

Evaluation Report for Category B, Subcategory 2.1, 2.2, 2.3, and 2.4 Application

Application Number: 2006-3759
Application: Category B.2.1 (Guarantee), B.2.2 (Form of Active), B.2.3 (Identity of Formulants), and B.2.4 (Proportion of Formulants)
Product: GF-1667 Herbicide Manufacturing Concentrate
Registration Number: 28783
Active ingredients (a.i.): glyphosate, as dimethylamine salt
PMRA Document Number: 1498882

Background

The source of glyphosate acid, Glyphosate Technical Herbicide (Reg. No. 26450) containing 96.3% glyphosate was first registered in 2000.

Purpose of Application

The purpose of this application was to register GF-1667 Herbicide Manufacturing Concentrate, a new manufacturing concentrate intended for use in the manufacture of end use products. The manufacturing concentrate contains the registered technical active ingredient Glyphosate Technical Herbicide (Reg. No. 26450) as a source of glyphosate acid, along with the formulant dimethylamine to make a new form of glyphosate salt. For specific details of uses, application rates and methods, precautions, restrictions and personal protective equipment requirements, refer to the product label.

Chemistry Assessment

GF-1667 Herbicide Manufacturing Concentrate is a yellow solution containing glyphosate, present as dimethylamine salt, at a nominal concentration of 49%. The formulation has a density of 1.26 g/mL and pH of 4.53. With the exception of the storage stability and corrosion characteristics studies that are currently in progress, the chemistry requirements for GF-1667 Manufacturing Concentrate have been completed.

Health Assessment

GF-1667 Herbicide Manufacturing Concentrate is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 5000$ mg/kg), and inhalation routes ($LC_{50} > 5.21$ mg/L). It is minimally irritating to the eye and skin of rabbits. It is not considered to be a dermal sensitizer.

Environmental Assessment

No environmental studies were required to support the registration of GF-1667 Herbicide Manufacturing Concentrate. This product is for manufacturing, formulating and repackaging purposes only, thus environmental exposure is expected to be minimal. The properties of glyphosate as the dimethylamine salt are expected to be similar to those of currently registered glyphosate products.

Value Assessment

A value assessment is not required for a manufacturing concentrate.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that GF-1667 Herbicide Manufacturing Concentrate is eligible for full registration, with registration being contingent upon fulfilling the following requirements by September 1, 2009:

- submission of a storage stability study (DACO 3.5.10); and
- submission of a corrosion characteristics study (DACO 3.5.14).

References List

Studies/Information Provided by Applicant/Registrant

Chemistry Assessment

- | | |
|---------|---|
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| 1261882 | 2005, Group A- Product Identity, Composition, and Analysis for Glyphosate DMA 62% Technical Solution; a Manufacturing-use Product Containing N-(phosphonomethyl)glycine, NAFST-05-128, MRID: N/A, DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.2.3,3.3.1,3.4.1 |
| 1261883 | 2005, Analysis of Product Samples for Active Ingredient in GF-1667 Manufacturing Concentrate, FOR-05-052, MRID: N/A, DACO: 3.3.1 |
| 1261884 | 2005, Determination of Colour, Physical State, Odour, Oxidizing and Reducing Action, Flammability, Explodability, pH, Viscosity and Density of GF-1667, a Liquid Manufacturing Use Product Containing Glyphosate, FAPC053278, MRID: N/A, DACO: 3.5.1,3.5.11,3.5 |
| 1261885 | 2006, Two Week Accelerated Storage Stability of GF-1667 in Glass, FOR- |

05-060, MRID: N/A, DACO: 3.5.10
1261886 2006, Corrosion Characteristics, N/A, MRID: N/A, DACO: 3.5.14
1261887 2006, Container Material and Description, N/A, MRID: N/A, DACO: 3.5.5
1261888 2005, Determination of Dissociation of Glyphosate DMA Salt, DOS/464,
MRID: N/A, DACO: 3.7

Health Assessment

1261890 2005, GF-1667: Acute Oral Toxicity Up and Down Procedure in Rats,
17457, MRID: N/A, DACO: 4.2.1,4.6.1
1261891 2005, GF-1667: Acute Dermal Toxicity Study in Rats - Limit Test, 17458,
DACO: 4.2.2,4.6.2
1261892 2005, GF1667: Acute Liquid Aerosol Inhalation Toxicity Study in
F344/DUCRL Rats, 051152, MRID: N/A, DACO: 4.2.3,4.6.3
1261893 2005, GF-1667: Primary Eye Irritation Study in Rabbits, 17459, MRID: N/A,
DACO: 4.2.4,4.6.4
1261894 2005, GF-1667: Primary Skin Irritation in Rabbits, 17460, DACO:
4.2.5,4.6.5
1261895 2005, GF-1667: Local Lymph Node Assay in BALB/cAnNCrI Mice, 051096,
MRID: N/A, DACO: 4.2.6,4.6.6

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