

Evaluation Report for Category B, Subcategory B Application

Application Number: 2017-1495
Application: B.1.3 - New Specifications
Product: Bedoukian CM Pheromone
Registration Number: 32046
Active ingredients (a.i.): Codlelure
PMRA Document Number: 2776309

Purpose of Application

The purpose of this application was to amend the product specifications to allow for manufacture of the technical active with an alternate manufacturing method.

Chemistry Assessment

Common Name: Codlelure
IUPAC* Chemical Name: (8*E*,10*E*)-dodeca-8,10-dien-1-ol
CAS† Chemical Name: (8*E*,10*E*)-8,10-dodecadien-1-ol

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Bedoukian CM Pheromone has the following properties:

Property	Result
Colour and physical state	White to pale yellow solid
Nominal concentration	94%
Odour	Waxy, fatty odour
Density	0.87 g/mL
Vapour pressure	0.047 Pa
pH	Not provided
Solubility in water	34.15 mg/L
n-Octanol/water partition coefficient	Log K_{ow} = 4.34

The required chemistry data for Bedoukian CM Pheromone have been provided, reviewed, and found to be acceptable.

Health Assessment

Consisting of a straight-chained lepidopteran pheromone (SCLP), Bedoukian CM Pheromone is of low acute oral, dermal, and inhalation toxicity, is minimally irritating to the eyes, corrosive to the skin, but is not a dermal sensitizer. The label advises against inhalation and contact with the eyes and skin as mitigative measures.

The changes in the method of manufacture will not result in any additional health concerns regarding Bedoukian CM Pheromone.

Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the Pest Control Products Act (PCPA) for the purposes of adulteration provision of the Food and Drugs Act (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The changes in the method of manufacture for Bedoukian CM Pheromone will not result in an increase in dietary risks from food or drinking water. Consequently, the specification of an MRL for (E,E)-8,10-Dodecen-1-ol under the PCPA is not required.

Environmental and Value Assessment

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of the application to amend the specifications of the technical active. Based on the results of this review, the amendments to the specifications are acceptable.

References

PMRA Document Number	Reference
2744129	2017, Bedoukian CM Pheromone Reg # 32046 Manufacturing Summary, DACO: 2.11.1 CBI
2744130	2017, Bedoukian CM Pheromone Reg # 32046 Description of Starting Materials, DACO: 2.11.2 CBI
2744131	2017, Bedoukian CM Pheromone Reg #32046 Detailed Production Process Description, DACO: 2.11.3 CBI
2744132	2017, Bedoukian CM Pheromone Reg # 32046 Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2744133	2017, Bedoukian CM Pheromone Reg # 32046 Establishing Certified Limits, DACO: 2.12.1 CBI
2744134	2017, Bedoukian CM Pheromone Reg # 32046 Batch Data, DACO: 2.13.3 CBI
2768164	2017, PMRA Detailed Production Process Description, DACO: 2.11.3 CBI
2768165	2017, PMRA Methodology-Validation , DACO: 2.13.1 CBI
2768166	2017, PMRA Conformation of Identity, DACO: 2.13.2 CBI
2768167	2017, PMRA 5 Batch Data, DACO: 2.13.3 CBI
2768168	2017, PMRA Physical Chemical Properties Statment, DACO: 2.14
2773381	2017, Batch Data, DACO: 2.13.3 CBI

2399664	2014, Impurity ID/Discussion, DACO: 2.11.4 CBI
2479398	2015, DACO: Note To File
2466828	2014, Level D STL Memo, DACO: Memo
2744122	2017, Bedoukian CM Pheromone Reg # 32046 Cover Letter, DACO: 0.8
2744126	2017, Bedoukian CM Pheromone Reg # 32046 Proposed Label-English, DACO: 1.1.1
2744129	2017, Bedoukian CM Pheromone Reg # 32046 Manufacturing Summary, DACO: 2.11.1 CBI
2744131	2017, Bedoukian CM Pheromone Reg #32046 Detailed Production Process Description, DACO: 2.11.3 CBI
2744132	2017, Bedoukian CM Pheromone Reg # 32046 Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2744134	2017, Bedoukian CM Pheromone Reg # 32046 Batch Data, DACO: 2.13.3 CBI
2759109	2017, Statement of Product Specification Form CM, DACO: 0.1.6003

ISSN: 1911-8082

**8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services
Canada 2017**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.