

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2008-0173
Application: B.1.1; 1.3: Changes to TGAI Product Chemistry – New Sources
Same Registrant; Specifications
Product: Penncozeb Technical Fungicide
Registration Number: 25166
Active ingredients (a.i.): Mancozeb [MCZ]
PMRA Document Number : 1819986

Purpose of Application

The purpose of this application was to add a new source by the same registrant and to change the product specifications of Penncozeb Technical Fungicide, Reg. No. 25166.

Chemistry Assessment

Penncozeb Technical Fungicide is guaranteed to contain the active ingredient Mancozeb at a concentration of 87% (nominal). This product has density of 0.44 g/mL at 20°C and pH between 7 - 9. The chemistry requirements for Penncozeb Technical Fungicide are complete.

Health Assessments

The product from the new source of Penncozeb Technical Fungicide is considered to be chemically equivalent but not identical to the precedent registered product. Therefore, the toxicity profile is not expected to be significantly different and no toxicological data were required.

The food residue profiles for the proposed Penncozeb Technical Fungicides are expected to be similar to that of the original registered technical. Accordingly, no increase in dietary exposure is anticipated.

Environmental and Value Assessments

Environmental and value assessments are not required for this application.

Conclusion

Following the review of all available data, the PMRA can support the chemistry amendments made to Penncozeb Technical Fungicide, Reg. No. 25166.

References

Studies/Information Provided by Applicant/Registrant

PMRA No.	Title
1537271	2007, Preliminary Analyses of Five Representative Production Batches of Mancozeb Technical Grade Active Ingredient (TGAI) to Determine % Mancozeb and to Quantify its Associated Impurities, DACO: 2.13.3 CBI
1537272	2007, Preliminary Analyses of Five Representative Production Batches of Mancozeb Technical Grade Active Ingredient (TGAI) to Determine % Mancozeb and to Quantify its Associated Impurities, DACO: 2.13.3 CBI
1537274	2007, Preliminary Analyses of Five Representative Production Batches of Mancozeb Technical Grade Active Ingredient (TGAI) to Determine % Mancozeb and to Quantify its Associated Impurities, DACO: 2.13.3 CBI
1537275	2007, Preliminary Analyses of Five Representative Production Batches of Mancozeb Technical Grade Active Ingredient (TGAI) to Determine % Mancozeb and to Quantify its Associated Impurities, DACO: 2.13.3 CBI
1537276	2007, Preliminary Analyses of Five Representative Production Batches of Mancozeb Technical Grade Active Ingredient (TGAI) to Determine % Mancozeb and to Quantify its Associated Impurities, DACO: 2.13.3 CBI
1559679	1996, Appendix 1: Validation of the Analytical method DLA-012-1, Carbon Disulfide Determination in Dithiocarbamates by the "Sulfuric Acid Method", DACO: 2.13.1 CBI
1559681	1987, Appendix 2: Chromatograms for DIDT, ETU and Sulfur in Mancozeb, DACO: 2.13.3 CBI
1559682	1992, Appendix 4: UV/Vis Spectrum of Mancozeb. Final report, DACO: 2.14.12 CBI
1559683	1994, Appendix 3: Determination of the Solubility of Mancozeb in 2-Propanol and Xylene, DACO: 2.14.8 CBI
1559691	1995, Mancozeb Technical Product Chemistry Data, DACO: 2.1,2.10,2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.12.2,2.13.1,2.13.2,2.13.3,2.13.4,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
1559692	Appendix 1: Product Specifications for Starting Materials, DACO: 2.11.2 CBI
1559693	1991, Appendix 3: Validation of the Analytical Method PH-M 026.2.1: Ethylenebisdithiocarbamates, Determination of Sulphate, DACO: 2.13.1 CBI
1559694	1991, Appendix 4: Validation of the Analytical Method PH-M 27.1.1: Ethylenebisdithiocarbamates, HPLC Determination of DIDT and Sulphate, DACO: 2.13.1 CBI

- 1559695 1991, Appendix 6: The Validation of the Analytical Method PH-M 026.3.3: Ethylenebis(dithiocarbamates), Determination of Inorganic Manganese Salts, DACO: 2.13.1 **CBI**
- 1559696 1991, Appendix 7: The Validation of the Analytical Method PH-M 026.4.1: Ethylenebis(dithiocarbamates), Determination of Sulphide, DACO: 2.13.1 **CBI**
- 1559697 1991, Appendix 8: The Validation of the Analytical Method PH-M 026.5.1: Ethylenebis(dithiocarbamates), Determination of Sodium, DACO: 2.13.1 **CBI**
- 1559698 1991, Appendix 9: The Validation of the Analytical Method PH-M 026.1.3: Ethylene-1,2-bis(dithiocarbamates), Determination by HPTLC of ETD, DACO: 2.13.1 **CBI**
- 1559700 1991, Appendix 11: The Validation of the Analytical Method PH-M 024.2.2: Hexamine, Spectrometric Determination in Ethylene-1,2-bisdithiocarbamates, DACO: 2.13.1 **CBI**
- 1559701 1991, Appendix 12: The Validation of the Analytical Method PH-M 027.2.2: Lignosulphonates, Determination by HPLC in Ethylene-1,2-bis(dithiocarbamates) (EBDC), DACO: 2.13.1 **CBI**
- 1559709 1996, Mancozeb TK Determination of Active Ingredient in 10 Consecutive Batches. Final Report DL 96-106 Revised, DACO: 2.13.3 **CBI**
- 1559710 1987, Chromatograms for Lignosulfonate in Mancozeb., DACO: 2.13.3 **CBI**
- 1559731 1982, The Octanol/Water Partition Coefficients of Dithane M-45, M-22, Z-78 and Ethylenethiourea, DACO: 2.14.11 **CBI**
- 1559732 1997, Confirmatory Spectra for ETU, DIDT and Sulfur in Mancozeb, DACO: 2.13.4,2.14.12 **CBI**
- 1766690 1998, DIDT and sulphur in five representative samples, DACO: 2.12.1,2.13.3 **CBI**
- 1766692 1998, Mancozeb Technical preliminary analyses of five representative samples, DACO: 2.12.1,2.13.3 **CBI**
- 1766693 1998, Mancozeb Technical assay of five representative batches, DACO: 2.12.1,2.13.3 **CBI**
- 1766694 2009, Mancozeb Manufacturing & Nitrosamines, DACO: 2.13.4 **CBI**

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