

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2011-0786
Application: Changes to TGAI product chemistry: new source (site) same registrant, specifications
Product: Neudosan TGAI
Registration Number: 27882
Active ingredient (a.i.): Potassium salts of fatty acids
PMRA Document Number English PDF: 2075355

Purpose of Application

The purpose of this application was to add two new sources and to modify the product specifications.

Chemistry Assessment

Common Name: Potassium salts of fatty acids
IUPAC Chemical Name: Fatty acids, C₈₋₁₈ and C₁₈-unsaturated, potassium salts
CAS Chemical Name: Fatty acids, C₈₋₁₈ and C₁₈-unsaturated, potassium salts

Neudosan TGAI has the following properties:

Property	Result
Colour and physical state	Pale amber liquid
Nominal concentration	47.00%
Odour	Characteristic fatty acid odour
Density	1.035-1.039 g/mL (at 20°C)
Vapour pressure	7.21 kPa (at 20°C); 8.98 kPa (at 30°C); 11.21 kPa (at 40°C); 14.05 kPa (at 50°C); 16.46 kPa (at 60°C)
pH	8.60 ± 0.15
Solubility in water	90.9 g/L (at pH 5); 93.4 g/L (at pH 7); 181.8 g/L (at pH 9)
n-Octanol/water partition coefficient	Oleic acid log K _{ow} = 7.73 Potassium oleate log K _{ow} = 3.92

The chemistry requirements for Neudosan TGAI have been completed.

Health Assessment

A health assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

A value assessment was not required for this application.

Conclusion

An evaluation of available scientific information found that the new sources are chemically equivalent to the registered source(s). Therefore, the value of the product and its health and environmental risk are not affected under the approved conditions of use.

References

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| 2015810 | 2011, Neudosan TGAI Binder 2 Revised Jan11, DACO: 2.0, 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.12.2, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.16 |
| 2066494 | 2011, Neudosan TGAI Volume 2 corrected June11, DACO: 2.0, 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14, 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15, 2.16 |

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