Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2010-4840
Application: Product chemistry - specifications
Product: Citrobug Formula HE-5000 Essential Oils
Registration Number: 31191
Active ingredients (a.i.): Camphor oil, eucalyptus oil, oil of geranium, lemon oil, pine oil
PMRA Document Number: 2350929

Purpose of Application

The purpose of this application was to register a new technical product based on an historical precedent product, Citrobug Formule HE-5000 Essential Oils (Registration Number 25796), but with citronella removed from the active mixture.

Chemistry Assessment

Common Name: Mixture of lemon, eucalyptus, pine needle, geranium and camphor oils
IUPAC Chemical Name: N/A
CAS Chemical Name: N/A
Citrobug Formula HE-5000 Essential Oils has the following properties:

Property	Result
Colour and physical state	Yellow liquid
Nominal concentration	Lemon Oil……...23.11% Eucalyptus Oil……..…..23.13% Pine Needle Oil……23.11% Geranium Oil……..23.11% Camphor Oil……..7.54%
Odour	Eucalyptus lemon oil odour
Density	0.886 g/mL at 20°C
Vapour pressure	N/A
pH	4.12
Solubility in water	Insoluble

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Property	Result
n-Octanol/water partition coefficient	N/A

The chemistry requirements for Citrobug Formula HE-5000 Essential Oils have been fulfilled.

Health Assessments

The application for the technical grade active ingredient (TGAI), Citrobug Formula HE-5000 Essential Oils, is based on an increase in the concentration of the lemon oil, eucalyptus oil, geranium oil, and pine needle oil active ingredients from 13.5% to 23.11% each, and increase in the concentration of the camphor oil active ingredient from 4.5% to 7.54%. A review of the toxicity of the TGAI was conducted based on a submitted summary of acute toxicity information on the TGAI, toxicity information included in MSDSs submitted for each of the active ingredients, acute toxicity studies submitted for the previous formulation the TGAI, and available published information on the acute toxicity of the active ingredients.

The TGAI is considered be of low acute oral and dermal toxicity. Although no skin sensitization studies were submitted for the TGAI, based on published information, several of the active ingredients and some of their components are potential skin sensitizers. Consequently, a precautionary statement is included on the label for the TGAI indicating that it may cause skin reactions on sensitive individuals.

Although a submitted summary of the acute toxicity of the TGAI indicated that it was not irritating to the skin or the eyes, complete skin and eye irritation studies were not submitted. Also, information in the MSDSs submitted for the active ingredients indicates that they are potential skin, eye, mucous membrane, and respiratory tract irritants; there are published literature reports of mild to moderate skin irritation induced by the active ingredients in laboratory animals and human volunteers; and there are incident reports from the California Department of Pesticide Regulation of eye, skin, and respiratory tract irritation in workers exposed to pine oil. Finally, published literature reports indicate that *d*-limonene, a major component of lemon oil, and citronellol, a major component of geranium oil are capable of causing eye irritation. Consequently, in the absence of submitted studies, and as precautionary approach, the TGAI is considered to be a moderate skin and eye irritant, and to be potentially irritating to the respiratory tract.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. There were no health-related incident reports submitted to the PMRA for end-use products containing lemon oil, eucalyptus oil, geranium oil, pine needle oil or camphor oil as of July 26, 2013.

From 1992 to 2010 there were 144 cases of illness reported to the California Pesticide Surveillance Program that were definitely, probably or possibly attributable to exposure to the active ingredient, pine oil or pine oil in combination with other ingredients in products. Thirty of these cases involved accidental or intentional ingestion of disinfectants or cleaners by children and adults. There were sixty-one cases of accidental skin or eye exposures or inhalation of vapours from products containing combinations of pine oil and a variety of other ingredients (e.g., naled, petroleum distillates, sodium hypochlorite, phenolic disinfectants, quaternary ammonia, etc.) used for agricultural and non-agricultural applications. Fifty-three non-agricultural cases were attributed to exposure to pine oil alone, of which the majority were considered to be definitely associated with exposure, and of those, most involved accidental eye exposure to pine oil based disinfectants and cleaners with some skin and inhalation exposures. The most common symptoms reported related to eye irritation (e.g., redness, swollen eyes, burning sensation) with signs of skin irritation, nausea, dizziness, shortness of breath, difficulty breathing, coughing, and other symptoms in a smaller number of cases. Based on publicly available information on household and natural health products in the U.S. and Canada, the concentration of pine oil in the TGAI is likely to be within the range of concentrations in some of the products involved in the incidents reported on in California. Consequently, the incident reports provide some support for an association between exposure to pine oil and irritant effects, and in turn, the potential eye, skin, and respiratory irritancy of the TGAI containing pine needle oil.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has completed an assessment of the available information and is able to support the registration Citrobug Formule HE-5000 Essential Oils.

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Additional Information Considered

Published Information

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