

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2008-1805
Application: New technical grade active
Product: Passion-Krafts Oleoresin of Black Pepper Technical
Registration Number: 29549
Active ingredients (a.i.): Oleoresin of Black Pepper (Piperine)
PMRA Document Number : 1847482

Background

Oleoresin of black pepper has been grandfathered in registered end use products. Due to an application for a new formulation of end use product with this active, as per Memorandum to Registrants, Applicants and their Representatives dated 06 July 2004, the active must now be registered, in order to be used in the new end use product.

Purpose of Application

The purpose of this submission was to register a grandfathered technical by a registrant with a currently registered EP and was classified as a Category B1.1–S-OBLR-N-TGAI-New source of active ingredient.

Chemistry Assessment

Common Name: Piperine, not approved by ISO

IUPAC Chemical Name: 1-[(2*E*,4*E*)-5-(1,3-Benzodioxol-5-yl)penta-2,4-dienoyl]piperidine

CAS Chemical Name: 2,4-Pentadien-1-one, 5-(1,3-benzodioxol-5-yl)-1-(1-piperidinyl)-, (2*E*,4*E*)-

Oleoresin of Black Pepper (Piperine) has the following properties:

Property	Result
Colour and physical state	Dark olive green liquid
Nominal concentration	40.2%
Odour	Peppery odour
Specific gravity	1.193
Vapour pressure	Not required if product meets FCC specifications
pH	Not required if product meets FCC specifications
Solubility in water	Totally insoluble
n-Octanol/water partition coefficient	Not required if product meets FCC specifications

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 Black Pepper Technical is eligible for full registration.

References

Studies/Information Provided by Applicant/Registrant

1602672	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; Chemistry Requirements for (TGAI) or ISP
1602673	DACO 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4; 2008; Manufacturing Oleoresin of Black Pepper
1602676	DACO 2.13, 2.13.2, 2.13.3, 2.13.4; 2006; Preliminary Analysis, Estimation of Piperine Content in Pepper Oleoresins
1602677	DACO 2.14, 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; Chemical and Physical properties
1813334	DACO 2.11.3; 2009; Production Flow Diagram for Oleoresin Black Pepper
1602675	DACO 2.13, 2.13.1; 1986; ASTA, Method for Oleoresin of Black Pepper
1813336	DACO 2.13.2, 2.13.13; 2008; Certificate of Analysis
1602669	DACO 0.9, MSDS – Material Safety Data Sheet
1813333	DACO 2.2; 2009; Manufacturing Site

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