1.2.2 and C.1.5 | Szymoszek, Andrzej | 2016 | QSAR profiling of impurity [REDACTED] of Lenacil using OECD Toolbox v3.3.5 101581-201605-18-Szy-2 GLP: No Published: No | N | Y | The data presented contains information on composition of the active substance, information is of commercial interest. | FMC | No, submitted for the purpose of renewal |
| CA, 1.8.1/02 (IIA 1.8-01) Vol.4 C.1.2.1 – Study No. 1 | Gonzalez, A. | 1995 | Synthesis process of lenacil GLP: No Pub | N | Y | The study is necessary for the regulatory decision and contains information of commercial interest (manufacturing process). | FMC | Initial Monograph – November 2007 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------------|-----------------|---|-------------------------|------------------------|--|----------------|--|
| CA 1.11/01 (IIA 1.11-01) Vol.4 C1.2.3 – Study No. 1 | Wittig A. | 2000 | Lenacil technical determination of purity and content in five batches UCL Umwelt Control Labor GmbH Report No. PT00/015 GLP: yes Published: No | N | Y | The study is necessary for the regulatory decision and contains information on the composition of the active substance | FMC | Initial Monograph – November 2007 |
| (IIA 1.11-02) Vol.4 C1.2.3 | Hansen S.W. | 1998 | Technical grade lenacil (DPX-B0634). Analysis and certification of product ingredients. E.I. du Pont de Nemours and Company, Report No. AMR 3747-96 GLP: yes Published: No | N | N | | FMC | Initial Monograph – November 2007 |
| CA, 1.11/02 (KCA 1.11/01 and KCA 1.11/03) Vol.4 C.1.2.3 – Study No. 2 | Repp, M. C. | 2016 a | Batch analysis of Lenacil (DPX-B0634) Technical RV1 E. I. du Pont de Nemours and Company DuPont-47336 and DuPont-47336 Confidential GLP: Yes Published: No | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA, 1.11/03 (KCA 1.11/02 and KCA 1.11/04) Vol.4 C.1.2.3 – Study No. 3 | Mc Alpin, J. G. | 2016 | Batch analysis of Lenacil (DPX-B0634) Technical E. I. du Pont de Nemours and Company DuPont 44060 GLP: Yes Published: No | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|---------------------------------|--------------------------------|--|--------------|---|
| CA 1.11/04 Vol.4 C.1.4 | Repp, M. C. | 2016 b | Characterisation of Lenacil Toxicological Batches DPX-B0634-050, DPX-B0634-091, DPX-B0634-158 and DPX-B0634-159 E.I. du Pont de Nemours and Company, USA Report 47543 GLP : Yes Published : No | N | N | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Note: the study has been submitted in the course of the assessment |
| CA, 4.1.1(a)/05 (KCA 4.1.1/01 and 4.1.1/06) Vol. 4 C.1.2.3 – Study No. 1 | Repp, M. C. | 2015 | Validation of the analytical method for determination of lenacil (DPX-B0634) in technical grade lenacil and lenacil end-use products DuPont-44061 GLP: Yes Published: No | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted and contains information on composition of the active substance. | FMC | No, submitted for the purpose of renewal The study is only used as supportive information |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|-----------------------------|-------------|---|---------------------------------|--------------------------------|--|--------------|--|
| CA, 4.1.1(b)/ 01 (IIA 1.11/01) Vol.4 C.1.2.3 – Study No. 1 | Wittig A. | 2000 | Lenacil technical determination of purity and content in five batches UCL Umwelt Control Labor GmbH Report No. PR00/015 GLP: Yes Published: No | N | Y | The study contains information on the composition of the active substance | FMC | Initial Monograph – November 2007 |
| CA, 4.1.1(b)/02 (KCA 4.1.1/02) Vol.4 C.1.2.3.2.2 – Study No. 2 | Repp, M. C., McNally, M. E. | 2015 | Description and validation of the analytical methods for determination of impurities in technical grade DPX-B0634 DuPont-44062 GLP: Yes Published: No | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted and contains information on composition of the active substance. | FMC | No, submitted for the purpose of renewal |
| CA, 4.1.1(b)/03 (KCA 4.1.1/03) Vol.4 C.1.2.3.2.2 – Study No. 3 | Repp, M. C., McNally, M. E. | 2015 | Description and validation of the analytical method for determination of tri-sec-butylphenol polyglycol ether in technical grade lenacil (DPX-B0634) DuPont-45930 GLP: Yes Published: No | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted and contains information on composition of the active substance. | FMC | No, submitted for the purpose of renewal |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|------------------|-------------|---|-----------------------------|----------------------------|--|--------------|-----------------------------------|
| CA 5.4.1 | Reynolds, V.L. | 1989 | Mutagenicity testing of IN E1512-2 in the Salmonella typhimurium plate incorporation assay DuPont Haskell Laboratory HLR 550-89 GLP: Yes Published: No | N | Y | | FMC | Initial monograph – November 2007 |
| CA 5.8.1 | ██████████ | 1989 | Approximate lethal dose (ALD) of E1512-2 in rats, HLR564-89 ████████████████████ HLR 564-89 GLP: Yes Published: No | N | N | | FMC | Initial monograph – November 2007 |

And doc. J – Doc. No. DuPont-43886 EU, Revision No. 1 – 07 October 2016.

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).

A.2. PHYSICAL AND CHEMICAL PROPERTIES**A.2.1. Active substance**

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|--|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|--|--------------|---------------------------------|
| 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 |
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| CA, 2.3/02 (IIA 2.4.1-01) Vol.3 CA-B2.3/02 | 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 2017 |
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|--------------------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|--------------------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|--------------------------|-------------|---|-----------------------------|----------------------------|---|--------------|--|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|----------------------------|------|--|----------------------|---------------------|---|-------|---------------------------------|
| 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 | |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|-----------------------------|----------------------------|---|--------------|---------------------------------|
| 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 |

| Data Requirement No. according to Reg. (EU) 283/2013, (Reference in dossier) Reference in Vol.3 CA-B.2 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP Status Published or not | Vertebrate study Y/N | Data Protection Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|------------|------|--|-------------------------|------------------------|---|-------|---------------------------------|
| 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).

A.2.2. Representative formulation – Lenacil 500 g/L SC

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|-----------|--------------------------|--|----------------------------|--------------------------------------|---|-------|--------------------------------------|
| B 2.1/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |

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| B 2.2/01 | Curl, M.G. | 2006 | Expert statement of the explosive properties of Lenacil SC formulated preparation Not given TSGE 19-10-03.EXP GLP: No Published: No | N | N | - | FMC | No, submitted for purpose of renewal The study was already considered at national level for the zonal evaluation of Venzar 500 SC |
| B 2.2/02 | Curl, M.G. | 2006 | Expert statement of the explosive properties of Lenacil SC formulated preparation Not given TSGE 19-10-03.EXP GLP: No Published: No | N | N | - | FMC | No, submitted for purpose of renewal The study was already considered at national level for the zonal evaluation of Venzar 500 SC |

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|----------|---------------------------------|------|--|---|---|---|-----|--|
| B 2.3/01 | Meinerling, M., Herrmann, S. | 2006 | Determination of the Physico-Chemical Properties and the Accelerated Storage Stability of Venzar 500SC IBACON 26994204 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 at national level for the zonal evaluation of Venzar 500 SC | FMC | No, submitted for purpose of renewal The study was already considered at national level for the zonal evaluation of Venzar 500 SC |
| B 2.3/03 | Fisher, A. | 2006 | Determination of the auto-ignition temperature of Lenacil 500g/L SC in accordance with EEC-Guideline A.15 AllessaChemie GmbH B 081/2005 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 at national level for the zonal evaluation of Venzar 500 SC | FMC | No, submitted for purpose of renewal The study was already considered at national level for the zonal evaluation of Venzar 500 SC |

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|----------|-----------|--------------------------|--|---|---|---|-----|--------------------------------------|
| B 2.4/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.4/03 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |

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| B 2.5/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| B 2.5/02 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| B 2.6/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |

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| B 2.7/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| B 2.7/02 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| B 2.7/03 | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |

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| B 2.8.2/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.8.3/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |

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| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.8.3/02 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |

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| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.8.5.1/01 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |

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| B 2.8.5.1/02 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.8.7/02 | Cornet, C | 2015 (First interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM 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 | No, submitted for purpose of renewal |

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| | Cornet, C | 2016 (Second interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (second interim report) 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 | No, submitted for purpose of renewal |
| | Cornet, C | 2017 (Third interim) | Physical and chemical properties and storage stability tests for a SC formulation containing 500 g/L of lenacil Centre Wallon de Recherches Agronomiques (CRA-W) 23814 IM (third interim report) 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 | No, submitted for purpose of renewal |
| B 2.9/01 | Huby, J-P | 2014 | DPX-B0634 500G/L SC: Laboratory study of physical compatibility in water DuPont de Nemours ERDC AT-14-007 GLP: No 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 | No, submitted for purpose of renewal |

A.3. DATA ON APPLICATION AND EFFICACY

A.3.1. Active substance

Document M-CA, section 3

www.weedscience.org

Ryan GF. 1970. Resistance of common groundsel to simazine and atrazine. Weed Sci. 18:614–16

Publicly available literature of decades of sugar beet research can be found in several Member States. Sugar beet research Institutes of EU (e.g., IFZ in DE, IRBAB/KBIVB in BE, ITB in FR, IRS in NL), but also DANISCO, British Sugar, SÜDZUCKER and AGRANA are members of the IIRB (International Institute for Beet Research).

A.3.2. Representative formulation – Lenacil 500 g/L SC

Document C, Document D2, Document M-CP, section 3

publicly available literature of decades of sugar beet research can be found in several Member States. Sugar beet research Institutes of EU (e.g., IFZ in DE, IRBAB/KBIVB in BE, ITB in FR, IRS in NL), but also DANISCO, British Sugar, SÜDZUCKER and AGRANA are members of the IIRB (International Institute for Beet Research).

Evaluation of Lenacil 500 g/L SC in the Southern Zone: "Lenacil_RR_1107_Part_B_core_VENZAR_50_SC_(DPX-B0634_500SC_Lenacil_500_gL_SC)_EI_DuPont_de_Nemours_and_Company_EL_2015-06-30" available on CIRCABC

Evaluation of Lenacil 500 g/L SC in the Central Zone: "lenacil Final re-registration (voluntary worksharing) VENZAR 500 SC Du Pont De Nemours BE 2015-08-07" available on CIRCABC

A.4. FURTHER INFORMATION**A.4.1. Active substance**

None, except the MSDS of the material.

A.4.2. Representative formulation – Lenacil 500 g/L SC

| Data Point according to Reg. 284/2013, (reference in caddy) Reference in Vol.3 B.4 | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|------------------|-------------|--|---------------------------------|--|--|--------------|--|
| CP 4.4 (KCP 4.2/01) B.4.4 | Meinerling, M | 2006 | Determination of the Effectiveness of Cleaning Procedures of Venzar 500 SC. IBACON, Rossdorf, Germany, Report n°: 26999361, GLP, Unpublished | 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 at national level for the zonal evaluation of Venzar 500 SC | DuPont | No, submitted for purpose of renewal The study was already considered at national level for the zonal evaluation of Venzar 500 SC |

A.5. METHODS OF ANALYSIS

A.5.1. Active substance

| Data Point according to reg. (EC) 283/2013 [data point as initially referred by notifier in CADDY] Ref. in Vol.3 CA-B.5 | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|--------------|------|--|-------------------------|--------------------------------|--|-------|---------------------------------|
| CA 4.1.1(a)/01 (IIA 1.11/02) Vol.3 CA-B.5.1.1.1 Study No. 1 | Hansen, S.W. | 1998 | Technical grade lenacil (DPX-B0634). Analysis and certification of product ingredients E.I. Du Pont De Nemours and Company, Delaware DuPont Report No.: AMR 3747-96 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |
| CA 4.1.1(a)/02 (IIA 1.11/01) Vol.3 CA-B.5.1.1.1 Study No. 2 | Wittig | 2000 | Lenacil technical determination of purity and content in five batches UCL Umwelt Control Labor GmbH, Köln, Germany DuPont Report No.: PR00/015 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |
| CA 4.1.1(a)/03 [CKA 4.1.1/04] | Nagaraj K. | 2012 | Validation of the analytical method for determination of lenacil (DPX-B0634) in technical grade lenacil and lenacil end-use products | N | Y | The study is necessary for the regulatory decision and has not | FMC | No, submitted for the purpose |

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|--|-------------------------------------|------|--|---|---|--|-----|--|
| Vol.3 CA-B.5.1.1.1 – Study No. 3 | | | Syngene International Limited DuPont-34533 GLP, Unpublished | | | previously been protected or submitted. RMS: The study was already considered for the zonal dossier of Venzar 80 WP | | of the renewal The study was already considered for the zonal dossier of Venzar 80 WP |
| CA 4.1.1(a)/04 [KCA 4.1.1/05] Vol.3 CA-B.5.1.1.1 – Study No 4 | Anonymous | 2016 | Lenacil (DPX-B0634); Determination of DPX-B0634; Reversed-Phase High Performance Liquid Chromatographic (RPLC) and/or Ultra Performance Liquid Chromatography Assay Method B0634.220.03.ES Not GLP: Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of the renewal |
| CA 4.1.1(a)/05 [KCA, 4.1.1/06] Vol.3 CA-B.5.1.1.1 – Study No. 5 | Repp, M. C. | 2015 | Validation of the analytical method for determination of lenacil (DPX-B0634) in technical grade lenacil and lenacil end-use products DuPont-44061 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted and contains information on composition of the active substance. | FMC | No, submitted for the purpose of the renewal |
| CA 4.1.2(a)/01 [IIA 7.1.2/04] Vol.3 CA-B.5.1.2.1 – Study No. 1 | Kane, T. | 2004 | IN-KE 121, Adsorption/Desorption on soil, Huntingdon Life Sciences Ltd., ACD Report No. 063/042264 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the fate study |
| CA 4.1.2(a)/02 [KCA | Wright, D., Gilbert, J., Heslop, D. | 2011 | IN-KF313: Adsorption/ desorption study in three soil. Covance Laboratories Ltd | N | Y | The study is necessary for the regulatory decision and has not | FMC | No, submitted for |

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|---|--------------|------|---|---|---|--|-----|--|
| 4.1.2/01, also in KCA 7.1.3.1.2/01] | | | Report No. :8224952 GLP, Unpublished | | | previously been protected or submitted | | the purpose of renewal. Analytical/ validation data from the fate study |
| Vol.3 CA- B.5.1.2.1 – Study No. 2 | | | | | | | | |
| CA 4.1.2(a)/03 [KCA 4.1.2.2/01] | Jooß, S. | 2015 | Development and validation of an LC/MS/MS method for the determination of the lenacil metabolite IN-KF 313 in surface water PTRL Europe, Germany P3463G GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| Vol.3 CA- B.5.1.2.1 – Study No. 3 | | | | | | | | |
| CA 4.1.2(c)/01 [IIA 5.3.1.1- 01] | ■■■■■ ■■■ | 2002 | Lenacil technical: preliminary study by dietary administration to Han Wistar rats for 4 weeks DuPont Report No.: ACD 001/010098 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the tox. study |
| Vol.3 CA- B.5.1.2.3 – Study No. 1 | | | | | | | | |
| CA 4.1.2(c)/02 [IIA 5.3.2.2- 01] | ■■■■■ | 1991 | Subchronic oral toxicity: 90 day study with DPX-B634-91 (Lenacil) feeding study in mice DuPont Report No.: HLR293-91 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the tox. study |
| Vol.3 CA- B.5.1.2.3 – Study No. 2 | | | | | | | | |
| CA 4.1.2(c)/03 [IIA 5.5.2- 01] | ■■■■■ | 1994 | Oncogenicity study with DPX-B634-91 (Lenacil) eighteen-month feeding study in mice DuPont Report No.: HLR336-93 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 |

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|---|----------|--------|--|---|---|--|-----|--|
| Vol.3 CA-B.5.1.2.3 – Study No. 3 | | | | | | | | Analytical/ validation data from the tox. study |
| CA 4.1.2(c)/04 [IIA 5.6.1.2-01] Vol.3 CA-B.5.1.2.3 – Study No. 4 | ██████ | 2003a | Lenacil technical: Study of effects on reproductive performance in Han Wistar Rats treated continuously through two successive generations by dietary administration DuPont Report No.: ACD 020/023865 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the tox. study |
| CA 4.1.2(c)/05 [IIA 5.6.2.1-04] Vol.3 CA-B.5.1.2.3 – Study No. 5 | ██████ | 2003 b | Lenacil technical: Study of effects on embryo-fetal development in CD rats treated continuously by gavage administration DuPont Report No.: ACD 058/032316 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the tox. study |
| CA 4.1.2(e)/01 [IIA 4.2.1.1-01 and IIA 6.3-02b] Vol.3 CA-B.5.1.2.5.1 – Study No. 1 | Mende | 2002 | Analytical Final Report – Generation of Samples for the determination of Residues of Venzar 80 % WP (containing 80 % Lenacil) in Sugar Beets. Five Sites in Europe, 2001 GAB Biotechnology GmbH, Germany DuPont Report No.: 20011048/E1-FPSB GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |
| CA 4.1.2(e)/02 [IIA 4.2.1.1-02] Vol.3 CA-B.5.1.2.5.1 – Study No. 2 | Turnbull | 2003 | Validation of Analytical Methodology for the Determination of Lenacil in Sugar Beet Pesticides and Veterinary Medicines Team D, Central Science Laboratory (CSL), UK DuPont Report No.: PDG-107 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |

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|--|----------------------------|------|---|---|---|--|-----|---|
| CA 4.1.2(e)/03 [IIA 6.3-03b] Vol.3 CA- B.5.1.2.5.1 – Study No. 3 | Hamberger, R | 2002 | Analytical Report – Generation of samples for the determination of residues of Venzar (80% WP (containing 08% lenacil) in sugar beets, one site in Europe, 2002. GAB Biotechnology GmbH, Germany DuPont Report No.: 20011048/E2-FPSB GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 The study is a residue study considered for the results of the procedural recoveries |
| CA 4.1.2(e)/04 [IIA 4.2.1.1-03] Vol.3 CA- B.5.1.2.5.1 – Study No. 4 | Tillkes M. | 1998 | Magnitude of residue of lenacil and trisulfuron methyl in sugar beet grown in France following application of Venzar and DPX-MX843-1 – Season 1995 DuPont Report No.: F-95-001-RES → Analytical Part: Gas-Chromatographic Determination of Pesticides Residues after Clean-up by Gel-Permeation Chromatography and Mini-Silica Gel-Column Chromatography. 6. Communication: Replacement of dichloromethane by ethyl acetate/cyclohexane in liquid-liquid partition and simplified conditions for extraction and liquid – liquid partition (Specht <i>et al.</i> , 1995 – <i>Fresenius J. Anal. Chem.</i> 353, 183-190) Dr. Specht & Partner, Germany Specht & Partner No. DUP-9701/az. 56301/97 Report No. F-95-001-RES GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Analytical/ validation data from the residue study |
| CA 4.1.2(e)/05 [IIA 4.2.1.1- | Anderson I., Kakkonen J.E. | 2006 | Decline of lenacil residues in sugar beet (root and tuber vegetables) following a single application of Venzar® 80WP (Lenacil)-Southern Europe, Season 2005 | N | N | | FMC | Initial monograph November 2007 |

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|---|--|------|---|---|---|--|-----|---|
| 04 and IIA 6.3-04] Vol.3 CA- B.5.1.2.5.1 – Study No. 5 | Witte A. for the analytical part | | Charles River Laboratories, UK DuPont Report No.: CRL 688479 | | | | | Analytical/ validation data from the tox. study |
| CA 4.1.2(f)/01 [CA 8.1.1.1/01, previously IIA 8.1.1-01] Vol.3 CA- B.5.1.2.6 – Study No. 1 | ██████ ██████ | 2002 | Lenacil technical Acute oral toxicity (LD ₅₀) to the mallard duck ████████████████████ DuPont Report No.: ACD 048/022425 GLP, unpublished | Y | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/02 [CA 8.1.1.1/02, previously IIA 8.1.1-02] Vol.3 CA- B.5.1.2.6 – Study No. 2 | ████████ ██ | 2002 | Lenacil Technical: Acute Oral Toxicity (LD ₅₀) to the Bobwhite Quail ████████████████████ DuPont Report No.: ACD 049/022426 GLP, unpublished | Y | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/03 [CA 8.2.6.1/01, previously IIA 8.2.6-02] Vol.3 CA- B.5.1.2.6 – Study No. 3 | Flatman, D. | 2003 | Leancil technical; algal growth inhibition assay <i>Selenastrum capricornutum</i> Huntingdon Life Sciences, UK DuPont Report No.: ACD 034/022511 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |

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|---|------------------|------|--|---|---|--|-----|---|
| CA 4.1.2(f)/04 [CA 8.2.1/01, previously IIA 8.2.1-03] Vol.3 CA- B.5.1.2.6 – Study No. 4 | ██████████ | 2003 | Lenacil technical – Acute toxicity to fish (<i>Cyprinus carpio</i>) ██████████ DuPont Report No.: ACD 035/22512 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/05 [CA 8.2.6.2/01, previously IIA 8.2.6-01] Vol.3 CA- B.5.1.2.6 – Study No. 5 | Flatman, D. | 2003 | Lenacil technical; algal growth inhibition assay <i>Navicula pelliculosa</i> Huntingdon Life Sciences, UK DuPont Report No.: ACD 036/024694 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/06 [CA 8.2.7/01, previously IIA 8.2.8-01] Vol.3 CA- B.5.1.2.6 – Study No. 6 | Flatman, D. | 2003 | Lenacil technical; higher plant (<i>Lemna</i>) growth inhibition test Huntingdon Life Sciences, UK DuPont Report No.: ACD 039/023827 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/07 [CA 8.2.6.1/03, previously IIA 8.2.6-04] | Jenkins, C.A. | 2004 | IN-KE 121 algal growth inhibition assay Huntingdon Life Sciences, UK DuPont Report No.: ACD 064/042730 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |

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|---|------------------------------|------|--|---|---|--|-----|---|
| Vol.3 CA-B.5.1.2.6 – Study No. 7 | | | | | | | | Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08 [CA 8.2.6.1/04, previously IIA 8.2.6-05] Vol.3 CA-B.5.1.2.6 – Study No. 8 | Jenkins, C.A. | 2004 | IN-KF 313 algal growth inhibition assay <i>Selenastrum capricornutum</i> Huntingdon Life Sciences, UK DuPont Report No.: ACD 066/042848 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08.0 1 (KCP 10.6.2/01) Vol.3 CA-B.5.1.2.6 – Study No. 8.01 | Gossman a. and Meinerling M. | 2006 | Effects of Venzar 500 SC on Terrestrial (Non-Target) Plants: Seedling emergence and seedling Growth Test IBACON GmbH, Germany Project 26803086 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08.0 2 (KCP 10.2.3/01) Vol.3 CA-B.5.1.2.6 – Study No. 8.02 | Jenkins C.A. | 2005 | Lenacil (Venzar 80% WP) Effects on primary productivity and macrophyte biomass in field-based microcosms Huntingdon Life Sciences Ltd, UK Report ACD 072/043691 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |

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| CA 4.1.2(f)/08.0 3 (KCA 8.2.1/03[IIA 8.2.1-02]) Vol.3 CA- B.5.1.2.6 – Study No. 8.03 | | 1991 b | Static, acute, 96-hour LC50 of DPX-B634-91 (lenacil) to fathead minnow (<i>Pimephales promelas</i>) [REDACTED] [REDACTED] Report No. 198-91 MR-4581-884 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08.0 4 (KCA 8.2.1/02 [IIA 8.2.1-01]) Vol.3 CA- B.5.1.2.6 – Study No. 8.04 | | 1991a | Static, acute, 96-hour LC50 of DPX-B634-91 (lenacil) to rainbow trout (<i>Oncorhynchus mykiss</i>) [REDACTED] [REDACTED] Report No. 199-91 MR-4581-884 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08.0 5 (KCA 8.2.2.1/01) Vol.3 CA- B.5.1.2.6 – Study No. 8.05 | | 1991c | Flow-through, 21-day toxicity of DPX-B634-91 (lenacil) to rainbow trout (<i>Oncorhynchus mykiss</i>) [REDACTED] [REDACTED] Report No. 200-91 MR-4581-884 GLP, Unpublished | Y | N | | FMC | Initial monograph November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/08.0 6 (KCA 8.2.4.1/01) | Hutton D.G. | 1989a | Static acute 48-hour EC50 of DPX-B634-84 to fed <i>Daphnia magna</i> Haskell Laboratory for Toxicology and Industrial Medicine, USA Haskell Laboratory Report No. 86-89 MR-4581-675 | Y | N | | FMC | Initial monograph November 2007 |

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| [KCA 4.1.2.16/02 and KCA 8.2.4.1/02] Vol.3 CA-B.5.1.2.6 – Study No. 10 | | | BioChem agrar, Machern OT Gerichhain, Germany Report n°: 15 10 48 031 W, GLP, Unpublished | | | decision and has not previously been protected or submitted | | the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/11 [KCA 4.1.2.16/03 and KCA 8.2.5.1/02] Vol.3 CA-B.5.1.2.6 – Study No. 11 | Renner P | 2016 b | Toxicity of Lenacil technical to <i>Daphnia magna</i> in a 21-day semi-static test. BioChem agrar, Machern OT Gerichhain, Germany Report n°: 15 10 48 032 W, GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/12 [KCA 4.1.2.16/04 and KCA 8.2.6.2/03] Vol.3 CA-B.5.1.2.6 – Study No. 12 | Wenzel, A. | 2014 a | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on the growth of <i>Synechococcus leopoliensis</i> . Fraunhofer (IME) DPT 001/4-10/C GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/13 [KCA 4.1.2.16/05 and KCA 8.2.6.2/04] | Wenzel, A. | 2014 b | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on the growth of <i>Anabaena flos-aquae</i> . DPT-001/4-10/E. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical |

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| Vol.3 CA-B.5.1.2.6 – Study No. 13 | | | | | | | | method were part of the ecotox. study |
| CA 4.1.2(f)/14 [KCA 4.1.2.16/06 and KCA 8.2.6.2/02] Vol.3 CA-B.5.1.2.6 – Study No. 14 | Wenzel, A. | 2014c | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on the growth of <i>Ankistrodesmus falcatus</i> . DPT-001/4-10/F. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/15 [KCA 4.1.2.16/07 and KCA 8.2.6.2/05] Vol.3 CA-B.5.1.2.6 – Study No. 15 | Wenzel, A. | 2014d | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on the growth of <i>Closterium cornu</i> . DPT-001/4-10/G. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/16 [KCA 4.1.2.16/08 and KCA 8.2.6.2/06] Vol.3 CA-B.5.1.2.6 – Study No. 16 | Wenzel, A. | 2014e | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on the growth of <i>Xanthonema debile</i> . DPT-001/4-10/I. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/17 | Wenzel, A. | 2014f | Freshwater Alga and Cyanobacteria, Growth Inhibition Test: Effect of Lenacil technical on | N | Y | The study is necessary for the regulatory | FMC | No, submitted for |

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|--|---------------------|------|---|---|---|---|-----|--|
| [KCA 4.1.2.16/09 and KCA 8.2.6.2/07] Vol.3 CA-B.5.1.2.6 – Study No. 17 | | | the growth of <i>Nannochloropsis limnetica</i>. DPT-001/4-10/H. GLP, Unpublished | | | decision and has not previously been protected or submitted | | the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/18 [KCA 4.1.2.16/10 and KCA 8.2.7/03] Vol.3 CA-B.5.1.2.6 – Study No. 18 | Wenzel, A. | 2012 | Macrophytes, growth inhibition test. Effect of Lenacil technical on the growth of <i>Elodea canadensis</i> in the presence of sediment DPT-001/4-80/C. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/19 [KCA 4.1.2.16/11 and KCA 8.2.7/02] Vol.3 CA-B.5.1.2.6 – Study No. 19 | Wenzel, A. | 2012 | Macrophytes, growth inhibition test. Effect of Lenacil technical on the growth of <i>Chara globularis</i> in the presence of sediment DPT-001/4-80/D. GLP, Unpublished | N | Y | The study is necessary for the regulatory decision and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/20 [KCA 4.1.2.16/12 and KCP 10.6.2/02] | Stürz S., Knebel N. | 2016 | Lenacil 500 g/LG SC: Effects on terrestrial (non-target) plants: Vegetative Vigour Test ibacon GmbH, Germany 95231087 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical |

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| [CA 8.1.1.3/01, previously IIA 8.1.3-01] Vol.3 CA-B.5.1.2.6 – Study No. 22 | ██████ ██████ ██████ | | ████████████████████ DuPont Report No.: AMR 3419-95 | | | | | November 2007 Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/23 [KCA 4.1.2.17/01 and KCP 10.3.1.2/01] Vol.3 CA-B.5.1.2.6 – Study No. 23 | Haupt S., Knebel N. | 2016 | Lenacil 500 g/LG SC: Chronic oral toxicity test on honey bee (<i>Apis mellifera</i> L.) in the laboratory ibacon GmbH, Germany Report No.: 95231136 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/24 [KCA 4.1.2.17/02 and KCA 8.3.1.2-02] Vol.3 CA-B.5.1.2.6 – Study No. 24 | Haupt S., Knebel N. | 2016 | Lenacil 500 g/LG SC: Chronic oral toxicity test on bumble bee (<i>Bombus terrestris</i> L.) in the laboratory ibacon GmbH, Germany Report No.: 95231107 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical method were part of the ecotox. study |
| CA 4.1.2(f)/25 [KCA 4.1.2.17/03 and KCA 8.3.1.4-01] | Haupt S., Knebel N. | 2016 | Lenacil 500 g/LG SC: Honey bees (<i>Apis mellifera</i> L.) larval toxicity test , repeated exposure ibacon GmbH, Germany Report No.: 95231032 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal Description and data on the analytical |

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|---|------------|------|--|---|-----|--|-----|--|
| Vol.3 CA-B.5.1.2.6 – Study No. 25 | | | | | | | | method were part of the ecotox. study |
| CA 4.1.2(g)/01 [IIA 4.2.3.1-01] Vol.3 CA-B.5.1.2.7 – Study No. 1 | Wittig, A. | 2002 | Validation of a Monitoring Method for Determination of Lenacil Residues in Surface Water, Tap Water and Ground Water UCL GmbH Köln, Germany DuPont Report No.: PR02/001 GLP, Unpublished | N | N | | FMC | Initial monograph November 2007 |
| CA 4.2(a)/01 [KCA 4.2.1/01] Vol.3 CA-B.5.2.1 – Study No. 1 | Witte, A. | 2011 | Validation of an analytical method for determination of residues of lenacil in rape seeds (oily matrix) Chemisches Institut Pforzheim GmbH 10T02203-01-VMRA GLP, Unpublished | N | Y) | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. RMS: Study has already been considered and protected at zonal level (Venzar 80 WP and Venzar 500 SC) | FMC | No, submitted for the purpose of renewal but study has already been considered at zonal level (Venzar 80 WP and Venzar 500 SC) |
| CA 4.2(a)/02 [KCA 4.2.1/02] Vol.3 CA-B.5.2.1 – Study No. 2 | Witte, A. | 2015 | Validation of an analytical method for determination of residues of lenacil in a plant commodity with high water content (lettuce) Chemisches Institut Pforzheim GmbH 14S07170-01-VMLE GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA 4.2(a)/03 [KCA 4.2.1/03] | Witte, A. | 2011 | Validation of an analytical method for determination of residues of lenacil in wheat grain (dry matrix) and lemon fruit (acidic matrix) Chemisches Institut Pforzheim GmbH 11T02203-01-VMPL | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC | No, submitted for the purpose of renewal but study already |

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|---|------------------------------|------|--|---|---|--|-----|---|
| Vol.3 CA-B.5.2.1 – Study No. 3 | | | GLP, Unpublished | | | RMS: Study has already been considered and protected at zonal level (Venzar 80 WP and Venzar 500 SC) | | considered at zonal level (Venzar 80 WP and Venzar 500 SC) |
| CA 4.2(a)/04 [KCA 4.2.1/04] Vol.3 CA-B.5.2.1 – Study No. 4 | Mende, P. | 2011 | Independent Laboratory Validation (ILV) of an analytical method for determination of residues of lenacil in rape seeds Eurofins Agrosience Services GmbH S10-03652 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. RMS: Study has already been considered and protected at zonal level (Venzar 80 WP and Venzar 500 SC) | FMC | No, submitted for the purpose of renewal but study already considered at zonal level (Venzar 80 WP and Venzar 500 SC) |
| CA 4.2(a)/05 [KCA 4.2.1/05] Vol.3 CA-B.5.2.1 – Study No. 5 | Richter S., Stanislawski, T. | 2015 | Independent Laboratory Validation (ILV) of the German DFG S19 Multi-Residue Method for the Determination of Lenacil in Two Crop Types, using LC/MS/MS PTRL Europe P 3464 G GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA 4.2(a)/06 [KCA 4.2.2/01] Vol.3 CA-B.5.2.2 – Study No. 1 | Wagner, B. | 2016 | Validation of an analytical method for the determination of residues of lenacil in matrices of animal origin (milk, eggs, meat, fat, kidney/liver) CIP Chemisches Institut Pforzheim GmbH 15S07170-01-VMAT GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA 4.2(a)/07 [KCA 4.2.2/02] | Bodsch, J. | 2016 | Study plan - Independent Laboratory Validation of analytical method 15S07170-01-VMAT for the determination of residues of Lenacil in matrices of animal origin (milk, eggs, meat, fat, kidney/liver) by LC-MS/MS | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and | FMC | No, submitted for the purpose of renewal |

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|---|-------------------------|------|---|---|---|---|-----|--|
| Vol.3 CA-B.5.2.2 – Study No. 2 | | | SGS INSTITUT FRESENIUS GmbH IF-16/03724646 GLP, Unpublished | | | has not previously been protected or submitted | | |
| CA 4.2(a)/08 [KCA 4.2.2/03] Vol.3 CA-B.5.2.2 – Study No. 3 | Bodsch, J. | 2016 | Amendment No.1 to Final Report: Independent Laboratory Validation of analytical method 15S07170-01-VMAT for the determination of residues of Lenacil in matrices of animal origin (milk, eggs, meat, fat, kidney/liver) by LC-MS/MS SGS INSTITUT FRESENIUS GmbH IF-16/03724646 AR GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA 4.2(b)/01 [IIA 4.2.2.1-01] Vol.3 CA-B.5.2.3 – Study No. 1 | Brodsky J. and Zietz E. | 1990 | Determination of residues of lenacil in soil (treated with Venzar, Season 1989, Germany) Batelle Europe – Frankfurt Division DuPont Report No.: BE-A-11-90-10-BF GLP, Unpublished | N | N | | FMC | Initial monograph – November 2007 |
| CA 4.2(b)/02 [IIA 4.2.2.1/02] Vol.3 CA-B.5.2.3 – Study No. 2 | Mende P. | 2003 | Analytical Report – Venzar 80% WP (containing 80% lenacil) related soil dissipation on bare soil, four sites in Europe, 2001 GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH, Germany DuPont Report No.: 20011048/E1-FSD GLP, Unpublished | N | N | | FMC | Initial monograph – November 2007 |
| CA 4.2(b)/03 [KCA 4.2.4/01] Vol.3 CA-B.5.2.4 – Study No. 1 | Witte, A., | 2009 | Development and validation of an analytical method for the determination of residues of lenacil in drinking and surface water CIP Chemisches Institut Pforzheim GmbH 09D02203-01-VMWA GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |

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|--|------------|------|--|---|---|---|-----|--|
| CA 4.2(b)/04 [KCA 4.2.4/02] Vol.3 CA-B.5.2.4 – Study No. 2 | Link, T.H. | 2016 | Independent Laboratory Validation of analytical method 09D02203-01-VMWA for the determination of residues of Lenacil in tap water by LC-MS/MS SGS INSTITUT FRESENIUS GmbH IF-15/03444276 GLP, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted | FMC | No, submitted for the purpose of renewal |
| CA 4.2(c)/01 [IIA 4.2.4.1-01] Vol.3 CA-B.5.2.5 – Study No. 1 | Rawle, N. | 2005 | Validation of an analytical method for the determination of residues of lenacil in air CEM Analytical Services Ltd. (CEMAS) CEMS-2788 GLP, Unpublished | N | N | | FMC | Initial monograph – November 2007 |

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).

A.5.2. Representative formulation – Lenacil 500 g/L SC

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------|---------------------------------|------|--|----------------------------|--------------------------------------|---|-------|---|
| B 5.1.1.1/01 | Meinerling, M., Herrmann, S. | 2006 | Validation of an analytical method for the determination of lenacil in a SC formulation Rossdorf, Germany 26995101 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 The study was however already considered at national level for the zonal evaluation of Venzar 500 SC | FMC | No, submitted for purpose of renewal The study was however already considered at national level for the zonal evaluation of Venzar 500 SC |
| B 5.1.1.1/02 | Anonymous | 2016 | Lenacil (DPX-B0634); Determination of DPX-B0634; Reversed-Phase High Performance Liquid Chromatographic (RPLC) and/or Ultra Performance Liquid Chromatography Assay Method B0634.220.03.ES GLP: No 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 | No, submitted for purpose of renewal |

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).

A.6. TOXICOLOGY AND METABOLISM DATA

A.6.1. Active substance

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|-------------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| B.6.1.1 | ██████████ | 1996 | Absorption, distribution, metabolism and excretion of [2- 14C]-lenacil ([2-14C]- DPX-B634) in the rat ██████████ HLR 62-94 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.1.3 | Piñeiro Costas, N | 2016 | Interspecies comparison of in vitro metabolism of [Pyrimidine-2- 14C]Lenacil in mouse, rat, dog and human hepatocytes. DuPont Project 512721 GLP: Yes Published: No | N | N | | | N |
| B.6.2.1 | ██████████ | 2001 | Lenacil technical acute oral toxicity to the rat (acute toxic class method) ██████████ ACD 004/013224/AC GLP: Yes Published: No | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| B.6.2.2 | ██████████ | 2001 | Lenacil technical acute dermal toxicity to the rat ██████████ ACD 005/013220/AC GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.2.3 | ██████████ | 2001 | Lenacil technical acute (four-hour) inhalation study in rats ██████████ ACD 021/013229 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.2.4 | ██████████ | 2001 | Lenacil technical skin irritation to the rabbit ██████████ ACD 006/013201/SE GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.2.5 | ██████████ | 2001 | Lenacil technical eye irritation to the rabbit ██████████ ACD 007/013273/SE GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.2.6 | ██████████ | 1992 | Closed-patch repeated insult dermal sensitization study | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|----------------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | (maximization method) with DPX-B634-91 in guinea pigs ██████████ ██████████ HLO 34-92 GLP: Yes Published: No | | | | | |
| B.6.2.7 | Westerink, W.M.A. | 2016 | Evaluation of in vitro phototoxicity of lenacil TGAI in 3T3 fibroblasts using the neutral red uptake assay WIL Research Europe B.V. 511052 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 | DuPont | N |
| B.6.3.1 | ██████████ | 2001 | Lenacil technical preliminary study by dietary administration to Han Wistar rats for 4 weeks ██████████ ██████████ ACD 001/010098 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.3.1 | ██████████ | 2001 | Lenacil technical preliminary study by dietary | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | administration to beagle dogs for 4 weeks [REDACTED] [REDACTED] ACD 003/013230 GLP: Yes Published: No | | | | | |
| B.6.3.2 | [REDACTED] | 2002 | Lenacil technical toxicity study by dietary administration to Han Wistar rats for 13 weeks followed by a 4 week recovery period [REDACTED] [REDACTED] ACD 002/013903 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.3.2 | [REDACTED] | 2004 | Lenacil technical additional histopathological investigations to a toxicity study by dietary administration to han wistar rats for 13 weeks followed by a 4-week recovery period [REDACTED] [REDACTED] ACD 055/024499 GLP: Yes | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|--------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | Published: No | | | | | |
| B.6.3.2 | ██████████ | 1991 | Subchronic oral toxicity: 90-day study with DPX- B634- 91 (lenacil) feeding study in mice ██████████ ██████████ HLR 293-91 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.3.2 | ██████████ | 2002 | Lenacil technical toxicity study by dietary administration to beagle dogs for 13 weeks ██████████ ██████████ ACD 022/014297 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| | | | | | | | | |
| B.6.4.1 | May, K. | 2001 | Lenacil technical bacterial mutation assay Huntingdon Life Sciences Ltd ACD 016/013217 GLP: Yes Published: No | N | Y | | DuPont | Y |
| B.6.4.1 | Russel, J.F. | 1977 | Mutagenic activity of uracil, 3-cyclohexyl-5,6,- | N | N | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|---|------|--|----------------------------|--------------------------------------|---|---------|------------------------|
| | | | trimethylene in the Salmonella/microsome assay DuPont Haskell Laboratory HLR 601-77 GLP: Yes Published: No | | | | | |
| B.6.4.1 | D'Amico, S.W. | 1994 | Mutagenicity testing of DPX-B634-107 (lenacil) in the Salmonella typhimurium plate incorporation assay DuPont Haskell Laboratory HLR 413-94 GLP: Yes Published: No | N | N | | DuPont | Y |
| B.6.4.1 | Grancharov, K., Gorneva, G., Mladenova, J., Norpoth, K., Golovinsky, E. | 1986 | Lack of genotoxic and cytotoxic effects of the herbicide lenacil on mouse tumor cells and on some Salmonella typhimurium strains Arzneimittelforschung 369110, 1660-1663 GLP: Yes Published: Yes | N | N | | Authors | Y |
| B.6.4.1 | Allais, L | 2001 | Lenacil technical in vitro mammalian chromosome | N | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|----------------------------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | aberration test in human lymphocytes Huntingdon Life Sciences Ltd ACD 017/013707 GLP: Yes Published: No | | | | | |
| B.6.4.1 | Kellum, S.N. | 2017 | Lenacil (DPX-B0634) technical: <i>In vitro</i> mammalian chromosomal aberration test in human peripheral blood DuPont Report No.: 49348 GLP: Yes Published: No | | | | DuPont | N |
| B.6.4.1 | Clare, G | 2003 | Lenacil technical in vitro mammalian cell gene mutation test Huntingdon Life Sciences Ltd ACD 053/023530 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.4.1 | ██████████ ██████████ ████ | 1990 | Lenacil: assessment of genotoxicity in an unscheduled DNA synthesis assay using adult rat hepatocyte primary cultures ██████████████████ ██████████ | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|-----------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | IRI 6135 GLP: Yes Published: No | | | | | |
| B.6.4.2 | | 2001 | Lenacil technical mouse micronucleus test ACD 018/013472 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.5 | | 2002 | Lenacil technical combined chronic toxicity and carcinogenicity study by dietary administration to han wistar rats over 104 weeks interim report: 0-52 weeks ACD 045/024288 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.5 | | 2004 | Lenacil technical combined chronic toxicity and carcinogenicity study by dietary administration to han wistar rats over 104 weeks ACD 045/042214 | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | GLP: Yes Published: No | | | | | |
| B.6.5 | ██████████ | 1994 | Oncogenicity study with DPX-B634-91 (lenacil) eighteen-month feeding study in mice ██████████ HLR 336-93 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.5 | ██████████ | 2002 | Lenacil technical preliminary study of effects on reproductive performance in Han Wistar rats by dietary administration ██████████ ACD 019/010186 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.6.1 | ██████████ | 2003 | Lenacil technical study of effects on reproductive performance in han wistar rats treated continuously through two successive generations by dietary administration ██████████ ACD 020/023865 | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | GLP: Yes Published: No | | | | | |
| B.6.6.2 | ██████████ | 1978 | Embryotoxic and teratogenic study in rats with lenacil (INB-634) ██████████ HLR 405-78 GLP: Yes Published: No | Y | N | | DuPont | Y |
| B.6.6.2 | ██████████ | 1996 | DPX-B634-91 (lenacil): Pilot developmental toxicity study in rats ██████████ HLR 996-96 GLP: Yes Published: No | Y | N | | DuPont | Y |
| B.6.6.2 | ██████████ | 2003 | Lenacil technical preliminary study of effects on embryo- fetal development in CD rats treated by oral gavage administration ██████████ ACD 057/030001 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.6.2 | ██████████ | 2003 | Lenacil technical study on effects on embryo-fetal | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|---------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | development in CD rats treated by oral gavage administration [REDACTED] [REDACTED] ACD 058/032316 GLP: Yes Published: No | | | | | |
| B.6.6.2 | [REDACTED] | 1991 | Teratogenicity study of DPX-B634-91 in rabbits [REDACTED] [REDACTED] HLR 626-91 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.8.1 | Kurubaran, S. | 2016 | Expert statement: Assessment of the toxicological relevance of the groundwater metabolites of lenacil and proposal with a view to a human health-based risk assessment Dr Knoell Consult Limited DuPont-47276 GLP: No Published: No | N | N | | DuPont | Y |
| B.6.8.1 | Tier, G.T | 2014 | Position paper title: A non-testing approach to evaluate the relevance of specific groundwater metabolites of lenacil | N | N | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | E.I. du Pont de Nemours and Company DuPont-39162 GLP: No Published: No | | | | | |
| B.6.8.2 | ██████████ | 2004 | Lenacil technical Investigation into potential effects on thyroid function after 20 weeks of treatment in female Han Wistar rats using the "perchlorate discharge test" ██████████ ACD 060/033946 GLP: Yes Published: No | Y | Y | | DuPont | Y |
| B.6.8.2 | ██████████ | 2007 | Lenacil technical Investigation into potential effects on thyroid function after 20 weeks of treatment in female Han Wistar rats using the "perchlorate discharge test". Amendment No.1 ██████████ ACD 060/033946 GLP: Yes Published: No | Y | Y | | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|-------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| B.6.8.3 | ██████████ | 2018 | Lenacil (DPX-B0634) technical: Estrogen receptor binding assay using rat uterine cytosol (ER-RUC). DuPont 49349 GLP:Yes Published: No | Y | | | DuPont | N |
| B.6.8.3 | Rijk, J.C.W | 2018 | Evaluation of the estrogenic agonist and antagonist activity of lenacil (DPX-B0634) technical using the stably transfected human estrogen receptor- α transactivation assay DuPont 49351 GLP:Yes Published: No | N | | | DuPont | N |
| B.6.8.3 | ██████████ | 2018 | Lenacil (DPX-B0634) technical: Androgen receptor binding assay using rat prostate cytosol (AR-RPC) DuPont 49367 GLP:Yes Published: No | Y | | | DuPont | N |
| B.6.8.3 | Rijk, J.C.W | 2018 | Evaluation of the androgenic agonist and antagonist activity of | N | | | DuPont | N |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|--------------|------|---|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | lenacil (DPX-B0634) technical using the stably transfected human androgen receptor transcriptional activation assay (AR EcoScreen™) DuPont 50113 GLP:Yes Published: No | | | | | |
| B.6.8.3 | | 2018 | Lenacil (DPX-B0634) technical: 6-day uterotrophic assay for detecting estrogenic activity in ovariectomized rats DuPont 49350 GLP:Yes Published: No | Y | | | DuPont | N |
| B.6.8.3 | Rijk, J.C. | 2019 | Lenacil (DPX-B0634) technical : <i>in vitro</i> aromatase inhibition using human recombinant microsomes. FMC-51364 GLP: Yes Published: No | N | | | FMC | N |
| B.6.8.3 | Verkaart, S. | 2019 | Screening Lenacil (DPX- B0634) technical for modulation of steroidogenesis using the | N | | | FMC | N |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|---------------|------|--|----------------------------|--------------------------------------|---|--------|------------------------|
| | | | human H295R adeno- carcinoma cell line. FMC-51365 GLP: Yes Published: No | | | | | |
| B.6.8.3 | | 2019 | Lenacil (DPX-B0634) technical: thyroid mechanistic 14-day feeding study in rats. 49350 GLP: Yes Published: No | N | | | FMC | N |
| B.6.8.3 | Wohlman, I.M. | 2019 | Lenacil (B0634) Technical: Assessment of Experimental Data to Characterise Evidence of Endocrine Disrupting Potential. FMC-51816 GLP: No Published: No | N | Y | | FMC | N |
| B.6.9.1 | Klotzbach, K | 2016 | Medical expertise for the lenacil production E.I. du Pont de Nemours and Company 101581-5-9-1-01 GLP: No Published: No | N | N | | DuPont | N |

A.6.2. Representative formulation – Lenacil 500 g/L SC

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|--|----------------------------|--------------------------------------|--|--------|------------------------|
| B.6.1.1 | ██████████ | 2005 | Acute Oral Toxicity. Acute Toxic Class Method with Venzar 500 SC. ██████████ report no. 052411 GLP: Yes Published: No | Y | Yes | 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. | DuPont | Y |
| B.6.1.2 | ██████████ | 2005 | Acute Dermal Toxicity (Limit Test) with Venzar 500 SC. ██████████ report no. 052412 GLP: Yes Published: No | Y | Yes | 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 | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|------------|------|---|----------------------------|--------------------------------------|--|--------|------------------------|
| | | | | | | not expired at the time of submission of this dossier. | | |
| B.6.1.4 | ██████████ | 2005 | Acute Dermal Irritation/Corrosion with Venzar 500 SC. BSL ██████████ no. 052413 GLP: Yes Published: No | Y | Yes | 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. | DuPont | Y |
| B.6.1.5 | ██████████ | 2005 | Acute Eye Irritation/Corrosion with Venzar 500 SC. ██████████ ██████████ report no. 052414 GLP: Yes Published: No | Y | Yes | 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 | DuPont | Y |

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|-----------|------|---|----------------------------|--------------------------------------|---|-------|------------------------|
| | | | | | | protection has not expired at the time of submission of this dossier. | | |

A.7. RESIDUE DATA

| Datapoint/ dossier ref. (cf. Reg. (EU) 283/2013) [former EU dossier ref.] | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|---------------------------|------|---|----------------------------|--------------------------------------|--|-------|--|
| CA, 6.1 [IIA, 6.0/01] | Hamberger, R. | 2002 | Analytical report. Generation of samples for the determination of residues of Venzar (80% WP (containing 08% lenacil) in sugar beets, one site in Europe, 2002. IFU Umweltanalytik GmbH, Report No.: 20011048/E2-FPSB GLP: Yes, Unpublished | N | N | - | FMC* | DAR (2007- 2009) |
| CA, 6.2.1 [IIA, 6.1/01] | Zhang, M.; Glunt, C.D. | 2002 | Metabolism of lenacil in sugar beets. DuPont Doc. No.: 3649-95 GLP: Yes, Unpublished | N | N | - | FMC* | DAR (2007- 2009) |
| CA, 6.2.1/01 (supportive/ supplementary only) | Chrzanowski, R.L. | 1978 | Metabolism of ¹⁴ C-Lenacil in Spinach. DuPont Biochemicals Department, Wilmington, Delaware, USA, Report No.: D-2-3 GLP : No Unpublished | N | N | - | FMC* | Submitted for the purpose of renewal; DRAR (2019) |
| CA, 6.2.1/02 (supportive/ supplementary only) | Chrzanowski, R.L. | 1978 | Metabolism of ¹⁴ C-Lenacil in Strawberries. DuPont Biochemicals Department, Wilmington, Delaware, USA, Report No.: LLME-3-78 GLP : No Unpublished | N | N | - | FMC* | Submitted for the purpose of renewal; DRAR (2019) |
| CA, 6.2.1 [IIA, 6.3/01] | Tillkes, M. | 1998 | Magnitude of residue of lenacil and triflurosulfuron methyl in sugar beet grown in France following application of Venzar® and DPX-MX843-1 | N | N | - | FMC* | DAR (2007- 2009) |

| Datapoint/ dossier ref. (cf. Reg. (EU) 283/2013) <i>[former EU dossier ref.]</i> | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|---------------------------------|------|--|----------------------------|--------------------------------------|--|-------|------------------------|
| | | | Season 1995. Dr Specht & Partner, DuPont Report No.: F-95-001-RES. GLP, Unpublished | | | | | |
| CA, 6.3.1 <i>[IIA, 6.3/02]</i> | Pollmann, B | 2002 | Generation of samples for the determination if residues of Venzar (80% WP (containing 08% lenacil) in sugar beets, five site in Europe, 2001. GAB Biotechnologie GmbH IFU Umweltanalytik GmbH Report No.: 20011048/E1-FPSB GLP: Yes, Unpublished → incl. analytical report (Mende, P., 2002) | N | N | - | FMC* | DAR (2007- 2009) |
| CA, 6.3.1 <i>[IIA, 6.3/03]</i> | Pollmann, B | 2002 | Generation of samples for the determination if residues of Venzar (80% WP (containing 08% lenacil) in sugar beets, one site in Europe, 2002. GAB Biotechnologie GmbH IFU Umweltanalytik GmbH, Report No.: 20011048/E2-FPSB GLP: Yes, Unpublished → incl. analytical report (Hamberger, R., 2002) | N | N | - | FMC* | DAR (2007- 2009) |
| CA, 6.3.1 <i>[IIA, 6.3/04]</i> | Anderson, I., Kakkonen, J.E. | 2002 | Decline of lenacil residues in sugar beet (root and tuber vegetables) following a single application of Venzar® 80WP (lenacil) – Southern Europe, Season 2005. Report No.: CRL 688479 | N | N | - | FMC* | DAR (2007- 2009) |

| Datapoint/ dossier ref. (cf. Reg. (EU) 283/2013) <i>[former EU dossier ref.]</i> | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|--|------|---|----------------------------|--------------------------------------|---|--------|---------------------------|
| | | | GLP: Yes, Unpublished → incl. analytical phase report (Witte, A., 2006) | | | | | |
| CA 6.3 (supportive/ supplementary only) | Kucharski, M., Sakowski, J., Wujek, B., Trajdos, J. | 2011 | Influence of adjuvants addition on lenacil residues in plant and soil Polish Journal of Agronomy (2011), Volume 5, pp. 39–42 Non-GLP, published | N | N | Not applicable | public | DRAR (2019) |
| CA, 6.6.1/01 | Hurst, L., Fletcher, T. | 2013 | [14C]-Lenacil: Uptake and metabolism in confined rotational crops. Smithers Viscient (ESG) Ltd., Report No.: 8240837 GLP, Unpublished | N | Y | Applicant: “The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected. Although the study was previously submitted in the framework of post-approval confirmatory data, data protection is now claimed by the applicant because no EU data protection under 91/414/EEC has been granted for this study. Accordingly, data protection should be granted at MS level either with post Annex I product reregistration (30 months) or with a new product registration (10 years).” RMS: The study had previously been submitted and considered at EU level, to address the confirmatory data | FMC* | DAR addendum (2013) |

| Datapoint/ dossier ref. (cf. Reg. (EU) 283/2013) [former EU dossier ref.] | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|-----------|------|--|----------------------------|--------------------------------------|--|-------|------------------------|
| | | | | | | <p>request following the original EU review under 91/414/EEC. Thus, the study is to be regarded rather as a part of the original approval dossier and cannot be considered as 'necessary' in the sense of art. 7(1)(d) of Reg. 844/2012.</p> <p>Furthermore, the study has also been submitted at national/zonal level in some MSs (e.g. BE), in the framework of the national authorisation procedure (re-registration of PPPs containing lenacil).</p> <p>Therefore, the applicant's claim that the study "<i>has not previously been protected</i>" deserves careful consideration at MS level; A study cannot be granted data protection 2 times (cf. Reg. (EC) No 1107/2009 art. 59(2)(b)).</p> | | |

* FMC: FMC International Switzerland Sàrl

A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

A.8.1. Active substance

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--|-------------------------------|------|---|----------------------------|--------------------------------------|--|--|----------------------------------|
| 7.1.1.1 also listed in CA 7.1.2.1.1 | Theis, M. | 2003 | Lenacil - fate and behaviour in soil DuPont Report No.: A&M 00- 077-FR A&M Labor GmbH, Germany GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.1.1.1 | Dixon, K., Alderman, D. | 2011 | [¹⁴ C]-lenacil: Identification of polar soil metabolites DuPont Report No.: 8224956 Covance Laboratories Limited (UK) GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | Addendum to the DAR (2013) |

| | | | | | | | | |
|--|------------------|-------|--|---|---|--|--|----------------------------------|
| CA 7.1.1.1 also listed in CA 7.1.4.2 | Goodyear, D. | 2012 | [¹⁴ C]-lenacil: Identification of polar soil metabolites formed from the degradation of lenacil in soil and their presence in soil lysimeter leachate DuPont Report No.: none, Position Paper GLP: not applicable, Unpublished | N | N | - | FMC Agricu ltural Solutio ns A/S | Addendum to the DAR (2013) |
| CA 7.1.1.2.1 | Berg, D.S. | 1994a | Degradation rate of ¹⁴ C- lenacil in soil, 1994a, DuPont Report No. AMR 2400-92 | N | N | - | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.1.1.3 | Millais, A.J. | 2002 | Lenacil photodegradati on on soil DuPont Report No.: ACD 041/023429 Huntigdon Life Sciences Ltd. GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.1.2.1.1 also listed in CA 7.1.1.1 | Theis, M. | 2003 | Lenacil fate and behaviour in soil | N | Y | The study is necessary for the regulatory decision, conducted | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |

| | | | | | | | | |
|-----------------|---|------|--|---|---|--|--------------------------------|-----------------|
| | | | DuPont Report No.: A&M 00-077-FR A&M Labor GmbH, Germany GLP: Yes, Unpublished | | | according to GLP and has previously been protected or submitted. | | |
| CA 7.1.2.1.1 | Millais, A. (in previous submission Girkin was given as the author) | 2003 | Lenacil - aerobic rate of degradation in one soil type at 10°C and in four soils at 20°C DuPont Report No.: ACD 042/023664 Huntigdon Life Sciences Ltd. GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricultural Solutions A/S | DAR (2007-2009) |
| 7.1.2.1.1/01 | Hurst, L. | 2012 | [¹⁴ C]-Lenacil: Aerobic soil metabolism and transformation DuPont Report No.: 8247509 Smithers Viscient Ltd., Harrogate, UK GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.1.2.1.1/02 | Department of Health (UK) | 2012 | GLP Certificate Smithers Viscient Ltd., Harrogate, UK <i>This GLP Certificate is</i> | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |

| | | | | | | | | |
|-----------------|--|-------|--|---|---|---|--------------------------------|-----------------|
| | | | <i>provided to supplement the study of Hurst (2012) submitted under point CA 7.1.2.1.1/01.</i> | | | | | |
| CA 7.2.1.2 | Berg, D.S. | 1994b | Degradation Rate of IN-KF313 in Three Soils, 1994b, DuPont Report No. AMR 2545-92 | N | N | - | FMC Agricultural Solutions A/S | DAR (2007-2009) |
| CA 7.1.2.1.2/01 | Schnitzler, F. | 2016a | Statement - Validity of US soil degradation studies Report No.: 101581-5 Dr. Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, Unpublished | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.1.2.1.2/02 | Wösten, J.H.M., Lilly, A., Nemes, A., Le Bas, C. | 1998 | Using existing soil data to derive hydraulic parameters for simulation models in environmental studies and in land use planning | N | N | - | Public Literature | DRAR (2019) |

| | | | | | | | | |
|-----------------|--|------|---|---|---|-------------------|-------------|-----------------|
| | | | Final Report on European Union Funded project. Report 156. DLO-Staring Centre, Wageningen. GLP: No, Published | | | | | |
| CA 7.1.2.1.2/03 | Basch, H., Gadebusch, H.H. | 1968 | In vitro antimicrobial activity of dimethylsulfoxide Applied Microbiology Vol. 16, No. 12: 1953-1954 GLP: No, Published | N | - | Public Literature | DRAR (2019) | CA 7.1.2.1.2/03 |
| CA 7.1.2.1.2/04 | Wadhwani, T., Desai, K., Patel, D., Lawani, D., Bahale, P., Joshi, P., Kothari, V. | 2008 | Effect of various solvents on bacterial growth in context of determining MIC of various antimicrobials The Internet Journal of Microbiology Volume 7 Number 1: 1-6 GLP: No, Published | N | - | Public Literature | DRAR (2019) | CA 7.1.2.1.2/04 |

| | | | | | | | | |
|------------------------|--|------|--|---|---|---|--------------------------------|-------------|
| CA 7.1.2.1.2/ 05 | Elo, H., Kuure, M., Pelttari, E. | 2015 | Correlation of the antimicrobial activity of salicylaldehydes with broadening of the NMR signal of the hydroxyl proton. Possible involvement of proton exchange processes in the antimicrobial activity European Journal of Medicinal Chemistry 92: 750-753 GLP: No, Published | N | N | - | Public Literature | |
| CA 7.1.2.1.5/ 01 | Kreschnak, C. Schnitzler, F. | 2016 | Estimation of kinetic endpoints for lenacil and its metabolites from aerobic laboratory soil degradation studies Report No.: 101581-1 Dr. Knoell Consult GmbH, Mannheim. | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |

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| | | | Germany GLP: Not applicable, Unpublished | | | | | |
| CA 7.1.2.2.1 | Pollmann, B. | 2003 | Venzar 80% WP (containing 80% lenacil) related soil dissipation on bare soil, four sites in Europe, 2001 DuPont Report No.: 20011048/E1- FSD GAB Biotechnologie GmbH & IFU Umweltanalyti k GmbH GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.1.3.1.1 | Sheftic, G.D., Priester, T.M. | 1992 | Batch equilibrium (adsorption/des orption) study with [2- 14C]lenacil DuPont Report No.: AMR 2332-92 E.I. du Pont de Nemours and Company (USA), Harris Laboratories, Inc. (USA), Lambda | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been submitted but not been protected. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |

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|-----------------|------------|------|---|---|---|---|--------------------------------------|---------------------|
| | | | Research (USA) GLP: Yes, Unpublished | | | | | |
| CA 7.1.3.1.1 | Girkin, R. | 2002 | Lenacil adsorption/desorption on soil DuPont Report No.: ACD 044/022152 Huntingdon Life Sciences Ltd. GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricultural Solutions A/S | DAR (2007- 2009) |
| CA 7.1.3.1.2 | Berg, D.S. | 1996 | Batch equilibrium (adsorption/desorption) study with IN-KF313 DuPont Report No.: AMR 2948-94 GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been submitted but not been protected. | FMC Agricultural Solutions A/S | DAR (2007- 2009) |
| CA 7.1.3.1.2 | Kane, T. | 2004 | IN-KE121 adsorption/desorption on soil DuPont Report No.: ACD 063/042264 Huntingdon Life Sciences Ltd., UK GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricultural Solutions A/S | DAR (2007- 2009) |

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|------------------------|---|--------|--|---|---|--|--------------------------------|-----------------|
| CA 7.1.3.1.2/ 01 | Wright, D., Gilbert, J., Heslop, D. | 2011 | IN-KF313: Adsorption/desorption study in three soils DuPont Report No.: 8224952 Covance Laboratories (UK), Harrogate, North Yorkshire, UK GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.1.3.1.2/ 02 | Department of Health (UK) | 2011 | GLP Certificate Covance Laboratories, Harrogate, North Yorkshire, UK <i>This GLP Certificate was provided to supplement the study of Wright et al. (2011) submitted under CA 7.1.3.1.2/01.</i> | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.1.4.2 | Schnöder, F. | 2004 a | Lysimeter study with ¹⁴ C-lenacil (Revision No. 1) and | N | Y | The study is necessary for the regulatory decision, conducted according to | FMC Agricultural Solutions A/S | DAR (2007-2009) |

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|-------------|--------------|--------|--|---|---|---|--------------------------------|----------------------------|
| | | | Amendment to Final Report DuPont Report No.: AMR 3498-95 (Revision No. 1) Test Facility Report No. for Amendment to Final Report: 0550-022 Covance Laboratories GmbH, Germany GLP: Yes, Unpublished | | | GLP and has previously been protected or submitted. | | |
| CA 7.1.4.2 | Schnöder, F. | 2004 b | Position Paper: Unknown Degradation Products of Lenacil in Leachate Water from a Lysimeter Study DuPont Report No.: none, position paper related to study AMR 3498-95, Revision No. 1 GLP: not applicable, Unpublished | N | N | - | FMC Agricultural Solutions A/S | DAR (2007-2009) |
| CA 7.1.4.2, | Goodyear, D. | 2012 | [¹⁴ C]-lenacil: Identification of polar soil | N | N | - | FMC Agricultural | Addendum to the DAR (2013) |

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|---------------------------------|--------------------------------------|------|---|---|---|---|--|----------------|
| also listed in CA 7.1.1.1 | | | metabolites formed from the degradation of lenacil in soil and their presence in soil lysimeter leachate DuPont Report No.: none, Position Paper GLP: not applicable, Unpublished | | | | Solutio ns A/S | |
| CA 7.1.4.2/0 1 | Hein, W. | 2016 | Microlysimeter study with ¹⁴ C- Lenacil for the characterizatio n of metabolite pattern in leachates from two different soil types Report No.: AS454 RLP AgroScience GmbH, Neustadt an der Weinstraße, Germany GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |
| CA 7.1.4.2/0 2 | Weuthen, M., Schnitzler, F. | 2016 | Statement – Microlysimeter Study Report No.: 101581-9 | N | N | - | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |

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|----------------------|-----------------|------|--|---|---|---|--|---------------------|
| | | | Dr. Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, Unpublished | | | | | |
| CA 7.1.4.2/0 3 | Gärtner, C. | 2016 | Structural elucidation of lenacil metabolites (Interim report) Report No.: Not available yet Fraunhofer Institute for Molecular Biology and Applied Ecology IME GLP: No (Interim Report), Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |
| CA 7.2.1.1 | Caldwell, E. | 2002 | ¹⁴ C-lenacil hydrolysis under laboratory conditions DuPont Report No.: ACD 046/013764 Huntingdon Life Sciences Ltd., UK | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |

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| | | | GLP: Yes, Unpublished | | | | | |
| CA 7.2.1.1 | Boucher, C.R. | 1993 | Hydrolysis of [carbonyl-2- ¹⁴ C]lenacil (DPX-B634) in buffer solutions of pH 5, 7 and 9 DuPont Report No.: AMR 2430-92 E.I. du Pont de Nemours and Company, Wilmington, Delaware, USA GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.2.1.2 | Millais, A. | 2002 | Lenacil quantum yield of direct phototransform ation DuPont Report No.: ACD 047/022138 Huntingdon Life Sciences Ltd. GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
| CA 7.2.1.2 | Boucher, C.R. | 1994 | Photodegradati on of lenacil ([carbonyl-2- ¹⁴ C]DPX- B634) in pH 5, 7 and 9 buffers conducted in | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |

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|----------------------|-------------------|-------|--|---|---|---|--|---------------------|
| | | | simulated sunlight DuPont Report No.: AMR 2431-92 E.I. du Pont de Nemours and Company, Wilmington, Delaware, USA GLP: Yes, Unpublished | | | been protected or submitted. | | |
| CA 7.2.1.2/0 1 | Schnitzler, F. | 2016b | Statement - Aquatic photolysis - Non-relevance of IN-KQ961 Report No.: 101581-6 Dr. Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, Unpublished | N | N | - | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |
| CA 7.2.2.1 | Barnes, S.P. | 2001 | Lenacil technical assessment of ready biodegradabilit y: Modified Sturm test DuPont Report No.: ACD 037/013644 Huntingdon Life Sciences Ltd., UK | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |

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|----------------------|-------------|------|--|---|---|--|--------------------------------|-----------------|
| | | | GLP: Yes, Unpublished | | | | | |
| CA 7.2.2.2/0 1 | Stewart, L. | 2016 | Lenacil: Aerobic mineralisation in surface water Report No.: 812625 Charles River Laboratories Edinburgh Ltd., East Lothian, UK GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has not previously been protected or submitted. | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.2.2.3 | Theis, M. | 2002 | Lenacil - Fate and behaviour in water-sediment DuPont Report No.: A&M 00-078-FR A&M Labor für Analytik und Metabolismusforschung, Germany GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricultural Solutions A/S | DAR (2007-2009) |
| CA 7.2.2.3/0 1 | Pietsch, K. | 2016 | Evaluation of kinetic endpoints for lenacil and its metabolites from one laboratory water-sediment study | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |

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|---------------|-------------------------------|------|---|---|---|---|--------------------------------|-------------|
| | | | Report No.: 101581-2 Dr. Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, Unpublished | | | | | |
| CA 7.2.2.3/03 | Weuthen, M. | 2016 | Statement - Assignment of unknown metabolites in the study E. Knoch Report No.: 101581-7 Dr. Knoell Consult GmbH, GLP: Not applicable, Unpublished | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |
| CA 7.2.2.5/01 | Schnitzler, F. & Herrmann, M. | 2016 | Statement - Potential effects of water treatment processes Report No.: 101581-8 Dr. Knoell Consult GmbH, GLP: Not applicable, Unpublished | N | N | - | FMC Agricultural Solutions A/S | DRAR (2019) |

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|----------|---------------|------|--|---|---|---|--|---------------------|
| CA 7.3.1 | Comb, A.L. | 2002 | Lenacil (pure grade) physico- chemical properties DuPont Report No.: ACD 025/014039 Huntingdon Life Sciences Ltd., UK GLP: Yes, Unpublished | N | Y | The study is necessary for the regulatory decision, conducted according to GLP and has previously been protected or submitted. | FMC Agricu ltural Solutio ns A/S | DAR (2007- 2009) |
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A.8.2. Representative formulation – Lenacil 500 g/L SC

| Data Point | Author(s) | Year | Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|----------------|--------------------------------|------|---|----------------------------|--------------------------------------|--|--|------------------------|
| CP 9.2.4/01 | Núñez García- Cuerva, L. | 2016 | Predicted environmental concentrations of lenacil and its metabolites in groundwater following applications to sugar beets – a modelling assessment using the FOCUS groundwater scenarios Company Report No. 101581-3 Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, not published | N | N | - | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |

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|----------------|--------------------------------|------|---|---|---|---|--|----------------|
| CP 9.2.5/01 | Núñez García- Cuerva, L. | 2016 | Predicted environmental concentrations of lenacil and its metabolites in surface water following application to sugar beets – a modelling assessment using the FOCUS surface water scenarios Company Report No. 101581-4 Knoell Consult GmbH, Mannheim, Germany GLP: Not applicable, not published | N | N | - | FMC Agricu ltural Solutio ns A/S | DRAR (2019) |
|----------------|--------------------------------|------|---|---|---|---|--|----------------|

A.9. ECOTOXICOLOGY DATA

A.9.1. Active substance

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-------------------|------------------|-------|---|-------------------------|--------------------------------|--|---|---------------------------------|
| KCA 8.1.1.1/01 | ██████ ██████ | 2002a | Lenacil technical acute oral toxicity (LD ₅₀) to the mallard duck ACD 048/022425 ████████████████████ GLP: Yes Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.1.1.1/02 | ██████ ██████ | 2002b | Lenacil technical acute oral toxicity (LD ₅₀) to the bobwhite quail ACD 049/022426 ████████████████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.1.1.2/01 | ██████ ██████ | 2004a | Lenacil technical dietary toxicity (LC ₅₀) to the bobwhite quail DPT 637/033931 ████████████████████ GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-------------------|--|-------|---|-------------------------|--------------------------------|--|---|---------------------------------|
| KCA 8.1.1.3/01 | ██████████ ██████████ ██████████ ██████████ ████ | 1996 | DPX-B634-91 (lenacil): A reproduction study with the northern bobwhite AMR 3419-95 ████████████████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.1/01 | ██████████ | 2003a | Lenacil technical acute toxicity to fish (Cyprinus carpio) ACD 035/022512 ████████████████████, ██████████ GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.1/02 | ██████████ | 1991a | Static, acute, 96-hour LC50 of DPX-B634-91 (lenacil) to rainbow trout (Oncorhynchus mykiss) HLR 199-91, Revision No. 1 ████████████████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|----------------|--------------------------|-------|---|-------------------------|--------------------------------|---|--------------------------------|------------------------------|
| KCA 8.2.1/03 | ██████████ | 1991b | Static, acute, 96-hour LC50 of DPX-B634-91 (lenacil) to fathead minnows (<i>Pimephales promelas</i>) (revision 1) HLR 198-91, Revision No. 1 ██████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.2.1/01 | ██████████ | 1991c | Flow-through, 21-day toxicity of DPX-B634-91 (lenacil) to rainbow trout (<i>Oncorhynchus mykiss</i>) HLR 200-91, Revision No. 1 ██████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.2.1/02 | ██████████ ██████████ | 1996 | Early life-stage toxicity of DPX-B634-91 (lenacil) to rainbow trout, <i>Oncorhynchus mykiss</i> HLR 235-96 ██████████ GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.4.1/01 | Hutton, D.G. | 1989a | Static acute 48-hour EC50 of DPX-B634-84 to fed <i>Daphnia magna</i> , HLR 86-89, DuPont Haskell Laboratory, GLP: Yes Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-----------------|---|-------|--|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA, 8.2.4.1/02 | Renner, P. | 2016a | Acute toxicity of Lenacil technical to Daphnia magna in a 48-hour static test 15 10 48 031 W Biochem agrar GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA 8.2.5.1/01 | Hutton, D.G. <i>Study no longer considered acceptable for use in risk assessment</i> | 1989b | Chronic toxicity of DPX-B634-84 (Lenacil) to Daphnia magna, HLR 130-89, DuPont, GLP: Yes Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.5.1/02 | Renner, P. | 2016b | Toxicity of lenacil technical to Daphnia magna in a 21-day semi-static reproduction test 15 10 48 032 W Biochem agrar GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-------------------|--|-------|--|-------------------------|--------------------------------|--|---|---------------------------------|
| KCA 8.2.6.1/01 | Flatman, D. | 2003c | Lenacil technical algal growth inhibition assay Selenastrum capricornutum ACD 034/022511 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.6.1/02 | Douglas, M.T., Handley, J.W. <i>Study no longer considered acceptable for use in risk assessment</i> | 1988 | The algistatic activity of lenacil technical DPT 171(K)/88189 Huntingdon Research Centre Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | Y | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-------------------|------------------|-------|---|-------------------------|--------------------------------|--|---|---------------------------------|
| KCA 8.2.6.1/03 | Jenkins, C.A. | 2004a | IN-KE121 algal growth inhibition assay ACD 064/042730 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.6.1/04 | Jenkins, C.A. | 2004b | IN-KF313 algal growth inhibition assay Selenastrum capricornutum ACD 066/042848 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------------|-------------|-------|--|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA 8.2.6.2/01 | Flatman, D. | 2003b | Lenacil technical algal growth inhibition assay Navicula pelliculosa ACD 036/024694 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | Y | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.2.6.2/02 | Wenzel, A | 2014a | Effect of Lenacil technical on the growth of <i>Ankistrodesmus falcatus</i> DPT-001/4-10/F Fraunhofer IME, Schmallenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA, 8.2.6.2/03 | Wenzel, A | 2014b | Effect of Lenacil technical on the growth of <i>Synechococcus leopoliensis</i> DPT-001/4-10/C Fraunhofer IME, Schmallenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-----------------|---|-------|---|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA, 8.2.6.2/04 | Wenzel, A | 2014c | Effect of Lenacil technical on the growth of <i>Anabaena flos-aquae</i> DPT-001/4-10/E Fraunhofer IME, Schmallingenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA, 8.2.6.2/05 | Wenzel, A | 2014d | Effect of Lenacil technical on the growth of <i>Closterium cornu</i> DPT-001/4-10/G Fraunhofer IME, Schmallingenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA, 8.2.6.2/06 | Wenzel, A | 2014e | Effect of Lenacil technical on the growth of <i>Xanthomonas debile</i> DPT 001/4 10/I Fraunhofer IME, Schmallingenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA, 8.2.6.2/07 | Wenzel, A <i>Study not acceptable for use in risk assessment</i> | 2014f | Effect of Lenacil technical on the growth of <i>Nannochloropsis limnetica</i> DPT-001/4-10/H Fraunhofer IME, Schmallingenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------------|-------------|-------|--|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA 8.2.7/01 | Flatman, D. | 2003d | Lenacil technical higher plant (Lemna) growth inhibition test ACD 039/023827 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA, 8.2.7/02 | Wenzel, A. | 2012a | Macrophytes, growth inhibition test - effect of Lenacil technical on the growth of Chara globularis in the presence of sediment DPT-001/4-80/D Fraunhofer IME, Schmallenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA, 8.2.7/03 | Wenzel, A. | 2012b | Macrophytes, growth inhibition test. Effect of Lenacil technical on the growth of Elodea canadensis in the presence of sediment DPT-001/4-80/C Fraunhofer IME, Schmallenberg, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-------------------|---|-------|--|-------------------------|--------------------------------|---|--------------------------------------|------------------------------|
| KCA 8.3.1.1/01 | Hoxter K.A.; Bernard, W. L.; Beavers, J. B. <i>Study not acceptable for use in risk assessment</i> | 1994a | H-18,759: A dietary LC50 toxicity study with the honey bee, HLO 404-93 (second amendment) Wildlife International Ltd., Easton, Maryland 21601, United States of America GLP: Yes Published: No | N | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.3.1.1/02 | Hoxter K.A.; Bernard, W.L.; Beavers, J.B. <i>Study not acceptable for use in risk assessment</i> | 1994b | H-18,759: An acute contact toxicity study with the honey bee, HLO 405-93 (second amendment) Wildlife International Ltd., Easton, Maryland 21601, United States of America GLP: Yes Published: No | N | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------|---------------|------|--|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA 8.4.1/01 | Rodgers, M.H. | 2002 | Lenacil technical acute toxicity (LC50) to the earthworm ACD 027/014409 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.4.1/02 | Pavic, B | 2016 | Lenacil Technical: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil with 10% Peat 95231022 IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|-----------------|------------------|-------|--|-------------------------|--------------------------------|--|---|------------------------------|
| KCA 8.4.1/03 | Rodgers, M.H. | 2004a | IN-KF313 acute toxicity (LC50) to the earthworm ACD 062/043039 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.4.1/04 | Rodgers, M.H. | 2004b | IN-KE121 acute toxicity (LC50) to the earthworm ACD 061/043033 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------|--------------|-------|---|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA 8.4.1/05 | Pavic, B | 2015a | IN-KE121: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 10% peat 100471022 IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA 8.4.1/06 | Pavic, B | 2015b | IN-KE313: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 10% peat 100461022 IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCA 8.5/01 | Carter, J.N. | 2002 | Lenacil technical effects on soil non-target micro-organisms: nitrogen transformation, carbon transformation ACD 026/014045 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------|---|------|--|-------------------------|--------------------------------|--|--------------------------------|--------------------------------------|
| KCA 8.8/01 | Barnes, S.P. <i>Study no longer acceptable for use in the risk assessment.</i> | 2001 | Lenacil technical activated sludge - respiration inhibition test ACD 038/013510 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes, Published: No | N | Y | Previously protected, but the period of data protection has not expired at the time of submission of this dossier. Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCA 8.9/01 | Bro, E., Millot, F., Decors, A., Devillers, J. | 2015 | Quantification of potential exposure of grey partridge (<i>Perdix perdix</i>) to pesticide active substances in farmlands GLP: No Published: Yes (<i>Science of the Total Environment</i> 521–522: 315–325, 2015) | Y | N | Not applicable | Public | Submitted for the purpose of renewal |
| KCA 8.9/02 | Millot, F.; Berny, P.; Decors, A.; Bro, E. | 2015 | Little field evidence of direct acute and short-term effects of current pesticides on the grey partridge GLP: No Published: Yes (<i>Ecotoxicology and Environmental Safety</i> 117: 41–61, 2015) | Y | N | Not applicable | Public | Submitted for the purpose of renewal |

A.9.2. Representative formulation – Lenacil 500 g/L SC

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------------|-----------------------------------|------|--|----------------------------|--------------------------------------|---|---|--|
| KCP 10.2.1/01 | Pawlowski, S. and Wydra, V. | 2006 | Toxicity of Venzar 500 SC to <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test. 26801210 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.2.1/02 | Pawlowski, S. | 2006 | Toxicity of Venzar 500 SC to the aquatic plant <i>Lemna gibba</i> in a semi-static growth inhibition test 26802240 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.2.3/01 | Jenkins, C.A. | 2005 | Lenacil (Venzar 80 WP): Effects on primary productivity and macrophyte biomass in field based microcosms, ACD 072/043691 Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom GLP: Yes Published: No | N | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCP 10.2.3/03 | Hommen, U | 2014 | Re-evaluation of an outdoor microcosm study with lenacil DuPont-40797 Fraunhofer IME, Schmallenberg, Germany GLP: No Published: No | N | N | Not applicable | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------------|--------------------------|-------|--|----------------------------|--------------------------------------|--|---|--------------------------------------|
| KCP 10.3.1.1/01 | Haupt, S | 2016a | Lenacil 500g/L SC: Effects (Acute contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory 95231035 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.1.1/02 | Schmitzer, S | 2006a | Effects of Venzar 500 SC (acute and oral) on honeybees (<i>Apis mellifera</i> L.) in the laboratory. 268013035 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.1.1/03 | Haupt, S | 2016b | Lenacil 500g/L SC: Effects (Acute contact and Oral) on Bumble Bees (<i>Bombus terrestris</i> L.) in the Laboratory 95231105 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.1.2/01 | Haupt, S., Knebel, N. | 2016a | Lenacil 500 g/L SC: Chronic oral toxicity test on the honey bee (<i>Apis mellifera</i> L.) in the laboratory 95231136 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------------|--------------------------|-------|---|----------------------------|--------------------------------------|--|---|--------------------------------------|
| KCP 10.3.1.2/02 | Haupt, S., Knebel, N. | 2016b | Lenacil 500g/L SC: Chronic oral Toxicity Test on Bumble Bees (<i>Bombus terrestris</i> L.) in the Laboratory 95231107 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.1.3/01 | Haupt, S., Knebel, N. | 2016c | Lenacil 500g/L SC: Honey bees (<i>Apis mellifera</i> L.) larval toxicity test, repeated exposure 95231032 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.2.1/01 | Moll, M. | 2005 | Effects of Venzar 500SC on the parasitoid <i>Aphidius rhopalosiphii</i> in the laboratory - Dose response test 26811001 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.3.2.1/02 | Rosenkranz, B. | 2006 | Effects of Venzar 500SC on the predatory mite <i>Typhlodromus pyri</i> in the laboratory - Dose response test 26812063 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|--------------------|------------------|-------|---|----------------------------|--------------------------------------|---|---|--|
| KCP 10.3.2.1/03 | Schmitzer, S. | 2006b | Effects of Venzar 500SC on the carabid beetle <i>Poecilus cupreus</i> L. in the laboratory 26814006 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.4.1.1/01 | Luhrs, U. | 2005 | Acute toxicity (14 days) of Venzar 500SC to the earthworm <i>Eisenia fetida</i> in artificial soil 26816021 IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.4.1.1/02 | Luhrs, U. | 2006 | Effects of Venzar 500 SC on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil. 26817022. IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.5/01 | Reis, K.H. | 2006 | Effects of Venzar 500SC on the activity of the soil microflora in the laboratory 26815080 IBACON GmbH, Rossdorf, Germany GLP: Yes Published: No | | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |

| Data Point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|------------------|--------------------------------|------|---|----------------------------|--------------------------------------|--|---|--------------------------------------|
| KCP 10.5/02 | Shulz, L. | 2016 | Venzar 500 SC - Effects on the activity of soil microflora (Nitrogen transformation test) 15 10 48 058 N BioChem agrar Labor Fur Biologische und chemische Analytik GmbH Kupferstrabe 6, 04827 GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |
| KCP 10.6.2/02 | Goßmann, A., Meinerling, M. | 2006 | Effects of Venzar 500 SC on terrestrial (non-target) plants: seedling emergence and seedling growth test. 26803086 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | N | Not applicable | FMC Agricultural Solutions A/S | Original DAR (November 2007) |
| KCP 10.6.2/03 | Sturtz, S., Knebel, N. | 2016 | Lenacil 500 g/L SC: Effects on terrestrial (non-target) plants: Vegetative vigour test 95231087 IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP: Yes Published: No | N | Y | New data for AIR3 renewal; Study required to fulfil new data requirements according to 1107/2009 | FMC Agricultural Solutions A/S | Submitted for the purpose of renewal |