



New Source of Technical Grade Active Ingredient Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2007-2599
Application: Category B.1.2, New Source of Technical Grade Active Ingredient
Product: Bedoukian (S)-Verbenone Technical
Registration Number: 29519
Active ingredients (a.i.): Verbenone (PMB)
PMRA Document Number: 1837949

Background

Verbenone is an anti-aggregation pheromone produced by the mountain pine beetle and certain other bark beetles. At sufficient concentrations, verbenone provides a signal that host trees are fully occupied and therefore deters bark beetles from attacking the trees. Verbenone was first registered in the technical grade active ingredient (TGAI) for a pest control product in Canada in 2006.

Purpose of Application

The purpose of this application was to register a new TGAI containing verbenone from a new source. This new TGAI, Bedoukian (S)-Verbenone Technical (98.4% verbenone) is intended for use in the manufacture of Hercon Disrupt Micro-Flake VBN (reviewed under application number 2007-2176).

Chemistry Assessment

Common Name: Verbenone
Chemical Name: 4,6,6-trimethylbicyclo[3.1.1]hept-3-en-2-one

Bedoukian Verbenone Technical has the following properties:

| Property | Result | | | | | | |
|---------------------------------------|--|--|----------------|-----------|------|--------------|------|
| Colour and physical state | Light yellow liquid | | | | | | |
| Nominal concentration | 98.4% as determined by GC | | | | | | |
| Odour | Spicy, mint, camphor note with a hint of pine odour | | | | | | |
| Specific gravity | 0.975 | | | | | | |
| Vapour pressure | 0.136 mm Hg | | | | | | |
| pH | Not provided | | | | | | |
| Solubility in water | Estimated 75.5 mg/L | | | | | | |
| n-Octanol/water partition coefficient | <table> <thead> <tr> <th></th> <th><u>log Kow</u></th> </tr> </thead> <tbody> <tr> <td>estimated</td> <td>3.21</td> </tr> <tr> <td>experimental</td> <td>2.23</td> </tr> </tbody> </table> | | <u>log Kow</u> | estimated | 3.21 | experimental | 2.23 |
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| estimated | 3.21 | | | | | | |
| experimental | 2.23 | | | | | | |

The chemistry requirements for Bedoukian Verbenone Technical have been completed.

Health Assessments

Bedoukian (S)-Verbenone Technical is of slight acute oral toxicity (LD₅₀ (♀) 1800 mg/kg bw) in rats and low acute dermal toxicity (LD₅₀ (σ♀) > 2000 mg/kg bw) in rabbits.

Bedoukian (S)-Verbenone Technical is mildly irritating to the eyes, marked by mild to severe conjunctivitis and mild irritation of the iris in test animals, and is minimally irritating to the skin in rabbits.

Anticipating negligible exposure and based on available information, acute inhalation toxicity, dermal sensitization, short-term toxicity, prenatal developmental toxicity, and genotoxicity information was not required.

Environmental Assessment

Bedoukian (S)-Verbenone Technical is a pheromone, is highly volatile, and will dissipate rapidly once released into the environment. Thus, exposure of non-target organisms to the released pheromone is not a concern. However, birds could consume the technical contained in the micro-flake EP if the flakes are mistaken for a food item. The submitted information did not adequately characterize potential toxicity of verbenone TGAI to birds; therefore, additional information regarding consumption of flakes by birds has been requested. No other environmental concerns are noted for this TGAI.

Value Assessment

A value assessment is not required for TGAI products. Value of the end-use product, Hercon Disrupt Micro-Flake VBN, was assessed under application number 2007-2176.

Conclusion

The PMRA has completed an evaluation of the subject application and determined that the information was sufficient to support conditional registration of Bedoukian (S)-Verbenone Technical, with full registration contingent upon fulfillment of the following requirement:

Submission of Environmental Toxicology data, if warranted by the results of feeding studies with birds on the associated end-use product, Hercon Disrupt Micro-Flake VBN.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry Assessment

- 1400187 2006, Preliminary Analysis and Certified Limits, DACO:
2.12.1,2.12.2,2.13.1,2.13.2,2.13.3,3.3.1,3.3.2,830.1700,830.1750
- 1400188 2006, Preliminary Analysis and Certified Limits, DACO:
2.12.1,2.12.2,2.13.1,2.13.2,2.13.3,3.3.1,3.3.2,830.1700,830.1750 CBI
- 1400192 2006, Physical Chemical Properties, DACO:
2.14.1,2.14.10,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.2,3.5.3,3.5.6,3.5.9,8.2.3.2,830.6302,830.6303,830.6304,830.6313,830.6315,830.6316,830.6317,830.6319,830.6320,830.7100,830.7200,830.7220,830.7300,830.7370,830.7840,830.7950

2.0 Health Assessments

- 1400193 2006, Request for Waivers, DACO:
4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.3,4.5.4,4.6.1,4.6.2,4.6.3,4.6.4,4.6.5,4.6.6,4.7.1,850.1010,850.1075,850.2100,850.2200,870.1100,870.1200,870.1300,870.2400,870.2500,870.2600,870.3100,870.3700,870.5100,
9.3.2,9.3.4,9.3.5,9.4.2,9.4.3,9.4.4,9.4.6,9.5.2.1,9.5.2.2,9.5.2.3,9.5.4,9.6.2.1,9.6.2.2,9.6.2.3,9.6.2.4,9.6.2.5,9.6.4,9.8.6,M4.5.2
- 1400194 2006, Technical References Cited or Used in Application, DACO:
4.8(EPA),9.9(EPA)
- 1400195 2006, Technical References Cited or Used in Application, DACO:
4.8(EPA),9.9(EPA)

1400197 2006, Technical References Cited or Used in Application, DACO:
4.8(EPA),9.9(EPA)

3.0 Environmental Assessment

1395057 USDA Forest Service, 2000, Verbenone - Human Health and Ecological Risk Assessment, DACO:
9.9

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