Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2021-2208
Application: Changes to Technical Grade Active Ingredient (Product Chemistry) – Specifications
Product: HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin
Registration Number: 33569
Active ingredients (a.i.): Hop Beta Acids (Present as Potassium Salts)
PMRA Document Number : **3398715**

Purpose of Application

The purpose of this application was to change the manufacturing process and change the name of the technical product to HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin.

Chemistry Assessment

Common Name: Hop Beta Acids, present as potassium salts
IUPAC* Chemical Name: For the major β-acids:
Lupulone: 3,5-dihydroxy-4-(3-methylbutanoyl)-2,6,6-tris(3-methylbut-2-en-1-yl)cyclohexa-2,4-dien-1-one
Adlupulone: 3,5-dihydroxy-2-(2-methylbutanoyl)-4,6,6-tris(3-methylbut-2-en-1-yl)cyclohexa-2,4-dien-1-one
Colupulone: 3,5-dihydroxy-2,6,6-tris(3-methylbut-2-en-1-yl)-4-(2-methylpropanoyl)cyclohexa-2,4-dien-1-one
CAS† Chemical Name: For the major β-acids:
Lupulone: 2,4-cyclohexadien-1-one, 3,5-dihydroxy-2,6,6-tris(3-methyl-2-buten-1-yl)-4-(3-methyl-1-oxobutyl)-
Adlupulone: 2,4-cyclohexadien-1-one, 3,5-dihydroxy-4,6,6-tris(3-methyl-2-buten-1-yl)-2-(2-methyl-1-oxobutyl)-
Colupulone: 2,4-cyclohexadien-1-one, 3,5-dihydroxy-2,6,6-tris(3-methyl-2-buten-1-yl)-4-(2-methyl-1-oxopropyl)-

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin has the following properties:

Property	Result
Colour and physical state	dark brown viscous resin

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Property	Result
Nominal concentration	56.3 % hop beta acids (present as the potassium salts)
Odour	faint resinous, hop extract aroma
Density	1.103 g/mL
Vapour pressure	Not required
pH	10.08
Solubility in water	The beta acids in potassium salt form are very water soluble
n-Octanol/water partition coefficient	log Kow = 7.13 (for lupulone)

The required chemistry data for HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin have been provided, reviewed, and found to be acceptable.

Health Assessments

HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin is slightly acutely toxic via the oral route and extremely irritating to the eyes. Based on a long history of safe use, waivers were requested and granted for acute dermal and inhalation toxicity, primary skin irritation, and dermal sensitization.

The dietary risks from food and drinking water are considered to be negligible since hop beta acids are use in the brood chambers and not the honey supers, honey or wax are not to be harvested from the brood chambers, and hop beta acids have a low degree of volatility and a long history of use in foods without reports of adverse effects.

An occupational assessment was not required for this application.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the changes to HopGuard 3 Technical Grade of Active Ingredient, Potassium Beta Resin.

References

PMRA Document Number	Reference

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3234072	2018, Attachment 9 Comparison of manufacturing processes for HG II and HG III DH revs 12-9-18, DACO: 2.11.1 CBI
3234073	2018, Attachment 2 Rationale for amendment of HopGuard II with HopGuard III DH revs 12-14-18, DACO: 2.11.1 CBI
3234075	2013, 6. EPA Appl. for HopGuard 0432B vol 3 of 7 Confidential 225 pp 11-22-13, DACO: 2.11.3 CBI
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2783804	2012, An Acute Irritation Study of KBR by Ocular Administration in Rabbits, DACO: 4.2.4

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