



Evaluation Report for Category B, Subcategory B1.1; B.1.3 Application

Application Number: 2006-0416
Application: Addition of a new site of manufacture and to update the upper certified limits of certain impurities
Product: Glyphosate Technical Grade
Registration Number: 19535
Active ingredients (a.i.): Glyphosate
PMRA Document Number: 1403864

Background

Glyphosate is a non-selective systemic herbicide. It controls weeds via inhibition of the enzyme 5-enolpyruvylshikimate-3-phosphate synthetase (EPSPS) which is involved in the amino acid biosynthesis pathway in plants. Glyphosate Technical Grade was first registered for use in 1986, and is registered for use on a wide variety of crops

Purpose of Application

The purpose of the current petition is to add a new site of manufacture and to update the upper certified limits of certain impurities

Chemistry Assessment

Common Name: Glyphosate
IUPAC Chemical Name: *N*-(phosphonomethyl)glycine
CAS Chemical Name: *N*-(phosphonomethyl)glycine

Glyphosate Technical Grade has the following properties:

Property	Result
Colour and physical state	white powder
Nominal concentration	96.3%
Odour	none
Density	1.74 g/cm ³
Vapour pressure	1.31 x 10 ⁻² mPa (25°C)
pH	2.5 (1% aqueous solution)
Solubility in water	10.5 g/L @ 25°C, pH 1.9
n-Octanol/water partition coefficient	log K _{ow} < 3.2 (pH 2-5, 20°C)

The chemistry requirements for Glyphosate Technical Grade are complete.

Health Assessments

No toxicology review was conducted since results from the chemistry review indicate that the active ingredient produced at both the registered and new site of manufacture of Glyphosate Technical Grade are chemically equivalent. Therefore, the health risk profile of Glyphosate Technical Grade is expected to be similar to that of the original registered sources.

The request to add a new site of manufacture and to update the upper certified limits (Glyphosate Technical Grade) to product Reg. No. 19535 is not expected to alter the residues in food and feed crops treated with end use products containing glyphosate technical. Therefore, no increase in dietary exposure to glyphosate is anticipated.

Environmental Assessment

An environmental assessment was not required as an assessment was conducted on the glyphosate technical grade active ingredient.

Value Assessment

A value assessment is not required for the technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Glyphosate Technical Grade is eligible for conditional registration, with registration being contingent upon fulfilling the following requirements

References

PMRA #	Title:
1135213	Applicants Name and Address; Manufacturing Plants Name and Address, DACO: 2.1,2.2
1135214	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.11.1
1135215	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.11.2
1135216	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.11.3
1135217	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.11.4
1135218	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.12.1
1135219	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.13.1
1135220	2003, Analytical Methods for Glyphosate, LOD, NNG and Formaldehyde Used in Characterization of Glyphosate Technical Materials MON 0139 (Isopropylamine Salt) and MON 77973 (Wetcake), Monsanto Company, MSL 18398, DACO: 2.13.1
1135221	2003, Analytical Methods for Impurity Determination of Glyphosate Technical Materials MON 0139 (Isopropylamine Salt) and MON 77973 (Wetcake), Monsanto Company, MSL 18399, DACO: 2.13.1
1135222	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.13.2
1135223	RD314C: Product Chemistry Data to Support the Addition of Muscatine Source to Glyphosate Technical Grade and Amendment of Upper Limits of Impurity Levels., DACO: 2.13.4
1135224	2003, Analytical Profile of Glyphosate Technical (Wetcake)/MON 77973 From Monsanto São José dos Campos Plant., Monsanto Company, MSL-18272, DACO: 2.13.3
1135225	2003, Analytical Profile of Glyphosate Technical (Wetcake)/MON 77973 From Monsanto Zarate Plant., Monsanto Company, MSL-18273, DACO: 2.13.3
1135226	2003, Analytical Profile of Glyphosate Technical (Wetcake)/MON 77973 From Monsanto Antwerp Plant., Monsanto Company, MSL-18275, DACO: 2.13.3
1135227	2004, Analytical Profile of Glyphosate Technical (Wetcake)/MON 77973 From Monsanto Luling Plant., Monsanto Company, MSL-18276, DACO: 2.13.3
1135228	2004, Analytical Profile of Glyphosate Technical (Wetcake)/MON 77973 From Monsanto Muscatine Plant., Monsanto Company, MSL-19159, DACO: 2.13.3
1135229	Waiver Request, DACO: 2.3,2.4,2.5,2.6,2.7,2.8,2.9
1135230	Waiver Request., DACO: 2.14,2.15
1357236	2007, Summary of certified limits, DACO: 2.12.1
1357237	2007, Batch data for manufacturing sites converted to dry weight, DACO: 2.13.3
1357239	2007, Excel table of batch data converted to dry weight, DACO: 2.13.3
1363102	2007, Deficiency Response for submission 2006-0416, DACO: 0.8
1269370	2007, Chemistry Product Chemistry Data Review for the Registration of Glyphosate Technical Grade. DACO 2.0.

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