

Evaluation Report for Category B, Subcategory B.1.1, B.1.3 Application

Application Number: 2012-4573
Application: Changes to Technical Grade Active Ingredient; New Source Same Registrant and Specifications.
Product: Linuron Technical Herbicide
Registration Number: 21070
Active ingredients (a.i.): Linuron
PMRA Document Number: 2362707

Purpose of Application

The purpose of this application was to amend the product specifications of Linuron Technical Herbicide, (Registration Number 21070) and to change the manufacturing site.

Chemistry Assessment

Common Name: Linuron
 IUPAC* Chemical Name: 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea
 CAS† Chemical Name: *N'*-(3,4-dichlorophenyl)-*N*-methoxy-*N*-methylurea

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Linuron Technical Herbicide has the following properties:

Property	Result
Colour and physical state	Pale yellow powder
Nominal concentration	99.6%
Odour	Odourless
Density	420-520 g/L (21°C)
Vapour pressure	2.0 mPa
pH	6.60-8.00 (1% w/w)
Solubility in water	81 mg/L (20°C)
n-Octanol/water partition coefficient (K_{ow})	Log K_{ow} = 3.20

The chemistry requirements for Linuron Technical Herbicide have been fulfilled.

Health Assessments

The new source of Linuron Technical Herbicide results in a product that is toxicologically equivalent to the previous source. No toxicological data were required or reviewed.

Food residue and exposure assessments were not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The technical grade active ingredient was found to be chemically equivalent to the previously registered source of Linuron Technical Herbicide and was approved.

References

PMRA

Document

Number	Reference
2243128	Manufacturing summary, DACO: 2.11.1 CBI
2243129	2010 Description of starting materials, DACO: 2.11.2 CBI
2243130	Process description, DACO: 2.11.3 CBI
2243131	2005, Formation of impurities, DACO: 2.11.4 CBI
2243135	2011, Analytical method validation, DACO: 2.13.1,2.13.2 CBI
2243136	2011, Batch data, DACO: 2.13.3 CBI
2243137	2012, [CBI Removed] analysis, DACO: 2.13.4 CBI
2243138	2008, Physical and chemical data, DACO: 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9 CBI
2351451	2013, [CBI Removed] COA, DACO: 2.11.2 CBI
2351452	2013 Linuron manufacturing process, DACO: 2.11.3 CBI
2351453	2013, Declaration for batches MUSTER 1 to 5, DACO: 2.13.3 CBI
2351454	2012, Lot 0080612 COA, DACO: 2.13.3
2351455	2012, Lot 0100612 COA, DACO: 2.13.3
2351456	2012, Lot 0200712 COA, DACO: 2.13.3
2351457	2012, Lot 0210712 COA, DACO: 2.13.3
2351458	2012, Lot 0270712 COA, DACO: 2.13.3

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