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Proposed Re-evaluation Decision

PRVD2018-04

Ethyl Alcohol and Its Associated End-use Products

Consultation Document

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Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Science Evaluation	1
Proposed Regulatory Decision for Ethyl Alcohol	2
International Context	2
Next Steps	2
Additional Scientific Information	2
Science Evaluation	1
Introduction	1
1.0 The Technical Grade Active Ingredient	1
1.1 Identity	1
2.0 Human Health Assessment	1
2.1 Toxicology Summary	1
2.2 Occupational Exposure and Risk	2
2.3 Residential and Bystanders Exposure and Risk	2
2.4 Dietary Exposure and risk	3
2.5 Aggregate Exposure Assessment	3
2.6 Cumulative Assessment	3
3.0 Environmental Assessment	3
4.0 Value Assessment	3
5.0 Pest Control Product Policy Considerations	4
5.1 Toxic Substances Management Policy Considerations	4
5.2 Formulants and Contaminants of Health or Environmental Concern	4
6.0 Incident Reports	4
7.0 Conclusion	5
Appendix I Registered Ethyl Alcohol Products as of 1 November 2017	7
Appendix II Label Update for Products Containing Ethyl Alcohol	9
References	11

Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. The PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Ethyl alcohol is registered as a disinfectant and sanitizer. It is registered for domestic use as a sanitizer of hard non-porous surfaces and fabrics. It is also registered for commercial use as a disinfectant of maple sap tapping equipment (bits and spouts). Beside the pesticide uses, ethyl alcohol is widely used in consumer and pharmaceutical products such as food additives and cosmetics.

This document presents the proposed regulatory decision for the re-evaluation of ethyl alcohol including the proposed updates to the label directions to further protect human health and the environment, as well as the science evaluation on which the proposed decision was based. All products containing ethyl alcohol (as a disinfectant and sanitizer) registered as a pesticide in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public including the pesticide manufacturers and stakeholders may submit written comments and additional information to the PMRA. The final re-evaluation decision will be published taking into consideration the comments and information received.

Outcome of Science Evaluation

Ethyl alcohol has value as a sanitizer of hard non-porous surfaces (for example, empty garbage cans, bathroom surfaces), fabrics, and as a disinfectant of maple sap tapping equipment (bits and spouts).

Ethyl alcohol has a long history of use in consumer and pharmaceutical products. With respect to human health, ethyl alcohol is of low acute toxicity profile. It is mildly irritating to the eyes, minimally irritating to the skin, and is not anticipated to be a dermal sensitizer. It is poorly absorbed via skin and well absorbed by inhalation. Ethyl alcohol is not categorized as a carcinogen and it is not expected to be genotoxic.

Exposure to workers using ethyl alcohol for disinfection of maple sap tapping equipment (bits and spouts) is not expected to be of concern under the current label directions (for example, use is limited to outdoor use, and requires personal protective equipment). Exposure to individuals using ethyl alcohol for general surface and fabric sanitization is also not expected to be of concern under the current conditions of use. Based on the current use pattern of ethyl alcohol, the residential, bystanders and dietary exposures (food + water) are expected to be minimal and not of concern.

Ethyl alcohol is used in a localized manner (tapping bits and spouts disinfection, surface and fabric sanitization). When products containing ethyl alcohol is used in accordance with the current label directions, risks of concern to non-target terrestrial and aquatic organisms are not expected.

Proposed Regulatory Decision for Ethyl Alcohol

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that pesticide products containing ethyl alcohol are acceptable for continued registration for use and sale in Canada, provided that the proposed updates to label directions are in place.

Registered pesticide product labels include specific instructions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of ethyl alcohol, no additional risk mitigation measures are proposed by the PMRA. To meet current labelling standards, minor label updates (disposal) are proposed (Appendix II):

International Context

Ethyl alcohol is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States, European Union, and Australia. As of 24 August 2017, no decision by an OECD member country to prohibit all uses of ethyl alcohol for health or environmental reasons has been identified.

Next Steps

The public including the registrants and stakeholders are encouraged to submit comments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document.² The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with PMRA's responses.

Additional Scientific Information

No additional data are required.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

Introduction

Ethyl alcohol (also referred as alcohol anhydrous or ethanol) is currently registered as a disinfectant and sanitizer. It is registered for residential use as a surface sanitizer of hard non-porous surfaces and fabrics that are not typically or frequently washed (backpacks, sports bags, fabric shower curtains). It is not intended to be used on human clothing. The domestic products are ready-to-use products and are applied by using hand held sprayers. The products are applied on pre-cleaned surfaces and on fabrics and, allow the treated surface to air dry. Ethyl alcohol is also registered for commercial use as a ready to use disinfectant of maple sap tapping bits and spouts by professional handlers. This product is restricted to outdoor handling and use, and requires personal protective equipment for handling. It is used for periodically disinfecting the tapping bit by immersing the bits in the end-use product before inserting them into tree. It is also sprayed in the interior and exterior of the spout.

Currently, registered pest control products containing ethyl alcohol are listed in Appendix I.

1.0 The Technical Grade Active Ingredient

1.1 Identity

Common Name	Ethyl Alcohol
Function	disinfectant, sanitizer
Chemical Name	
International Union of Pure and Applied Chemistry (IUPAC):	ETHANOL
Chemical Abstracts Service (CAS):	ETHYL ALCOHOL
CAS Registry Number	64-17-5

2.0 Human Health Assessment

Based on the registered use pattern, exposure to ethyl alcohol can occur through handling of end use products, entering the treated sites or consuming food and drinking water. Two key factors are considered when assessing health risks; the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

2.1 Toxicology Summary

Ethyl alcohol has a long history of use in consumer products and pharmaceutical products such as food additives and cosmetics. It is of low acute toxicity via the oral, inhalation and dermal routes of exposure. It is a mild eye irritant. It is expected to be a minimal skin irritant. It is not

anticipated to be a dermal sensitizer. Ethyl alcohol is poorly absorbed by skin and readily absorbed via inhalation. Ethyl alcohol is first metabolized (> 90 %) to acetaldehyde, which is converted to acetate, and then to carbon dioxide, which is exhaled.

The toxicity of ethyl alcohol is extensively documented. In humans, long-term repeated exposure (oral) to ethanol may result in the development of progressive liver injury with fibrosis or exacerbate liver injury produced from other causes. Repeated ingestion of ethanol by pregnant mothers has been shown to adversely affect the central nervous system (CNS) of the fetus, producing a collection of effects which together constitute the fetal alcohol syndrome. The technical grade active labels currently include information related to liver injury and fetal alcohol syndrome from repeated exposure. Based on the available information, it is not possible to categorize ethyl alcohol as a carcinogen and it is not expected to be genotoxic.

No toxicological endpoints for quantitative risk assessment have been established by the PMRA. PMRA used a qualitative approach to assess the potential risks of ethyl alcohol to human health.

2.2 Occupational Exposure and Risk

Workers can be exposed to ethyl alcohol through handling the pesticide product and by coming in contact with treated surfaces or fabrics after application.

- Exposure to workers using ethyl alcohol for disinfection of maple sap tapping bits and spouts is expected to be minimal under the current use conditions. The current label directions include personal protective equipment (PPE) (long sleeved shirt and pants, goggles and/or face mask) for handlers. The product is restricted for outdoor handling and use and only authorized personnel are allowed to be present during handling and application of the product. Based on the above, potential exposure to occupational workers from the use of ethyl alcohol for maple sap use is expected to be minimal and not of concern. Exposure to workers using ethyl alcohol for general surface and fabric sanitization is also expected to be minimal and not of concern under the current conditions of use. Following application, exposure from contact with treated surfaces is expected to be minimal based on the high volatility of ethyl alcohol and requirement to let surfaces dry before contact.
- Given the low exposure potential and low toxicity profile of ethyl alcohol, occupational exposure, including post-application exposure, is not expected to be of concern under the current conditions of use. No further mitigation measures are proposed.

2.3 Residential and Bystanders Exposure and Risk

Ethyl alcohol is widely used in consumer products and pharmaceutical products (such as household cleaning, hand sanitizers, cough syrups, cosmetics and beverages). Ethyl alcohol is highly volatile and the current label directions of domestic products require to air dry surfaces (hard non-porous surfaces and fabrics) following treatment with the product. Further, toys and food contact surfaces must be washed with potable water after application. Based on the current pesticide use conditions, and the low toxicity profile of ethyl alcohol, residential and bystanders

exposure to ethyl alcohol is not expected to be of concern including homeowners, infants and children. No additional risk mitigation measures are proposed.

2.4 Dietary Exposure and risk

Ethyl alcohol has a long history of use in beverages. The use of ethyl alcohol as a disinfectant and sanitizer is expected to result in minimal residues of this active ingredient in food commodities. When ethyl alcohol is used for disinfection of spouts in maple sap production, based on the volatile nature of the active ingredient and its relatively low boiling point, it is not anticipated that any significant concentration of denatured ethyl alcohol residue will remain in the processed food. Additionally, the current label recommends that the first sap flow after application be discarded.

Residues in food commodities following the use of ethyl alcohol for surface sanitization are expected to be minimal given the high volatility of ethyl alcohol and based on the current label directions (food contact surfaces must be washed with potable water following application).

Contamination of drinking water sources is not expected based on the current use pattern.

On this base, dietary (food and drinking water) exposure to ethyl alcohol is not expected to be of concern. No additional mitigation measures are proposed.

2.5 Aggregate Exposure Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). For ethyl alcohol, aggregate exposure is not of concern based on the current use pattern. No additional mitigation measures are proposed.

2.6 Cumulative Assessment

The *Pest Control Products Act* requires that PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, PMRA did not identify any information indicating that ethyl alcohol shared a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

3.0 Environmental Assessment

Ethyl alcohol is highly volatile and is readily biodegradable in the environment. The active is used in a localized manner (maple sap tapping bits and spouts disinfection, and surface and fabric sanitization). Therefore, exposure to the environment is expected to be minimal and the potential risk to non-target organisms is not expected to be of concern based on the current use pattern. No additional mitigation measures are proposed. Updates to standard labels statements (disposal) are proposed to meet the current labelling practices.

4.0 Value Assessment

Ethyl alcohol has value as a disinfectant and sanitizer. Ethyl alcohol is a registered active ingredient for the disinfection of maple sap tapping bits and spouts. Ethyl alcohol is also one of few fabric sanitizers registered for application to fabrics.

5.0 Pest Control Product Policy Considerations

5.1 Toxic Substances Management Policy Considerations

In accordance with the PMRA Regulatory Directive DIR99-033, the assessment of ethyl alcohol against Track 1 criteria of Toxic Substances Management Policy (TSMP) under the *Canadian Environmental Protection Act* (CEPA) was conducted. It determined that:

- Based on the use pattern, environmental releases are expected to be minimal. Therefore, ethyl alcohol is not considered CEPA-toxic equivalent to the environment and does not meet all the Track 1 criteria.

5.2 Formulants and Contaminants of Health or Environmental Concern

During the re-evaluation of ethyl alcohol, contaminants in the technical were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.⁴ The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Ethyl alcohol products do not contain any contaminants of health or environmental concern.

6.0 Incident Reports

As of August 4, 2017, one human incident has been received by the PMRA; no domestic animal or environmental incidents have been reported to the Agency. The human incident occurred in the US. The individual was reported to have experienced respiratory irritation, oropharyngeal oedema, vomiting, and bradycardia within 30 minutes of accidentally ingesting an unknown amount of a pool algacide product containing multiple active ingredients. He was hospitalized for at least two days. This incident involved multiple active ingredients, which confounds any

³ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

⁴ *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

ethyl alcohol-specific conclusions regarding adverse effects. Additionally, the accidental ingestion of such a product is not a typical exposure scenario and is not expected to be repeated. Based on the review of the incidents reported to the PMRA, no risks of concern have been identified.

7.0 Conclusion

Ethyl alcohol is used for sanitization of hard non-porous surfaces and fabrics. It is also used for the disinfection of maple sap tapping bits and spouts. When used according to the current label directions, the potential occupational and non-occupational risks (including residential and dietary exposure (food + water)) are not expected to be of concern.

When products containing ethyl alcohol are used in accordance with the current label directions, risks of concern to non-target terrestrial and aquatic organisms are not expected.

Updates to label directions (disposal) are being proposed to meet the current labeling standards (Appendix II).

Appendix I Registered Ethyl Alcohol Products as of 1 November 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
28520	Technical	Federation Producteurs Acericoles	A.D.Q.2-J(Technique)	Liquid	92.5%
30586	Technical	Reckitt Benckiser Canada Inc.	SD Alcohol	Liquid	92.7%
26462	Commercial	Federation Producteurs Acericoles	DA-2J	Solution	63.2%
30587	Domestic	Reckitt Benckiser Canada Inc.	Lysol Disinfectant Spray	Liquid	58%
32135	Domestic	Reckitt Benckiser Canada Inc.	Lysol Brand II Disinfectant Spray	Liquid	58%

Appendix II Label Update for Products Containing Ethyl Alcohol

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

The following statement must be included in a section entitled DIRECTIONS FOR USE:

“DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

References**Published Information**

PMRA Document Number	Reference
1467289	Evaluation Report for Application Number: Sub No 2005-2231
1467291	Evaluation Report for Application Number: Sub No 2005-2232
2214293	Proposed Registration Decision, PRD2012-21: N-Alkyl (40% C12, 50% C14, 10% C16) Dimethyl Benzyl Ammonium Saccharinate and Ethyl Alcohol