Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-4719
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: OLEGROW INSECTICIDE SOAP COMMERCIAL
Registration Number: 34535
Active ingredient (a.i.): potassium salts of fatty acids
PMRA Document Number: 3327696

Purpose of Application

The purpose of this application was to register a new commercial class end-use product containing potassium salts of fatty acids, based on registered precedents, for use indoors, outdoors and in greenhouses, on labelled ornamentals, vegetables, fruits, shrubs and trees for control of various labelled insect and mite pests.

Chemistry Assessment

OLEGROW INSECTICIDE SOAP COMMERCIAL is formulated as a solution containing potassium salts of fatty acids at a concentration of 51.5%. This end-use product has a density of 0.96 g/mL and pH of 10.2. The required chemistry data for OLEGROW INSECTICIDE SOAP COMMERCIAL have been provided, reviewed and found to be acceptable.

Health Assessments

OLEGROW INSECTICIDE SOAP COMMERCIAL is considered to be of low acute toxicity by the oral, dermal and inhalation routes, is minimally irritating to the eye, and is not expected to be a dermal irritant, nor a dermal sensitizer.

Occupational risk to individuals handling and applying OLEGROW INSECTICIDE SOAP COMMERCIAL is acceptable when the product is used according to label directions. Precautionary statements, personal protective equipment and directions for use statements on the product label aimed at mitigating user exposure are adequate to protect individuals from any potential risk due to occupational exposure.

Bystander exposure will not result in health risks of concern when the product is used according to label directions. Consequently, the risk to bystanders and individuals in residential areas is acceptable.

There are no dietary (food or drinking water) concerns when the product is used according to label directions.

Canada

Maximum Residue Limit (MRL)

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 specification of an MRL is not required for potassium salt of fatty acids.

Environmental Assessment

The application rate and use pattern for OLEGROW INSECTICIDE SOAP COMMERCIAL is within the currently registered use pattern, and risk to the environment is acceptable if the product is used according to the label directions.

Value Assessment

A formulation comparison of OLEGROW INSECTICIDE SOAP COMMERCIAL and two similar precedent products was conducted to support insecticide and acaricide claims for the new product OLEGROW INSECTICIDE SOAP COMMERCIAL. Claims on the precedent product labels to control mites, aphids, mealybugs, spider mites, whiteflies, soft brown scale, psyllids, rose or pear slugs (sawfly larvae), earwigs and elm leafminer on fruit trees, fruit, vegetables, shrubs, ornamental and bedding plants and ornamental and shade trees grown commercially indoors, in greenhouses and outdoors were extrapolated to the OLEGROW INSECTICIDE SOAP COMMERCIAL label based on similarity of the formulations.

Registration of OLEGROW INSECTICIDE SOAP COMMERCIAL will provide Canadian growers with an additional product that may be used in commercial organic production to control common pests on a broad range of crops.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of OLEGROW INSECTICIDE SOAP COMMERCIAL.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3186387	2020, 3.0 insecticide olegrow concentré - complet, DACO: 3.0 CBI
3186389	2020, 3.2 Procédé de formulation insecticide olegrow concentré, DACO: 3.2 CBI
3186390	2020, 3.2.1 Description matère départ insecticide olégrow concentré, DACO: 3.2.1 CBI
3186391	2020, 3.2.2 description du procédé de formulation insecticide olégrow concentré, DACO: 3.2.2 CBI
3186392	2020, 3.2.3 Exposé sur la formation d'impureté toxicologique, DACO: 3.2.3 CBI
3186393	2020, 3.3-3.3.1 Spécification et limites certifiées, DACO: 3.3.1 CBI
3186394	2020, 3.4 Analyse du produit insecticide olegrow concentré, DACO: 3.4 CBI
3186395	2020, 3.4.1 Méthode danalyse règlementation insecticide olegrow concentré, DACO: 3.4.1 CBI
3186396	2020, 3.4.2 impureté ayant une importance sur le plan toxicologique insecticide olegrow concentré, DACO: 3.4.2 CBI
3186397	2020, 3.5 Propriétés physico chimique insecticide olegrow concentré, DACO: 3.5 CBI
3186398	2020, 3.5.10 stabilité en entreposage insecticide olegrow concentré, DACO: 3.5.10 CBI
3186399	2020, 3.5.11 flash point SGS insecticide olegrow concentré, DACO: 3.5.11 CBI
3186400	2020, 3.5.6 Viscosity Density SGS insecticide olegrow concentré, DACO: 3.5.6 CBI
3186401	2020, 3.5.7 pH insecticide olegrow concentré, DACO: 3.5.7 CBI
3186386	1992, 12.5 USEPA RED fact soap salts - detailed, DACO: M12.5
3186402	1992, 4.0 Toxicologie insecticide olegrow concentrée, DACO : 4.1
3186403	1992, Exposition profesionnel ou spectateur insecticide olegrow concentrée, DACO: 5.1
3186404	1992, 7.0 exposition alimentaire insecticide olegrow concentrée, DACO: 7.1

B. Additional Information Considered

Published Information

PMRA Document Number	Reference
3281712	HERA, 2002. Human and Environmental Risk Assessment on ingredients of European household cleaning products, Available online (accessed June 2021) https://www.heraproject.com/files/5-HH-04-HERA%20Fatty%20acid%20salts%20HH%20web%20wd.pdf

3281708 CIR, 1987. Mary-Ann Liebert, Inc., Publishers. J Am Col Toxicol 6(3): 321-401 (available online; accessed June 2021): https://www.cir-safety.org/sites/default/files/115_draft_steary_suppl3.pdf

3281753 EFSA, 2018. Re-evaluation of sodium, potassium, and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives. EFSA Journal. John Wiley and Sons Ltd.