

Evaluation Report for Category B, Subcategory B.1.1 Application

Application Number: 2007-5434
Application: B.1.1 : Change TGAI - New Source (site) same registrant
Product: Dodine Technical Fungicide
Registration Number: 21919
Active ingredients (a.i.): Dodine
PMRA Document Number: 1641770

Purpose of Application

The purpose of this application is to register a new site of manufacture for Dodine Technical Fungicide (Reg. No. 21919) by the same registrant.

Chemistry Assessment

Common Name: Dodine
 Chemical Name: dodecylguanidine monoacetate

Dodine Technical Fungicide has the following properties:

Property	Result
Colour and physical state	Slightly yellow solid
Nominal concentration	98 % (limits: 95.0 - 100.0 %)
Odour	No characteristic odour
Specific gravity	0.984
Vapour pressure	< 5.49 x 10 ⁻⁶ Pa (50°C)
pH	7.6 (1% suspension in water)
Solubility in water	930 mg/L at 20°C
n-Octanol–water partition coefficient	log K _{ow} = 1.00 at 25°C

The chemistry requirements for Dodine Technical Fungicide are complete.

Health, Environmental and Value Assessments

As Dodine Technical Fungicide is currently registered, health, environmental and value assessments were not required.

Conclusion

The new site of manufacture of Dodine Technical Fungicide is acceptable for full registration.

References

Studies/Information Provided by Applicant/Registrant

PMRA No	Title
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1455739	2003, Dodine: Product Identity, Composition and Certified Limits, DOD 111203, MRID: N/A, DACO: 2.11.2, 2.11.3, 2.11.4, 2.12.1 CBI
1455740	2002, Analytical Profile of Technical Dodine, CHI-020709, MRID: N/A, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
1586184	1997, Technical Chemistry file DOD-GQS-1. Technical Dodine Analysis of Ingredient in Five Representative Samples, R&D/CRLD/AN/9715328, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
1586050	1998, Technical Chemistry file DOD-GQS-1. Technical Dodine: Analysis of Product Ingredients., 96-59, DACO: 2.13.3 CBI
1586195	1998, Technical Chemistry file DOD-GQS-1. Dodine: Physical Characteristics, R&D/CRLD/AN/9816880, DACO: 2.14.1, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6 CBI
1586202	1999, Technical Chemistry file DOD-GQS-1. Dodine: water and solvent solubility, R&D/CRLD/AN/9816934, DACO: 2.14.7, 2.14.8 CBI
1586208	1999, Technical Chemistry file DOD-GQS-1. Dodine: vapor pressure, R&D/CRLD/AN/9915350, DACO: 2.14.9 CBI
1586217	1999, Technical Chemistry file DOD-GQS-1. Dodine: pH and dissociation constant, R&D/CRLD/AN/9915061, DACO: 2.14.10 CBI
1586252	1999, Technical Chemistry file DOD-GQS-1. Dodine: n-octanol/water partition coefficient, R&D/CRLD/AN/9915132, DACO: 2.14.11 CBI

- 1586257 1994, Technical Chemistry file DOD-GQS-1. Dodine: UV-Visible Characteristics, R&D/CRLD/AN/9416845, DACO: 2.14.12 CBI
- 1586261 1999, Technical Chemistry file DOD-GQS-1. Dodine: Stability, R&D/CRLD/AN/9915325, DACO: 2.14.13, 2.14.14 CBI

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