

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2009-2517
Application: New/Changes to the technical grade active ingredient: changes in product chemistry specifications and new source (site) by the same registrant
Product: Acephate Technical
Registration Number: 27917
Active ingredients (a.i.): Acephate
PMRA Document Number : 1947668

Purpose of Application

The purpose of this application was to add a new manufacturing site of the technical grade active ingredient acephate and change the product specifications of the currently registered product Acephate Technical, Registration Number 27917.

Chemistry Assessment

Common Name: Acephate
Chemical name: (RS)-(O,S-dimethyl acetylphosphoramidothioate) or
(RS)-N-[methoxy(methylthio)phosphinoyl]acetamide

Acephate has the following properties:

Property	Result												
Colour and Physical state	White/ Crystalline solid												
Nominal Concentration	98.0%												
Odour	Sharp odour similar to rotting vegetation												
Melting range	88-90 °C												
Density or specific gravity at 25°C	0.3445-0.3559 g/ mL												
Solvent solubility at 20°C	<table border="1"> <thead> <tr> <th>Solvent</th> <th>Solubility (g/L)</th> </tr> </thead> <tbody> <tr> <td>Acetone</td> <td>151</td> </tr> <tr> <td>Ethanol</td> <td>> 100</td> </tr> <tr> <td>Ethyl acetate</td> <td>35</td> </tr> <tr> <td>Benzene</td> <td>16</td> </tr> <tr> <td>Hexane</td> <td>0.1</td> </tr> </tbody> </table>	Solvent	Solubility (g/L)	Acetone	151	Ethanol	> 100	Ethyl acetate	35	Benzene	16	Hexane	0.1
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Acetone	151												
Ethanol	> 100												
Ethyl acetate	35												
Benzene	16												
Hexane	0.1												
Vapour pressure at 24°C	0.226 mPa												
pH	4.64												
Octanol/water partition coefficient (K _{ow})	log Kow = -0.89												

The chemistry requirements for Acephate Technical are complete.

Health Assessments

The Acephate Technical produced at the new site of manufacture is considered to be chemically equivalent to that of the currently registered source. On this basis, the toxicological profile of the Acephate Technical manufactured at the new site is not expected to be significantly different from that of the currently registered product and no toxicological data were required.

The food residue risk profile of the new source is expected to be similar to that of the currently registered Acephate Technical as both sources are considered chemically equivalent. Accordingly, no increase in dietary exposure to any segment of the population is anticipated.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that the addition of a new source for the production of Acephate Technical and the changes in the product specifications are acceptable.

References

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