

Evaluation Report for Category B, Subcategory B.1.1, B.1.3 and C.3.15 Application

Application Number: 2006-3808
Application: B.1.1 [New Source (Site of Manufacture)], B.1.3 [Specifications by Same Registrant] and C.3.15 [Label Amendments]
Product: Nufarm 2,4-D 2-Ethylhexyl Ester Technical
Registration Number: 17135
Active ingredients (a.i.): 2,4-D present as the 2-ethylhexyl ester at 64.3% a.e.
PMRA Document Number : 1466794

Background

The original submission of 2,4-D present as the 2-ethylhexyl ester active ingredient, “Nufarm 2,4-D 2-Ethylhexyl Ester Technical” (Reg. No. 17135) was first registered in 1982. This product is used in the reformulation of pesticides.

Purpose of Application

The purpose of this application is to add four new manufacturing sites, change the guarantee and some label amendments.

Chemistry Assessment

Common Name: 2,4-D-2-ethylhexyl
Chemical Name: (RS)-2-ethylhexyl (2,4-dichlorophenoxy)acetate

Nufarm 2,4-D 2-Ethylhexyl Ester Technical has the following properties.

Property	Result
Colour and physical state	Pale yellow liquid
Physical state	Liquid
Nominal Concentration	64.3%
Odour	Slightly phenolic
Boiling point /range	> 300°C (decomp)

Specific gravity at 20°C	1.15
Water solubility at 25°C	0.086 mg/L
Octanol/water partition coefficient	log P = 5.78
Vapour pressure	47.9 mPa

The chemistry requirements for Nufarm 2,4-D 2-Ethylhexyl Ester Technical” have been completed.

Health Assessments

The active ingredient produced at the registered and new sites of manufacture of Nufarm 2,4-D 2-Ethylhexyl Ester Technical are chemically equivalent. Therefore, the toxicology profile of Nufarm 2,4-D 2-Ethylhexyl Ester Technical is expected to be similar to that of the original registered source and no toxicological data were required.

To support the new sources of Nufarm 2,4-D 2-Ethylhexyl Ester Technical, no new residue data were submitted. The food residue risk profile of 2,4-D is expected to be similar to that of the original registered source of Nufarm 2,4-D 2-Ethylhexyl Ester Technical as all sources of the TGAI are chemically equivalent. Accordingly, no increase in dietary exposure is anticipated.

Environmental Assessment

An environmental assessment was not required under this application.

Value Assessment

A value assessment was not required under this application.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that the proposed sources are eligible for registration and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

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- 1263306 2005, 2,4-D 2-EHE Physico-Chemical Properties, NUF072/043301, DACO: 2.14.1,2.14.10,2.14.13,2.14.2,2.14.3,2.14.6,2.14.8
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