

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2016-0950
Application: Changes to technical grade active ingredient product chemistry –
 New source (site) for the same registrant
Product: NewAgco Glufosinate Technical
Registration Number: 30613
Active ingredients (a.i.): Glufosinate-ammonium
PMRA Document Number: 2683485

Purpose of Application

The purpose of this application was to add two new manufacturing sites of glufosinate-ammonium to the technical product, NewAgco Glufosinate Technical (Registration Number 30613).

Chemistry Assessment

Common Name: Glufosinate-ammonium
IUPAC* Chemical Name: Ammonium (2*RS*)-2-amino-4-(methylphosphinato)butyric acid
CAS† Chemical Name: 2-amino-4-(hydroxymethylphosphinyl)butanoic acid
 monoammonium salt

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

NewAgco Glufosinate Technical has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	97.5 %
Odour	Odourless
Density	1.34 g/mL
Vapour pressure	9.55×10^{-5} Pa at 20°C
pH	4.14
Solubility in water	1370 g/L at 22°C

Property	Result
n-Octanol/water partition coefficient	$\text{Log}_{10} P_{ow} < -1.77$

The required chemistry data for NewAgco Glufosinate Technical have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed a review of information provided in support of NewAgco Glufosinate Technical and found it sufficient to add two new manufacturing sites of glufosinate-ammonium to the technical product.

References

PMRA Document Number	Reference
2608540	2016, Manufacturer Information, DACO: 2.1, 2.2, 2.3, 2.3.1 CBI
2608541	2016, Manufacture Process of Glufosinate-Ammonium Technical, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4 CBI
2608542	2016, Manufacture process of Glufosinate- Ammonium Tech, DACO: 2.11.1, 2.11.2, 2.11.3 CBI
2608543	2016, Justification of Impurities, DACO: 2.11.4 CBI
2608544	2015, Glufosinate ammonium Technical Material: Enforcement Analytical Method, DACO: 2.13.1 CBI
2608545	2013, Preliminary Analysis of Glufosinate-Ammonium Tehnical Grade Active Ingredient (TGAI), DACO: 2.12.1, 2.13.2, 2.13.3 CBI
2608546	2014, Preliminary Analysis of Glufosinate-Ammonium TGAI, DACO: 2.12.1, 2.13.2, 2.13.3 CBI
2608547	2015, Chemical and Physical Characterization of Glufosinate-Ammonium TGAI, DACO: 2.14.1, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.4, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 830.7000 CBI
2608548	2013, Melting Point/Melting Range of Glufosinate-Ammonium Technical, DACO: 2.14.4 CBI
2608549	2013, Water Solubility of Glufosinate-Ammonium Technical, DACO: 2.14.7 CBI
2608550	2013, Vapour Pressure of Glufosinate-Ammonium Technical, DACO: 2.14.9 CBI
2608551	2013, Partition Coefficient (n-Octanol/Water) of Glufosinate-Ammonium Technical, DACO: 2.14.11 CBI
2608552	2015, Physical and Chemical Characteristics of Glufosinate Ammonium Technical Material, DACO: 2.14.1, 2.14.13, 2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.6, 830.7000 CBI
2677519	2016, Manufacturing Clarifications, DACO: 2.11.2, 2.11.3 CBI
2677521	2016, The Justification Of Impurities Of Glufosinate-Ammonium Technical, DACO: 2.11.4 CBI
2677524	2016, Clarification Response to First Point, DACO: 2.13.1 CBI
2677525	2013, Validation of Analytical Methodology for the Assay of [CBI Removed] in Glufosinate-Ammonium TGAI, DACO: 2.13.1 CBI
2677526	2012, Validation of Analytical Methodology for the Assay of Three Impurities in Glufosinate-Ammonium TGAI, DACO: 2.13.1 CBI
2677527	2012, Validation of Analytical Methodology for the Assay of One Impurity in Glufosinate-Ammonium TGAI, DACO: 2.13.1 CBI
2677528	2015, Preliminary Analysis of Glufosinate-Ammonium TGAI, DACO: 2.13.1 CBI

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