Evaluation Report for Category B, Subcategory 2.1, 2.3, & 2.4 Applications

Application Number: 2006-7858
Application: B.2.1 (New/Changes EP Product Chemistry-Guarantee)
B.2.3 (New/Changes EP Product Chemistry-Identity of Formulants)
B.2.4 (New/Changes EP Product Chemistry-Proportion of Formulants)
Product: Garlon XTR Herbicide
Registration Number: 28945
Active ingredients (a.i.): Triclopyr [TPR]
PMRA Document Number: 1565186

Purpose of Application

The purpose of this application is to register a new commercial product, Garlon XRT Herbicide. Garlon XRT Herbicide is a new formulation of a currently registered product, Garlon 4 Herbicide (Reg. No. 21053).

Chemistry Assessment

Garlon XRT Herbicide is a solution containing the active ingredient at a nominal concentration of 755 g/L. This product has a density of 1.2572 g/mL and pH of 4.49. The product chemistry database is complete with the exception of the storage stability and corrosion characteristics data for Garlon XRT Herbicide and its associated repacks.

Health Assessments

Garlon XRT Herbicide is of low toxicity to rats via the oral (LD_{50} = 2966 mg/kg), dermal (LD_{50} >5000 mg/kg) and inhalation routes (LC_{50} >5.90 mg/L). It is moderately irritating to the eye and mildly irritating to the skin of rabbits. It was found to be a potential skin sensitizer in mice.

The proposed product, Garlon XRT Herbicide, fits within the existing use pattern for triclopyr. The proposed active ingredient application rates, timing, and methods of application are similar to currently registered products containing triclopyr (Reg. No. 21053 and 28434). As such, the requested change in formulations and guarantee are not expected to result in an increase in occupational exposure.

Based on the product specifications, the new formulants are not expected to have an impact on the magnitude on the residues of triclopyr when Fencerow XRT Herbicide is used according to

the label. Thus, triclopyr residues are not expected to pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

Garlon XTR Herbicide is based on a more dilute precedent product, but the application rates of the active ingredient have not changed since the amount of product is scaled appropriately to account for the differences in concentration. Further, the proposed use scenario is already registered for the precedent product, hence the use of Garlon XTR Herbicide is not expected to increase the release of triclopyr to the environment.

Value Assessment

Data from 32 trials conducted in Canada (8 trials in 7 locations) and the US (24 trials in 10 locations) over a 4-year period (2003-2006) were submitted to support the registration of Garlon XRT Herbicide. Efficacy (in 32 trials) and crop safety (in 12 trials) of Garlon XRT Herbicide were directly compared to those of the registered Garlon 4 Herbicide.

Control of red maple, common ragweed, lamb's-quarters, pignut hickory, loblolly pine, balsam poplar, aspen poplar, black cherry, southern red oak, willow oak, prairie rose, black berry, curled dock, dandelion, and winged elm were visually assessed from 1 to 3 times during the growing season. Control of these weeds following the application of Garlon XRT Herbicide was comparable to that for Garlon 4 Herbicide.

The tolerance of 2 conifer species and 12 grass species to Garlon XRT Herbicide was visually assessed from 1 to 4 times during the growing season. For the tested conifer and grass species, crop injury and leaf chlorosis following the application of Garlon XRT Herbicide was comparable to that for Garlon 4 Herbicide. Data for dry matter yield collected for bromegrass, fescue, and timothy in 1 trial further supported the crop tolerance claim.

The performance of Garlon XRT Herbicide was, therefore, concluded to be similar to that of Garlon 4 Herbicide.

Conclusion

The Agency has completed an assessment of available information for Garlon XTR Herbicide and has found it sufficient to allow for full registration, with registration being contingent upon fulfilling the following data requirements:

- One-year storage stability data, DACO: 3.5.10
- Corrosion characteristics data, DACO: 3.5.14

References

A. List of Studies/Information Submitted by Registrant

Chemistry Assessment

PMRA #	Reference
1341880	2005, Group A - Product Identity, Composition, and Analysis for GF-1665 and GF-1371; an End Use Product Containing Triclopyr Butoxyethyl Ester, NAFST-05-117, MRID: N/A, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.4.2
1341881	2005, Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, Flammability, Explodability, pH, Viscosity and Density of GF-1665, an End Use Product Containing Triclopyr Butoxyethyl Ester, FAPC053337, MRID: N/A, DACO: 3.5.1, 3.5.11, 3.5.
1341882	2005, Accelerated Storage Stability Study of GF-1665; a Triclopyr Butoxyethyl Ester Emulsifiable Formulation, in Glass for 2 weeks at 54°C, FOR-05-037, MRID: N/A, DACO: 3.5.10
1366701	2007, Product Identification, N/A, MRID: N/A, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4
1366702	2007, Corrosion Characteristics, N/A, MRID: N/A, DACO: 3.5.14
1366703	2007, Dielectic Breakdown, N/A, MRID: N/A, DACO: 3.5.15
1387757	2007, Determination of Miscibility of GF-1665, an End-Use Product Containing Triclopyr Butotyl, FAPC073077, MRID: N/A, DACO: 3.5.13
1421643	2005, Analytical Method and Validation for the Determination of Triclopyr Butoxyethyl Ester in GF-1665 and GF-1371 Formulations, N/A, MRID: N/A, DACO: 3.4.1

Health Assessment

PMRA #	Reference
1341883	2005, GF-1665: Acute Oral Toxicity Up and Down Procedure in Rats, 050265, 17111, MRID: N/A, DACO: 4.6.1
1341884	2005, GF-1665: Acute Dermal Toxicity in Rats - Limit Test, 050266, 17112, MRID: N/A, DACO: 4.6.2
1341885	2005, GF-1665: Acute Liquid Aerosol Inhalation Toxicity Study in F344/DUCRL Rats, 051085, MRID: N/A, DACO: 4.6.3
1341886	2005, GF-1665: Primary Eye Irritation Study in Rabbits, 050268, 17113, MRID: N/A, DACO: 4.6.4

1341887 2005, GF-1665: Primary Skin Irritation Study in Rabbits, 050267, 17114, MRID: N/A, DACO: 4.6.5

1341888 2005, GF-1665: Local Lymph Node Assay in BALB/cAnNCrl Mice, 051082, MRID: N/A, DACO: 4.6.6

Value Assessment

PMRA # Reference

1047048 Garlon 4 formulation project biology review, November 2004. Dow AgroSciences. DACO: 10.1. pp. 31.

1394109 Part 10 - Efficacy and crop tolerance trial reports. Dow AgroSciences. DACO 10.2.3.3 and DACO: 10.3.2. March 18, 2007. pp. 139.

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