



Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2009-2456

Application: Changes to TGA I product chemistry: Specifications

Product: Deet Insect Repellent

Registration Number: 18068

Active ingredients (a.i.): Deet (n,n-diethyl-m-toluamide) plus related active toluamides (ortho & para isomers)

PMRA Document Number English PDF: 2015427

Purpose of Application

The purpose of the application was to register an alternate manufacturing process of Deet Insect Repellent.

Chemistry Assessment

Common Name: Deet Insect Repellent

Chemical Names: *N,N*-Diethyl-*m*-toluamide

N,N-Diethyl-*p*-toluamide

N,N-Diethyl-*o*-toluamide

Deet Insect Repellent Technical has the following properties:

Property	Result
Colour and physical state	Colourless to amber liquid
Nominal concentrations	<i>N,N</i> -Diethyl- <i>m</i> -toluamide.....98.14% (Limit 95 – 100%) <i>N,N</i> -Diethyl- <i>o</i> -toluamide.....0.08% (Limit 0.00 – 0.25%) <i>N,N</i> -Diethyl- <i>p</i> -toluamide.....0.03% (Limit 0.00 – 0.35%)
Odour	Odourless
Specific gravity	0.995 at 24°C

Property	Result
Vapour pressure	5.6×10^{-3} mm Hg at 20°C
pH	6.7
Solubility in water	Insoluble in water
<i>n</i> -Octanol/water partition coefficient	2.02

The chemistry requirements for Deet Insect Repellent have been completed

Health Assessments

A toxicology assessment was not required as the minor differences in specifications of Deet Insect Repellent using the alternate manufacturing process were not expected to have an impact on the toxicological profile.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA conducted an evaluation of the subject application and found the submitted information sufficient to support the alternate manufacturing process.

References

PMRA Document Number: 1779037

Reference: 2009, Description of starting materials, Data Numbering Code: 2.11.2 Confidential Business Information

PMRA Document Number: 1779038

Reference: 2009, Detailed production process description, Data Numbering Code: 2.11.3 Confidential Business Information

PMRA Document Number: 1902248

Reference: 2010, Preliminary analysis, Data Numbering Code: 2.13.3 Confidential Business Information

PMRA Document Number: 1940386

Reference: 2010, Support documentation to approve Deet alternate manufacturing process, Data Numbering Code: 2.11.3 Confidential Business Information

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