

## Importation For Manufacturing And Exportation (IMEP) Evaluation Report for Category D IMEP, Subcategory B.1.3 Application

**Application Number:** 2012-5701  
**Application:** Importation for Manufacturing and Exportation Program (IMEP)  
 B.1.3 (Product Chemistry – Specifications)  
**Product:** BEDOUKIAN OFM TECHNICAL PHEROMONE  
**Registration Number:** 26136  
**Active ingredients (a.i.):** (Z)-8-dodecen-1-yl acetate (ZDO), (E)-8-dodecen-1-yl acetate (EED) and (Z)-8-dodecen-1-ol (ZED)  
**PMRA Document Number :** 2292145

### Purpose of Application

The purpose of this submission was to amend the manufacturing process and impurity profile of the IMEP product, Bedoukian OFM Technical Pheromone (Reg. No. 26136), resulting in a change in guarantee.

### Chemistry Assessment

**Common Name:** Not assigned  
**Chemical Name:**  
 IUPAC ; (E)-8-dodecen-1-yl acetate, (Z)-8-dodecen-1-yl acetate and (Z)-8-dodecen-1-ol  
**CAS:** 8-dodecen-1-ol, acetate, (E)-, 8-dodecen-1-ol, acetate, (Z)- and 8-dodecen-1-ol,(Z)-

Bedoukian OFM Technical Pheromone has the following properties:

Property	Result
Colour and physical state	Clear to slightly yellow liquid
Nominal concentration	Z-8-dodecenyl acetate.....88% E-8-dodecenyl acetate.....8% Z-8-dodecenol.....1.3%
Odour	Not established
Density	0.87 – 0.89 g/mL
Vapour pressure	2.4 Pa at 25°C

Property	Result
pH	Not required for IMEP product
Solubility in water	Insoluble in water
n-Octanol/water partition coefficient	Not required for IMEP product

The chemistry requirements for Bedoukian OFM Technical Pheromone (IMEP) have been completed.

### **Health Assessments**

No health information or data were submitted for review, however, several statements that were present on the last approved label from Sub. No. 2009-3205 were missing on the proposed label for this submission:

Primary panel: “WARNING SKIN AND EYE IRRITANT” and “POTENTIAL SKIN SENSITIZER”

Secondary panel: “May cause dermal sensitization” is missing under the “PRECAUTIONS” section.

No studies were submitted to support the original registration of Bedoukian OFM Technical Pheromone under IMEP. Instead, toxicology data requirements were waived based on sound scientific rationales. At the time of review, the reviewer accepted the proposed label with no label modifications. This proposed label voluntarily contained the above-noted statements. Such statements, however, are not usually required for straight chain lepidopteran pheromones (SCLPs) unless toxic/irritating formulation ingredients are present in the formulation. No such formulation ingredients are present in Bedoukian OFM Technical Pheromone. In addition, no such statements were found on the U.S. EPA-approved label for this TGAI. Consequently, the missing statements are not required for this product.

### **Environmental Assessment**

The proposed manufacturing process of Bedoukian OFM Technical Pheromone resulting in changes in guarantee and impurity profile will not result in increased environmental exposure. Environment Canada has previously performed an environmental review of the mixture of OFM active components that indicated minimal risk to mammals, birds, and aquatic organisms (E94-01). It should also be noted that the proposed product formulation will not be used in Canada. Concerns with respect to disposal have been addressed through adequate label statements.

### **Value Assessment**

Value assessment was not required for this application.

### **Conclusion**

The PMRA has reviewed all available information and has determined that the amended registration of Bedoukian OFM Technical Pheromone is acceptable.

## References

### PMRA

Document Number	Title
-----------------	-------

2260798	Description of Starting Materials for Bedoukian OFM Technical Pheromone Reg 26136, DACO: 2.11.2 CBI
2260799	Manufacturing process for Bedoukian OFM Technical Pheromone Reg 26136, DACO: 2.11.3 CBI
2260800	Discussion of Formation of Impurities for Bedoukian OFM Technical Pheromone Reg 26136, DACO: 2.11.4 CBI
2260801	5 Batch Analysis for Bedoukian OFM Technical Pheromone Reg 26136, DACO: 2.13.3 CBI
2286788	Bedoukian OFM Technical Pheromone Reg #26136 methodology, DACO: 2.13.1 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2013

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.