

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2008-1806
Application: New source by different registrant
Product: Passion-Krafts Oleoresin of Red Pepper Technical
Registration Number: 29550
Active ingredients (a.i.): Capsaicin
PMRA Document Number : 1847485

Background

The first registered product containing capsaicin was registered in 1968. The product is manufactured at a registered site (SYB-1) and the equivalency was established to product PCP# 27908.

Purpose of Application

The purpose of this submission was to register a grandfathered technical Capsaicin by a registrant with a currently registered end use product and the submission was classified as a category B1.2-S-OBLR-N-TGAI.

Chemistry Assessment

Common Name: Capsaicin

Chemical Name: *N*-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methyl-6-noneamide

Oil of Black Pepper has the following properties:

Property	Result
Colour and physical state	Red
Nominal concentration	Capsaicin 3.5% Dihydrocapsaicin 2.64% Nordihydrocapsaicin 0.46% The product is guarantee to contain capsaicin and related capsaicinoids at a total nominal concentration of 6.6%.
Odour	Pungent aroma
Density	1.02-1.05
Vapour pressure	< 10 mm Hg
pH	Not supplied
Solubility in water	Insoluble to slightly soluble in water
n-Octanol/water partition coefficient	Waived as the product is a complex mixture of actives

Health and Environmental Assessments

N/A

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that Passion-Krafts Oleoresin of Red Pepper Technical is eligible for full registration.

References

Studies/Information Provided by Applicant/Registrant

1602708	DACO 2.0, 2.1, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9; 2008; Oleoresin of Red Pepper DACO 2.1-2.9
1602709	DACO 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4; 2008; Manufacturing of Oleoresin of red pepper
1602711	DACO 2.13, 2.13.1; 1986; Method for Oleoresin of red pepper
1602712	DACO 2.13.2, 2.13.3, 2.13.4; 2006; DACO 2.13.2-2.13.4 Oleoresin of red pepper
1602713	DACO 2.14.1, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.14.10, 2.14.11, 2.14.12, 2.14.13; 2008; DACO 2.14 Oleoresin of red pepper
1602714	DACO 2.14.14; 2008; DACO 2.14.14 Oleoresin of red pepper
1813314	DACO 2.11.3; 2009; Production Flow Diagram
1813315	DACO 2.13.2, 2.13.3; 2009; Certificate of analysis of 5 batches Oleoresin of Red Pepper
1813313	DACO 2.2; 2009; Manufacturing Site

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