

Evaluation Report for Category B, Subcategory B.1.3 Application

Application Number:	2008-2530
Application:	B.1.3 (Changes TGAI Product chemistry – specifications)
Product:	Neudosan TGAI
Registration Number:	27882
Active ingredients (a.i.):	Potassium salts of fatty acids
PMRA Document Number	: 1752771

Purpose of Application

The purpose of this application is to change the formulants in an integrated system product (ISP), Neudosan TGAI (Reg. No. 27882).

Chemistry Assessment

Common name: Potassium Salts of Fatty Acids Chemical name: Fatty acids, C_{8-18} and C_{18} -unsaturated, potassium salts

Neudosan TGAI has the following properties:

Property	Results
Colour and physical state	Amber liquid
Nominal concentration	47.0 %
Odour	Characteristic fatty acid odour
Density	1.037 g/mL
pH	10.51
n-Octanol/water partition coefficient	Log Kow for potassium oleate (representative component) is 3.92

The chemistry requirements for Neudosan TGAI have been completed.

Health Assessments

A health assessment was not required since there was only a change in formulants from the previously registered TGAI.

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 has completed the assessment of all available information and has concluded that the change in the formulation of Neudosan TGAI (Reg. No. 27882) is acceptable for registration.

References

16133402008, Binder 7, DACO: 2.0,2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.12.2,2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,16133412006, Storage Stability Neudosan Organic Signed 060513, DACO: 2.14.1416133422008, CBI Reference Document to Binder #7, DACO: 2.11.2,2.11.3,2.12.1 CBI17473742009, Binder 7 Revised Neudosan TGAI, DACO: 2.11.2,2.11.3,2.12.1 CBI

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