Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2024-0677
Application: Changes to Product Labels – New Site or Host
Applicant: W. Neudorff GmbH KG
Product: Kopa Insecticidal Soap
Registration Number: 31433
Active ingredient (a.i.): Potassium salts of fatty acids
PMRA Document Number: 3669677

Purpose of Application

The purpose of this application was to amend the label of Kopa Insecticidal Soap by adding greenhouse strawberry and outdoor and greenhouse cannabis to the use pattern.

Health Assessments

No additional data were provided or were required to amend the use pattern of Kopa Insecticidal Soap. Fatty acids are part of the normal metabolism of cells, and they are essential structural components of every cell. Potassium salts of fatty acids are of low acute toxicity via the oral, dermal and inhalation routes of exposure. They are mildly irritating to the eyes, moderately irritating to the skin, and are not dermal sensitizers.

The amendment to the use pattern of Kopa Insecticidal Soap is anticipated to have minimal impact on worker exposure, as the application rates to greenhouse strawberry and outdoor and greenhouse cannabis are identical to existing registered rates. Occupational exposure is expected to occur by the dermal and ocular routes of exposure during mixing, loading, application, clean-up and repair. To mitigate occupational exposure, workers are required to wear personal protective equipment (PPE). There is potential for dermal exposure to active ingredients in the fatty acids cluster when workers enter treated areas to perform post-application activities (for example, scouting treated areas). To mitigate this, the label of Kopa Insecticidal Soap includes a current list of standard PPE, a restricted re-entry interval (REI) of until sprays have dried, and a drift mitigation statement. Occupational, bystander, and residential exposure is not expected to result in health risks of concern when the product is used according to the label directions.

Fatty acids constitute a significant part of the normal human diet. Dietary residues from the use of end-use products containing fatty acids are not likely to exceed levels of exposure from naturally occurring fatty acids in foods. In addition, Kopa Insecticidal Soap is already registered for use on strawberries grown outdoors and cannabis grown indoors.

Potassium salts of fatty acids are soluble in water, dissociating into potassium and the fatty acid ions. Exposure to residues of fatty acids in drinking water is expected to be negligible because fatty acids are not persistent in the environment.

Canada

Application of Kopa Insecticidal Soap is permitted in cannabis during the vegetative and flowering stage.

Maximum Residue Limits

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*.

Kopa Insecticidal Soap is already registered for use on strawberries grown outdoors and cannabis grown indoors. Dietary risk from the use expansion of potassium salts of fatty acids to include greenhouse applications to strawberries and cannabis and outdoor applications to cannabis is acceptable, given the low toxicity profile of potassium salts of fatty acids. Consequently, the specification of an MRL, under the *Pest Control Products Act*, is not required for potassium salts of fatty acids.

Environmental Assessment

No additional risk is expected when Kopa Insecticidal Soap is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

The additional uses of Kopa Insecticidal Soap for control of aphids, mealybugs, mites, and scale insects on greenhouse strawberry and for control of aphids, spider mites, and whiteflies on greenhouse and field-grown cannabis were supported based on extrapolation from control of the same pests on field strawberry and on indoor cannabis, respectively, at the same application rate, and field trials showing no to very limited phytotoxicity in cannabis. Kopa Insecticidal Soap provides a new active ingredient for these uses.

Chemistry Assessment

A chemistry assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the amendments to the label of Kopa Insecticidal Soap.

References

PMRA Document Number	Reference
3557448	2024, Kopa Value and Exposure Volume, DACO: 10.1,10.2,10.3,10.3.1,5.2
3557449	2022, Crop Safety of Kopa and Vegol to Outdoor Hemp, DACO: 10.3.2(B)
3557450	2022, Crop Safety of Kopa and Vegol to Outdoor Hemp, DACO: 10.3.2(B)
3557451	2024, Crop Safety of Insecticide Applications on Outdoor Hemp, DACO: 10.3.2(B)