

Application to Register a New Manufacturing Site Evaluation Report for Category B, Subcategory 1.1 and 1.3 Application

Application Number: 2006-3276
Application: Category B.1.1, B.1.3-S-A-TGAI
Product: Tribenuron Methyl Technical Herbicide
Registration Number: 22330
Active ingredients (a.i.): Tribenuron Methyl Technical Herbicide
PMRA Document Number: 1753489

Background

The current manufacturing site is DuPont, Manati, Puerto Rico where Tribenuron Methyl Technical Herbicide has been manufactured to 97.3% purity with upper and lower certified limits of 100 and 95% respectively. The additional manufacturing site at DuPont Shanghai, P.R. China will be manufacturing Tribenuron Methyl Technical Herbicide at 97.6% purity with upper and lower limits of 100 and 95% respectively and the current manufacturing site will be increasing the purity of the product to match that of the Shanghai plant.

Purpose of Application

The purpose of the application is to increase the purity of the technical grade active ingredient and to add a new manufacturing site.

Chemistry Assessment

The chemistry requirements for Tribenuron Methyl Technical Herbicide are complete.

Health Assessments

With the new manufacturing site and new guarantee at the new and existing sites, Tribenuron Methyl Technical Herbicide is considered to be chemically equivalent at both sites. The guarantee is slightly changed from 97.3 to 97.6 % with a decrease in process-related impurities. The toxicity profile is not expected to be significantly different and as a result, no toxicological data were required.

The request to register a new manufacturing site and to alter the statement of product specification is not expected to alter the residues in food and feed crops treated with end use products containing Tribenuron-methyl Technical Herbicide. Therefore, no increase in dietary exposure to tribenuron-methyl is anticipated.

Environmental Assessment

No environmental assessment was required.

Value Assessment

No value assessment was required.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Tribenuron Methyl Technical Herbicide is eligible for registration.

References

- 1239682. 2005, Technical Grade Tribenuron Methyl (DPX-L5300) Analysis and Certification of Product Ingredients, AMR 4707-97, Revision No. 1, MRID: NA, DACO: 2.13.1,2.13.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
- 1239683. 2006, Technical Grade Tribenuron Methyl (DPX-L5300) Analysis and Certification of Product Ingredients, AMR 4707-97, Revision No. 1, MRID: NA, DACO: 2.13.1,2.13.2,2.13.3
- 1239685. 2006, Applicant's Name & Address, Manufacturer's Name & Address, NA, MRID: NA, DACO: 2.1,2.2
- 1262234. 1998, Technical Grade DPX-L5300 (Tribunon methyl) Manufacturing Description and Formation of Impurities, AMR 5161-98, DACO: 2.11.1,2.11.2,2.11.3,2.11.4

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