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Proposed Re-evaluation Decision

PRVD2018-02

# Soybean Oil and Its Associated End-use Products

*Consultation Document*

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## **Proposed Re-evaluation Decision**

Under the authority of 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 to all re-evaluations.

Soybean oil is registered as an indoor insecticide for domestic use to kill several household pests (for example ants, cockroaches, and spiders). It is also registered as a personal insect repellent for mosquitoes and black flies. Soybean oil is manufactured from a naturally occurring plant, has a long history of use as a food, and can be found incorporated into various cosmetics and natural health products. The indoor domestic insecticide products are sprayed directly onto target pests as a household crack and crevice spot treatment, and the personal insect repellent products are applied directly to the skin. Soybean oil end-use products are formulated as ready-to-use products.

This document presents the proposed regulatory decision for the re-evaluation of soybean oil and includes the proposed label updates to meet the current standards, as well as the science evaluation on which the proposed decision was based. All products containing soybean oil registered as an insecticide 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**

Soybean oil has value in providing non-conventional solutions for insect control. As an indoor domestic insecticide, soybean oil can play an important part in resistance management, and as a personal insect repellent, soybean oil has value in offering Canadians access to a plant-based personal repellent.

Soybean oil is manufactured from a naturally occurring plant, has a long history of use as a food, and can be found incorporated into various cosmetics and natural health products. In laboratory animals, the active ingredient was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was not a skin or eye irritant, and was not a skin sensitizer. Since soybean oil contains soy, a priority allergen, adequate warning statements (for example, "Warning, contains the allergen soy") appear on the technical grade active ingredient and end-use product labels.

When current label directions on pesticide products containing soybean oil are observed, exposures to all populations (including applicators and bystanders) are not of concern from the use of soybean oil as an indoor insecticide and personal insect repellent. Soybean oil is not

registered for use on food or outdoor sites; therefore, risks from dietary (food and drinking water) exposure to soybean oil is not of concern for all populations.

When used under the current label directions, environmental exposure to soybean oil is expected to be minimal. The potential environmental risks from these uses are not expected to be of concern.

## **Proposed Regulatory Decision for Soybean Oil**

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing soybean oil (used as an insecticide) 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 soybean oil, no additional risk mitigation measures are proposed by the PMRA. To meet current labelling standards, the following label updates are proposed (Refer to the details in Appendix II):

- Storage and disposal label statements.

## **International Context**

Soybean oil is currently acceptable for use in other Organization for Economic Co-operation and Development (OECD) member countries, including the United States of America, Mexico, and Chile. As of 30 October 2017, no decision by an OECD member country to prohibit all uses of soybean oil 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 period<sup>1</sup> 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.<sup>2</sup> 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 along with the PMRA's responses.

## **Additional Scientific Information**

No additional data are required.

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

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

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# **Science Evaluation**

## **1.0 Introduction**

Soybean oil is a ready-to-use domestic indoor insecticide used as a household crack and crevice spot treatment to kill several common household pests. End-use products are applied to areas such as cabinets, drawers, and closets, under sinks, and on walls, floors, and along baseboards. The ready-to-use products are to be applied directly onto the target pest until thoroughly covered to rapidly kill ants, cockroaches, crickets, earwigs, silverfish, carpet beetles, and spiders through suffocation. Soybean oil is applied as needed when pests are seen.

Soybean oil is also used as a personal insect repellent. It is registered for direct use on human skin to repel mosquitoes and black flies. It is to be applied as needed for as long as exposure to the pest(s) continues.

The registrant has indicated support for the re-evaluation of all products containing soybean oil, and currently registered products containing soybean oil are listed in Appendix I.

## **2.0 The Technical Grade Active Ingredient: Its Properties and Uses**

### **2.1 Identity of the Technical Grade Active Ingredient.**

<b>Common name</b>	Soybean oil	
<b>Function</b>	Insecticide	
<b>Chemical Family</b>	Essential oil	
<b>Chemical name</b>		
1 International Union of Pure and Applied Chemistry (IUPAC)	Not applicable	
2 Chemical Abstracts Service (CAS)	Soybean oil	
<b>CAS Registry Number</b>	8001-22-7	
<b>Molecular Formula</b>	Not applicable	
<b>Structural Formula</b>	Not applicable	
<b>Molecular Weight</b>	Not applicable	
<b>Registration Number</b>	25748	30833
<b>Purity of the Technical Grade Active Ingredient</b>	100.0%	100%

## **3.0 Human Health**

Based on the registered insecticide use pattern, exposure to soybean oil from domestic use can occur through applying the product in an indoor residential setting and / or by entering treated sites. When used as a personal insect repellent, direct exposure to soybean oil occurs through application to the skin. 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.

### **3.1 Toxicological Summary**

Soybean oil is manufactured from a naturally occurring plant. It has a long history of use in food and can be found incorporated into various products intended for use by the Canadian public (for example, cosmetics and natural health products).

Soybean oil is expected to be of low acute toxicity via the oral, dermal, and inhalation routes. In most individuals, soybean oil is not irritating to skin and eyes, and dermal sensitization is not expected. Nevertheless, soybean oil contains soy, a priority allergen, and current labels contain adequate warning statements related to the allergen (for example, “Warning, contains the allergen soy” and “This product may cause irritation, rash, or similar allergic reaction to skin of sensitive individuals.”). Based on the long history of use as a food source and in personal products, soybean oil is neither expected to be a mutagen nor a developmental toxicant, and it is not expected to be a carcinogen. For more details, refer to Proposed Registration Decision PRD2013-05, *Soybean Oil* and Proposed Regulatory Decision Document PRDD99-02, *Soybean Oil*.

Given the low toxicity profile of soybean, no toxicological endpoints have been established for quantitative risk assessment by the PMRA. As a result, the PMRA has used a qualitative approach to assess the potential risks to soybean oil.

### **3.2 Human Exposure and Risk**

When used as a domestic insecticide (7.5% soybean oil), individuals, such as homeowners, professional applicators using domestic products, and bystanders, can be exposed to soybean oil through applying the product and/or by entering treated sites. Soybean oil end-use products are packaged as ready-to-use products, and exposure from mixing and loading is not anticipated. As such, moderate exposure to individuals applying domestic end-use products containing soybean oil is expected via the dermal and inhalation routes. For bystanders, including children and toddlers, dermal exposure from wet surfaces following application is anticipated to be the primary route of exposure. In addition, non-dietary oral exposure in toddlers is anticipated via the transfer of residues from hand-to-mouth activities.

Current labels of domestic insecticide end-use products contain adequate mitigative and protective label statements (for example, “Remove food from the area before spraying.” and “Do not apply as a broadcast or space spray.”) to minimize exposure.

When used as a personal insect repellent (2% soybean oil), soybean oil is applied as needed directly to skin. As such, dermal exposure is expected to be the primary exposure route for all end-users. Most end-use products are packaged primarily as a lotion, but one end-use product is packaged as a spray pump. However, inhalation exposure is expected to be negligible given the physico-chemical characteristics of soybean oil (slightly viscous liquid, low vapour pressure). For toddlers and children, an additional exposure scenario is identified: non-dietary oral exposure resulting from the transfer of residues from the skin to the mouth from hand-to-mouth activities. Current labels contain adequate mitigative label statements (for example, “Do not apply to lips and keep out of eyes.” and “Do not apply to hands of young children.”) to minimize exposure other than the dermal route.

Considering the current label risk mitigation measures, the low toxicity profile of soybean oil, and its long history of use as a common food and in various cosmetics and natural health products, the potential risk from the use of soybean oil, as both a domestic insecticide as well as a personal insect repellent, is not expected to be of concern for all populations when used according to label directions.

No additional mitigation measures are proposed. Updates to labels to meet the current standard for storage and disposal are proposed (Appendix II).

### **3.3 Dietary Exposure and Risk**

Soybean and its refined extracts have a long history of use in food and animal feeds, and they can be considered normal constituents of the human diet. Nonetheless, soybean oil is not registered for use on any food commodity, and it is not expected to contaminate drinking water sources, based on the use pattern. On this basis, dietary exposure and risk from soybean oil as a domestic insecticide and personal insect repellent through the consumption of food and drinking water is not expected to be of concern for all populations. No mitigation measures are proposed.

### **3.4 Aggregate Exposure and Risk**

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 soybean oil, aggregate exposure is limited to residential exposures. However, these exposures are not expected to be of concern given the current label use and mitigative directions and the low toxicity profile of soybean oil. On this basis, aggregate exposure and risk is not expected to be of concern under the current conditions of use for all populations.

### **3.5 Cumulative Exposure and Risk**

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. The PMRA did not identify information indicating that soybean oil shares a common mechanism of toxicity with other pest control products. Furthermore, the potential risks from cumulative exposure of soybean oil with other such pest control products are not of concern, given the inherent low toxicity profile of the active ingredients.

## **4.0 Environment**

When used under the current label directions (indoor use and application to the skin), environmental exposure to soybean oil is expected to be minimal. The potential environmental risks from these uses are not expected to be of concern.

Updates to labels to meet the current labelling standard for storage and disposal are proposed (Appendix II).

## **5.0 Value**

Soybean oil has value in providing non-conventional solutions for insect control. As an insecticide for use in the home, soybean oil has value in that it can be combined with other pest control practices and products to help control unwanted insects. As well, soybean oil can play an important part in resistance management, since pests are unlikely to develop tolerance due to the non-conventional mode of action (suffocation). As a repellent, soybean oil offers Canadians an additional choice for protection from mosquitoes and black fly annoyances – it has value in offering Canadians access to a plant-based personal repellent.

## **6.0 Pest Control Product Policy Considerations**

### **6.1 Toxic Substances Management Policy Considerations**

In accordance with the PMRA Regulatory Directive DIR99-03,<sup>3</sup> the assessment of soybean oil against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. It determined that:

- Soybean oil is not considered a Track 1 substance.

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

## **6.2 Contaminants and Formulants of Health or Environmental Concern**

As part of re-evaluation, contaminants in the technical grade active ingredient are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.<sup>4</sup> 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). With respect to soybean oil, the PMRA has reached the following conclusion:

- Technical sources of soybean oil are considered as food grade, and impurities of human health or environmental concern as identified in the *Canada Gazette* are not expected to be present in the product.
- Soybean oil is also used as a formulant in various end-use products. Soy is considered as a formulant of concern in the *Canada Gazette* (as allergen); however, current labels contain adequate warning statements related to the allergen soy.

## **7.0 Incident Reports**

Starting 26 April 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.

As of 4 August 2017, no domestic animal or environmental incidents involving soybean oil have been reported to the PMRA. One human incident was reported – it was minor in severity – and unlikely that the incident/reported symptoms were caused by a product containing soybean oil. These incident report data are incorporated into the re-evaluation of soybean oil, and no risks of concern have been identified. No mitigation measures are proposed.

## **8.0 Conclusion**

Soybean oil has value in providing non-conventional solutions for insect control. Soybean oil is manufactured from a naturally occurring plant, and it has a long history of use in food and in various consumer products. With respect to human health, soybean oil has a low toxicity profile, and when used according to current label directions, the potential risk to human health is not expected to be of concern.

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<sup>4</sup> *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*.

However, it is noted that soybean oil contains soy, a priority allergen, and thus, the current labels contain adequate warning statements related to the allergen. Based on the current conditions of use, environmental exposure to soybean oil is expected to be minimal and is not of concern.

On this basis, Health Canada's Pest Management Regulatory Agency, under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing soybean oil for sale and use in Canada.

Updates to label directions are being proposed to meet the current labeling standards.

## Appendix I Registered Soybean Oil Products as of 16 November 2017

<b>Registration No.</b>	<b>Marketing Class</b>	<b>Registrant</b>	<b>Product Name</b>	<b>Formulation</b>	<b>Guarantee (%)</b>
25749	Domestic	Woodstream Canada Corporation	BLOCKER INSECT REPELLENT	Emulsifiable Concentrate	2
25750	Domestic	Woodstream Canada Corporation	BLOCKER INSECT REPELLENT LOTION	Emulsifiable Concentrate	2
25751	Domestic	Woodstream Canada Corporation	BLOCKER INSECT REPELLENT LIGHT HERBAL SCENT LOTION	Emulsifiable Concentrate	2
25752	Domestic	Woodstream Canada Corporation	BLOCKER INSECT REPELLENT EASY TO USE SPRAY	Emulsifiable Concentrate	2
30834	Domestic	Scotts Canada Ltd.	SCOTTS ECOSENSE INDOOR INSECT KILLER AEROSOL	Pressurized Product	7.5
30835	Domestic	Scotts Canada Ltd.	SCOTTS ECOSENSE INDOOR INSECT KILLER READY-TO-USE	Emulsifiable Concentrate	7.5
25748	Technical	Woodstream Canada Corporation	CONSEP SOYBEAN OIL TECHNICAL	Liquid	100
30833	Technical	Scotts Canada Ltd.	SCOTTS SOYBEAN OIL TECHNICAL	Liquid	100



## Appendix II      Label Amendments for Products Containing Soybean Oil

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.

- I)      The following statements must be included in a section entitled **STORAGE**:

*“To prevent contamination, store this product away from food or feed.”*

- II)     The following statements must be included in a section entitled **DISPOSAL**:

*“DO NOT reuse the empty containers. Dispose in household garbage. Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites.”*



## References

### A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT(S)

Unpublished information

<b>PMRA Document Number</b>	<b>Reference</b>
1519401	1996, 2.12.1 Manufacturing Summary, DACO: 2.12.1
1519402	1996, 2.12.2 Detailed Process Description / Formation of Impurities, DACO: 2.12.2
1519403	1996, 2.13 Specifications for US Pharmacopeia (USP) / British Pharmacopeia (BP) Grade Soybean Oil / Attachment 1 includes published material "The United States Pharmacopeia, The National Formulary, DACO: 2.13
1519406	1996, 2.14.1 Batch / Description, DACO: 2.14.2
1519408	1996, 2.16 Chemical / Physical Properties for the Active Ingredient Soybean Oil / Overview, DACO: 2.16
2134046	2011, TGAI Data Requirements for Registration (Part 2 of Data Submission), DACO: 2.1,2.11.1,2.11.2,2.11.3,2.11.4,2.13.2,2.13.4,2.14.1,2.14.13,2.14.2,2.14.3,2.14.6,2.15, 2.16,2.2,2.3,2.3.1,2.4,2.5,2.6 CBI
2134047	2011, Detailed Production Process Description, DACO: 2.11.3 CBI
2134052	2011, Scotts Miracle Gro Data Request, DACO: 2.13.2,2.13.3 CBI
2134058	2011, Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Specific Gravity, Viscosity and Storage Stability, DACO: 2.14.1, 2.14.13, 2.14.2, 2.14.3, 2.14.6 CBI

### B. ADDITIONAL INFORMATION CONSIDERED

Published information

<b>PMRA Document Number</b>	<b>Reference</b>
2275252	PRD2013-05. Soybean Oil, Proposed Registration Decision
2796628	PRDD99-02. Soybean Oil, Proposed Regulatory Decision Document.