

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2014-2402
Application: Changes to TGAI Product Chemistry – New Source (site) Same Registrant
Product: Bromoxynil Octanoate Technical
Registration Number: 19705
Active ingredients (a.i.): Bromoxynil
PMRA Document Number : 2532739

Purpose of Application

The purpose of this application was to add a new manufacturing site for Bromoxynil Octanoate Technical.

Chemistry Assessment

Common Name: Bromoxynil octanoate
CAS Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate
IUPAC Chemical Name: 2,6-dibromo-4-cyanophenyl octanoate

Bromoxynil Octanoate Technical has the following properties:

Property	Result
Colour and physical state	Tan to brown solid
Nominal concentration	65.9% as bromoxynil
Odour	Not more than slight
Density	1.64 g/cm ³
Vapour pressure	N/A
pH	4.3 (1% dilution)
Solubility in water	0.03 mg/L
n-Octanol/water partition coefficient (K _{ow})	Log K _{ow} = 5.9

The chemistry requirements for Bromoxynil Octanoate Technical have been fulfilled.

Health, Environmental and Value Assessments

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

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of Bromoxynil Octanoate Technical and has found the information sufficient to add a new manufacturing site.

References

PMRA Document Number	References
2438873	2014, Bromoxynil Octanoate Technical - Information to Address PMRA DACO Elements 2.1 and 2.2, DACO: 2.1,2.2 CBI
2438875	2013, Bromoxynil Octanoate Tech Manufacturing Process Description, DACO: 2.11.1,2.11.2,2.11.3 CBI
2438876	2013, Statement on formation of impurities, DACO: 2.11.4 CBI
2438877	2013, A discussion on the nomenclature of Impurities in bromoxynil octanoate technical, DACO: 2.11.4 CBI
2438878	2012, Preliminary analysis of bromoxynil octanoate TGAI, DACO: 2.12.1,2.13.2,2.13.3 CBI
2438882	2012, Validation of analytical methodology for the assay of [CBI removed] non-relevant Impurities in bromoxynil octanoate TGAI, DACO: 2.13.1 CBI
2438884	2011, Validation of analytical methodology for the assay of active ingredient in bromoxynil octanoate TGAI, DACO: 2.13.1 CBI
2438885	2012, Validation of analytical methodology for the assay of [CBI removed] non-relevant impurities in bromoxynil octanoate TGAI, DACO: 2.13.1 CBI
2438886	2012, Validation of analytical methodology for the assay of [CBI removed] in bromoxynil octanoate TGAI, DACO: 2.13.1 CBI
2482558	2013, Bromoxynil Octanoate Tech Manufacturing Process Description, DACO: 2.11,2.11.1,2.11.2 CBI

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