

Evaluation Report for Category D.1.0 Importation for Manufacturing and Exportation (IMEP) Application

Application Number: 2021-3993
Application: Importation for Manufacturing and Exportation Program (IMEP)
Product: Rosemary Oil - IMEP
Registration Number: 34313
Active ingredients (a.i.): Rosemary Oil (ROS)
PMRA Document Number : 3285770

Purpose of Application

The purpose of this application is to register a new technical active ingredient, Rosemary Oil - IMEP, under the Importation for Manufacturing and Export Program (IMEP).

Chemistry Assessment

Common Name: Rosemary oil
IUPAC* Chemical Name: N/A
CAS† Chemical Name: Oils, rosemary

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Rosemary Oil - IMEP has the following properties:

Property	Result
Colour and physical state	Clear liquid
Nominal concentration	100%
Odour	Characteristic
Density	0.892 – 0.912 g/mL at 25°C
Vapour pressure	0.057 Pa at 20°C
pH	Waived
Solubility in water	Expected to be insoluble.
n-Octanol/water partition coefficient	Waived

The required chemistry data for Rosemary Oil - IMEP have been provided, reviewed, and found to be acceptable.

Health Assessments

The technical grade active ingredient, Rosemary Oil – IMEP, is of low acute toxicity by the oral and dermal routes of exposure. It is a moderate skin irritant, extremely irritating or corrosive to the eye, and is a dermal sensitizer.

Environmental Assessment

The proposed registration of Rosemary Oil - IMEP as an IMEP is not expected to increase environmental risk. Concerns with respect to disposal and transport have been addressed through adequate label statements.

Conclusion

The PMRA has reviewed all available information and has determined that the registration of the new IMEP technical active ingredient, Rosemary Oil - IMEP, is acceptable.

References

PMRA No.	Reference
3271683	2021, physchem, DACO: 2.0 CBI
3271684	2021, analytical method, DACO: 2.15 CBI
3260335	2021, Essential Oil Tox Profile – For PMRA Data Supplementation, DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6
3271521	2021, MSDS – Material Safety Data Sheets – Rosemary Oil, DACO 0.9

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