

# **Evaluation Report for Category B, Subcategory B.1.3 Application**

| <b>Application Number:</b>  | 2008-2530   |
|-----------------------------|---|
| Application:                | B.1.3 (Changes TGAI Product chemistry – specifications) |
| Product:                    | Neudosan TGAI   |
| <b>Registration Number:</b> | 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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