



Evaluation Report for Category B, Subcategory 2.3, 2.4, 2.5 Application

Application Number: 2021-2207
Application: Changes to Manufacturing Concentrate (Product Chemistry) – Identity of Formulants, Proportion of Formulants, Formulation Type, and Name Change
Product: HopGuard 3 Liquid
Registration Number: 33570
Active ingredients (a.i.): Hop Beta Acids (Present as Potassium Salts)
PMRA Document Number : 3398389

Purpose of Application

The purpose of this application was to change the identification, type, and proportion of formulants, as well as change the manufacturing concentrate name to HopGuard 3 Liquid.

Chemistry Assessment

HopGuard 3 Liquid is formulated as an emulsifiable concentrate containing Hop Beta Acids (present as potassium salts) at a concentration of 16.0%. This manufacturing concentrate has a density of 1.080 g/mL and pH of 8.8. The required chemistry data for HopGuard 3 Liquid have been provided, reviewed and found to be acceptable.

Health Assessments

The change in formulation of HopGuard 3 Liquid is not anticipated to impact the toxicological profile. HopGuard 3 Liquid 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.

Occupational and dietary assessments were 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 Liquid.

References

PMRA Document Number	Reference
2783879	2015, Product Chemistry Data for the Technical Grade of Active Ingredient Potassium Salts of Hop Beta Acids, Manufacturing Use Product HopGuard Liquid and End Use Product HopGuard II CONFIDENTIAL ATTACHMENT, DACO: 2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3.1, 2.4, 2.5,2.6,2.7,2.8,2.9,3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14, 3.5.15,3.5.16,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.6,3.7,830.7000 CBI
2783881	2015, Product Chemistry Data for the Technical Grade Active Ingredient Potassium Salts of Hop Beta Acids, Manufacturing Use Product HopGuard Liquid and End Use Product HopGuard II, DACO: 2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2, 2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3.1, 2.4, 2.5,2.6,2.7,2.8,2.9,3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14, 3.5.15,3.5.16,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.6,3.7,830.7000
2783882	2013, Product Chemistry Data for the Technical Grade Active Ingredient Potassium Salts of Hop Beta Acids, Manufacturing Use Product HopGuard Liquid and End Use Product HopGuard II, DACO: 2.1,2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.12,2.12.1,2.13,2.13.1,2.13.2,2.13.3,2.13.4,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.15,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.15,2.16,2.2,2.3,2.3.1, 2.4, 2.5,2.6,2.7,2.8,2.9,3.0,3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2,3.2.3,3.3.1,3.4,3.4.1,3.4.2,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.16,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.6,3.7,830.7000
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3288342	2021, OUT21-055.pdf, DACO: 2.13.4 CBI
3288343	2021, OUT21-059.pdf, DACO: 2.13.4 CBI
3288561	2021, Graphic 1 Stability study of liquid HG-III. Time = 27 mo.png, DACO: 3.5.10 CBI
3288562	2018, HPGD III Viscosity Result.pdf, DACO: 3.5.9 CBI
3288563	2018, K1811938 Flash point.pdf, DACO: 3.5.11 CBI
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3372755	2022, Response to storage stability data deficiency for HopGuard 3 Liquid 7-19-22.docx, DACO: 3.5.10 CBI
3234073	2018, Attachment 2 Rationale for amendment of HopGuard II with HopGuard III DH revs 12-14-18 , DACO: 2.11.1, CBI
2783883	2013, Health Effects Waiver Rationale for the Technical Grade Active Ingredient-Potassium Salts of Hop Beta Acids and the End Use Product-HopGuard, DACO: 4.1,4.2,4.2.1,4.2.2,4.2.3,4.2.5,4.2.6,4.2.7,4.3.1,4.3.2, 4.3.3,4.3.4,4.3.5,4.3.6,4.4.1,4.4.2,4.4.3,4.4.4,4.4.5,4.5.1,4.5.10,4.5.11, 4.5.12,4.5.13,4.5.14,4.5.15,4.5.2,4.5.3,4.5.4,4.5.5,4.5.6,4.5.7,4.5.8,4.5.9, 4.6.2,4.6.3,4.6.4,4.6.5,4.6.7,4.6.8,4.6.9,4.7,4.8,4.8(A),4.8(B),86 - 1, 870.7200,870.78,IIIA 7.10

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