

Evaluation Report for Category B, Subcategory B.2.1, B.2.4 Application

Application Number: 2008-3966
Application: B.2.1 (New product chemistry - guarantee)
B.2.4 (New product chemistry – proportion of formulants)
Product: Tepraloxydim 30% MUP
Registration Number: 29489
Active ingredients (a.i.): Tepraloxydim (TPA)
PMRA Document Number : 1832825

Purpose of Application

The purpose of this application is to register a new tepraloxydim manufacturing use product with a change in guarantee, as well as identity and proportion of formulants.

Chemistry Assessment

Tepraloxydim 30% MUP is a liquid containing the active ingredient tepraloxydim at a nominal concentration of 30%. This product has a density of 1.053 g/mL at 20°C and pH of 3.8 for a 1% solution in water. The chemistry requirements for Tepraloxydim 30% MUP have been completed.

Health Assessments

The registration of Tepraloxydim 30% MUP is based on a precedent product, Equinox EC Herbicide (Registration Number 27603), containing 19.8% of the active ingredient. Due to the low oral, dermal and inhalation toxicity of both the precedent and active ingredient and the reduction in formulants, it is expected that the toxicity of the new manufacturing use product would not exceed the toxicity of the precedent product. No additional toxicological data are required.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has completed an assessment of the subject application and has found the provided data to be sufficient to registered a new tepraloxymid manufacturing use product, Tepraloxymid 30% MUP.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

- 773803 1997, Physical and Chemical Properties Report for BAS 620 00 H, DACO: 3.5.1,3.5.10,3.5.11,3.5.13,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9 CBI
- 1647611 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate - Chemical and Physical Properties, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4
- 1647612 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate - Formulation Process, DACO: 3.2,3.2.1,3.2.2,3.2.3 CBI
- 1647613 2001, Quality Control during the Manufacturing Process of Tepraloxymid (Code No.: BAS 620 H), DACO: 3.3.1,3.3.2 CBI
- 1647614 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Validation of Analytical Method, DACO: 3.4.1 CBI
- 1647615 2000, Validation of analytical method "Determination of impurities in Tepraloxymid 30%MUP (BAS 620 06H)", DACO: 3.4.2 CBI
- 1647617 2000, Tepraloxymid 30%MUP (BAS 620 06H) Preliminary Analysis of Product Samples, DACO: 3.4.2 CBI
- 1647620 2000, Validation of analytical method "Determination of CPOH in Tepraloxymid 30%MUP (BAS 620 06H)", DACO: 3.4.2 CBI
- 1647622 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Color and Physical state, DACO: 3.5.1,3.5.2
- 1647625 2000, Tepraloxymid 30%MUP (BAS 620 06H) - Odor, DACO: 3.5.3
- 1647627 1999, Data concerning the composition of the Plant Protection Product, DACO: 3.5.4 CBI
- 1647629 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate - Chemical and Physical Properties, DACO: 3.5.5 CBI
- 1647631 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Density, DACO: 3.5.6 CBI
- 1647633 2000, Tepraloxymid 30% MUP (BAS 620 06H) - pH, DACO: 3.5.7 CBI
- 1647635 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Oxidizing or Reducing Action, DACO: 3.5.8 CBI
- 1647637 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Viscosity, DACO: 3.5.9 CBI
- 1647638 2000, Tepraloxymid 30% MUP (BAS 620 06H) - Stability at elevated temperature, DACO: 3.5.10 CBI
- 1647640 1999, Safety characteristics of the crop protection product BAS 620 06 H, DACO: 3.5.11 CBI
- 1647642 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate - Chemical and Physical Properties, DACO: 3.5.12 CBI
- 1647644 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate - Chemical and Physical Properties, DACO: 3.5.14

1647646 2008, Chemistry Requirements for the Registration of Manufacturing Concentrate
- Chemical and Physical Properties, DACO: 3.5.15
1647647 2000, Tepraloxym 30%MUP (BAS 620 06H) - Boiling point, DACO: 3.7 CBI
1814213 2009, BAS 620H MUP Solvent Blank Chromatograms, DACO: 3.4.1 CBI
1814214 2002, BAS 620 H (MP): Storage Stability and Corrosion Characteristics in
Commercial Type Packaging, DACO: 3.5.10,3.5.14

ISSN: 1911-8082

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