Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1, 4.6 Application

Application Number: 2022-2549
Application: Changes TGAI Product Chemistry-New Source (Site), Fulfill Conditions of Registration
Product: Linuron Flake Technical
Registration Number: 19696
Active ingredient (a.i.): Linuron
PMRA Document Number: 3408264

Purpose of Application

The purpose of this application was to register a new manufacturing site for Linuron Flake Technical, and to fulfill the requirements to reduce impurities of concern identified in the Section 12 Notice (see application number 2003-1390) issued following the re-evaluation of linuron (RVD2020-10, *Linuron and its associated end-use products).*

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 Flake Technical has the following properties:

Property	Result
Colour and physical state	Off-white solid
Nominal concentration	100%
Odour	Odourless
Density	1.4963 g/mL
Vapour pressure	0.2 mPa
pH	7-9
Solubility in water	58.8 mg/L

Canada

Property	Result
n-Octanol/water partition coefficient	log K_{ow} = 3.07

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

Health Assessments

The estimated levels of Track 1 contaminants in the new source of Linuron Flake Technical have been reduced in comparison to previously registered sources of linuron, as required by the PMRA issued under the Section 12 notice resulting from the re-evaluation of Linuron. Linuron Flake Technical produced at the new manufacturing site is considered toxicologically equivalent to the previous manufacturing site; therefore, neither toxicology data nor label changes were required.

Residue and exposure assessments were not required for this application.

Environmental Assessment

The new source of technical linuron contains contaminants that have been identified in the federal government's Toxic Substances Management Policy (TSMP, 1995) as Track 1 substances. The PMRA's strategy to manage Track 1 contaminants in pest control products is captured in DIR99-03. Reduction in the levels of Track 1 contaminants is based on the requirement for virtual elimination of these substances, as per the TSMP. The TSMP recognizes that social, economic, and technical considerations must be taken into account in any management decision. Therefore, virtual elimination of Track 1 substances is a long-term goal to be implemented through a common sense approach.

The estimated levels of Track 1 contaminants in the new source have been reduced in comparison to previously registered sources of linuron, and as required by the PMRA issued under the Section 12 notice. Therefore, the Track 1 contaminant levels in the new source are considered to be in line with the PMRA's goal of virtual elimination under DIR99-03.

Value Assessment

A value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information acceptable to register the new source, and to replace the former one as a fulfillment of the requirements of the Section 12 notice for Linuron Flake Technical.

References

PMRA Document Number	Reference
3363408	2022, Five Batch Analysis of Linuron Flake Technical, DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI
3363411	2022, Linuron Flake Technical Description of the manufacturing process PCP # 19696, DACO: 2.11.1,2.11.3 CBI
3363412	2022, Linuron Flake Technical Description of the starting materials PCP # 19696, DACO: 2.11.2 CBI
3363413	2022, Linuron Flake Technical: Discussion of the Formation of Impurities PCP # 19696, DACO: 2.11.4 CBI
3363414	2022, Linuron Flake Technical Chemical and Physical Properties PCP # 19696, DACO: 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
3371635	2022, pH of Linuron Flake Technical, DACO: 2.14.15,830.7000 CBI
3394430	2022, Chemistry DACO: 2.13.3,2.13.4 CBI