

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2007-8441
Application: B.1.1 – New Source Same Registrant
Product: Sodium Omadine 40% Technical
Registration Number: 29714
Active ingredients (a.i.): Sodium Omadine
PMRA Document Number : 2575280

Purpose of Application

The purpose of this application was to remove the commercial uses from the product, Sodium Omadine 40% Technical, which previously had a dual technical/commercial classification.

Chemistry Assessment

Common Name: Sodium pyrithione
Chemical Name: Sodium 2-sulfidopyridine-N-oxide

Sodium Omadine 40% Technical has the following properties

| Property | Result |
|---------------------------------------|--|
| Colour and physical state | Amber solution |
| Nominal Concentration | 40.5 % |
| Odour | Mild |
| Boiling point/range | 108 |
| Specific gravity | 1.22 |
| Water solubility | 54.14 % w/w |
| Vapour pressure | 14.05 mm Hg |
| pH | 8.5 (10% in H ₂ O) |
| n-Octanol/water partition coefficient | Product is a salt which will dissociate completely in water. |

The chemistry requirements for Sodium Omadine 40% Technical have been completed.

Health Assessments

The removal of the commercial uses from the technical product is not expected to impact the toxicological profile of the product Sodium Omadine.

Environmental and Value Assessment

Environmental and value assessments were not required.

Conclusion

PMRA has reviewed the information provided in support of this application. PMRA has determined the removal of the commercial uses from the subject product is acceptable.

References

- 1511712 Technical Chemistry file [CBI REMOVED] Sodium Omadine, DACO: 2.99 CBI
- 1762642 2009, Sodium Omadine 40% Technical Starting Materials, Process, Formation of Impurities, DACO: 2.11.2,2.11.3,2.11.4 CBI
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- 1762645 2009, Statement of Product Specification, DACO: 2.12.2 CBI
- 1762646 2007, Five Batch Characterisation of Sodium Pyrithione Including Method Validation of Assay and Impurity Methods, DACO: 2.13.1,2.13.3 CBI

- 1762647 2007, Five Batch Characterisation of Sodium Pyrithione Including Method Validation of Assay and Impurity Methods, DACO: 2.13.3 CBI

- 1793925 The Stability of Sodium Pyrithione With Metals, DACO: 2.14.13
- 1793926 Accelerated Storage Stability of Sodium Omadine 40% Aqueous Solution, DACO: 2.14.13
- 1795176 2009, Statement of Product Specification, DACO: 2.12.2 CBI
- 1845358 This is an explanation of the methods for analysis of the impurity in question., DACO: 2.13.1 CBI
- 1845359 Identity of location and dates of product used in the 5-Batch Analysis., DACO: 2.13.3

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