

Evaluation Report for Category B, Subcategory B.4.1 Application

Application Number: 2005-3442
Application: Evaluation Report for Category B, subcategory B.4.1 Application
Product: Aceto 2,4-DB 2-ethylhexyl ester technical
Registration Number: 28139
Active ingredients (a.i.): Aceto 2,4-DB 2-ethylhexyl ester
PMRA Document Number: 1375547

Background

Technical active aceto 2,4-DB 2-ethylhexyl ester from the current source was granted temporary registration in November, 2005 on the basis of:

1. Authorization by the 2,4-DB Task Force to use the Task Force database on 2,4-DB and 2,4-DB 2-EHE.
2. The current source active is chemically similar to the registered source.
3. Address data gap in point value between data supporting the new source and the protected data supporting the currently registered TGAI source; the data gap identified being the acute inhalation toxicity study. (This requirement was determined by ESAD.)

With this application, a new acute inhalation toxicity study is submitted and evaluated.

Purpose of Application

The purpose of this submission is to convert the current Temporary Registration (PCP 28139) to Full Registration of the technical active aceto 2,4-DB 2-ethylhexyl ester.

Chemistry, Environmental, Value, and Maximum Residue Limits (MRLs) Assessments

Chemistry, environmental, value, and MRLs assessments are not required for this conversion application..

Health Assessment

The toxicity profile for technical aceto 2,4-DB 2-ethylhexyl ester herbicide from the current source is expected to be similar to that of the registered source. Based on the present evaluation of the acute inhalation toxicity data, aceto 2,4-DB 2-ethylhexyl ester is considered of low acute inhalation toxicity (rat inhalation LC50 >5.06 mg/L, actual concentration).

Conclusions

Based on the acute toxicity data, PMRA can support the conversion of the current Temporary Registration (PCP 28139) to Full Registration of the technical active aceto 2,4-DB 2-ethylhexyl ester. Please note that the current evaluation involves the review of the submitted acute inhalation toxicity study and the toxicological database on 2,4-DB 2-ethylhexyl ester is in the process of being re-evaluated.

Reference List

A. List of Studies/Information Submitted by Registrant

Health Assessment

PMRA # 1100465. August 1, 2005 (date cited on QA statement sheet; date not given on covering page of Report). 2,4-DB ethylhexyl ester: Acute inhalation toxicity (nose-only) study in the rat. SPL project number 2100/001, Safepharm Laboratories Limited, Derbyshire, UK. Study conducted May 26 - June 28, 2005. Unpublished.

Environmental and Value Assessments

No data were submitted.

B. Additional Information Considered

i) Published Information

No published information was used in the present review.

ii) Unpublished Information Considered

No unpublished information was used.

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