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Proposed Registration Decision

PRD2022-02

Sheep Fat, Trico and Trico Garden

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

Canada 

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Overview

Proposed registration decision for sheep fat

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Sheep Fat Technical, Trico and Trico Garden, containing the technical grade active ingredient sheep fat, as a repellent to deer, elk or moose from trees and shrubs in forestry, grapevines, apple trees and outdoor ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of sheep fat, Trico and Trico Garden.

What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the [Pesticides section](#) of Canada.ca.

¹ “Acceptable risks” as defined by subsection 2(2) of the *Pest Control Products Act*.

² “Value” as defined by subsection 2(1) of the *Pest Control Products Act*: “the product’s actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product’s (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.”

Before making a final registration decision on sheep fat, Trico and Trico Garden, Health Canada's PMRA will consider any comments received from the public in response to this consultation document³. Health Canada will then publish a Registration Decision⁴ on sheep fat, Trico and Trico Garden, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is sheep fat?

Sheep fat is the active ingredient in the commercial class product Trico and the domestic class product Trico Garden. Sheep fat is a new animal repellent that repels deer, elk or moose with a scent and taste that is repulsive to the target animals from trees and shrubs in forestry, grapevines, apple trees and outdoor ornamentals.

Health considerations

Can approved uses of sheep fat affect human health?

Sheep Fat is unlikely to affect human health when it is used according to label directions.

Potential exposure to sheep fat may occur when handling and applying the products Trico and Trico Garden, as well as during typical occupational and residential activities following application. When assessing health risks, two key factors are considered: 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. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed.

Publicly available toxicology information was submitted on the acute toxicity of the major sheep fat fatty acids as well as surrogate fatty acids. Sheep Fat Technical is considered to be of low acute toxicity by the oral, dermal and inhalation routes, mildly irritating to eye and skin and unlikely to be a dermal sensitizer. While some positive sensitization results from pure constituent

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

fatty acids were reported, Sheep Fat Technical was considered unlikely to be a dermal sensitizer based on an accepted rationale that considered the weight-of-evidence including the history of sheep fat in the human diet and fatty acids in consumer products. However, prolonged or frequently repeated skin contact to sheep fat may cause allergic reactions in some individuals.

The Registrant submitted publicly available information as well as a rationale to waive data requirements for short-term toxicity, developmental toxicity, genotoxicity and various other effects. Sheep fat is produced from fat tissues of sheep and has long been part of the human diet, including the Canadian diet. Sheep fat is a triglyceride that consists predominantly of glycerol with the following fatty acids: palmitic acid, stearic acid and oleic acid as well as smaller amounts of myristic, palmitoleic, heptadecanoic and linoleic acid. Saturated fatty acids are readily metabolized in the body into important components used for energy, signalling, etc., and generally oxidize to carbon dioxide and water.

Based on a weight-of-evidence of the available data for the major components of sheep fat and taking into consideration the history of use of sheep fat in the human diet and fatty acids in consumer products, the low toxicity profile of sheep fat, and the anticipated limited human exposure based on the proposed use patterns, no short-term toxicity, developmental toxicity, genotoxicity, or other adverse effects are anticipated for sheep fat.

The toxicological profiles of Trico and Trico Garden are considered to be similar to the toxicological profile of Sheep Fat Technical.

Residues in water and food

Dietary risks from food and water are acceptable.

Sheep fat has a long history of use in the human diet and is part of the Canadian diet. The proposed use pattern requires that application of Trico and Trico Garden to food crops (apples and grapes) must occur before flowering. In addition, the likelihood of residues of sheep fat in drinking water will be very low. Consequently, health risks are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

As Trico is a commercial product for use in forest nurseries and plantations (deciduous and coniferous trees and shrubs), apple orchards, and grapes (new and established plantations), with no residential uses, a residential applicator exposure assessment is not required. In the interest of promoting best management practices and to minimize human exposure from spray drift or from spray residues resulting from drift, a spray drift statement is required for the label.

Trico Garden is for domestic use on outdoor ornamentals (flowers, trees, and shrubs), apple trees, and grapevines. Domestic users handling and applying Trico Garden will be required to wear rubber gloves and protective eyewear. Unprotected persons must remain out of the treated

area until sprays have dried. Residential exposure to Trico Garden is therefore expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Occupational risks from handling Trico

Occupational risks are acceptable when Trico is used according to the label directions, which include protective measures.

Workers handling Trico can come into direct contact with sheep fat primarily on the skin, but incidental inhalation or eye exposure is possible, which is expected to be minimal. Sheep fat is not volatile; therefore, inhalation exposure, if any, would occur only if very fine droplets are formed during application and inhaled. For ocular exposure, potential exposure would only be during splashes when mixing/loading or if spray solution goes into the eye during application. To protect workers from exposure to Trico, the proposed label requires workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield) during mixing, loading, application, clean-up and repair. Health Canada considers this mitigation to be acceptable to protect against potential irritation and sensitization, in some sensitive individuals from prolonged or repeated exposure when handling Trico. In addition, the proposed label requires unprotected persons to remain out of the treated area until sprays have dried, and includes spray advisory statements to minimize spray drift. Health Canada requires further label statements that if early entry is necessary before sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield).

The occupational risks are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when sheep fat is introduced into the environment?

Environmental risk associated with the use of sheep fat is acceptable.

Sheep fat enters the environment when it is applied as an animal repellent for deer, elk and moose on forestry, apple orchards and grape vineyards. Sheep fat breaks down rapidly in the environment and is not expected to move downward in soil to groundwater. If sheep fat reaches water, it is not expected to mix with water but will be quickly broken down by bacteria. Sheep fat does not exhibit toxicity to terrestrial or aquatic wildlife or plants.

Value considerations

What is the value of Trico and Trico Garden?

Trico and Trico Garden prevents or reduces damage to trees and shrubs in forestry, outdoor ornamentals, apple trees, and grapevines caused by deer, elk or moose.

Deer, elk and moose cause damage to outdoor ornamentals, apple trees, and grapevines throughout the year by feeding and rubbing on plants.

Trico is a commercial class product applied to young trees and shrubs in forestry to prevent or reduce damage caused by deer, elk or moose. It is also used in agriculture to prevent damage to apple trees in orchards and grapevines caused by deer.

Trico Garden is a domestic class product applied to outdoor ornamentals, apple trees and grapevines to prevent damage caused by deer.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Sheep Fat Technical, Trico and Trico Garden to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures

Human health

Standard hazard and precautionary statements are required on the technical grade active ingredient label and the end-use product labels to inform workers and domestic users of the potential for eye and skin irritation as well as the possibility that prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Workers handling and applying Trico will be required to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield).

Domestic users handling and applying Trico Garden will be required to wear rubber gloves and protective eyewear.

For both end-use products, unprotected persons must remain out of the treated area until sprays have dried. If early entry is necessary before sprays have dried for Trico, unprotected persons must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield).

To limit bystander exposure, both end-use product labels require drift statements.

Precautionary statements are also required on both end-use product labels to use freshly prepared spray solution for each application and not to contaminate food or bodies of water.

Next steps

Before making a final registration decision on sheep fat, Trico and Trico Garden, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When the Health Canada makes its registration decision, it will publish a Registration Decision on sheep fat, Trico and Trico Garden (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

Science evaluation

Sheep fat

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance	Sheep fat
Function	Animal repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	N/A
2. Chemical Abstracts Service (CAS)	N/A
CAS number	98999-15-6
Molecular formula	N/A
Molecular weight	N/A
Structural formula	N/A
Purity of the active ingredient	99.94%

1.2 Physical and chemical properties of the active ingredient and end-use product

Technical product — Sheep fat technical

Property	Result
Colour and physical state	Yellow solid
Odour	Rancid
Melting range	36–44°C
Boiling point or range	The product is a solid
Density	0.9458 g/ml
Vapour pressure at 20°C	$< 10^{-12}$ Pa
Ultraviolet (UV)-visible spectrum	No absorbance maxima (λ_{max}) observed above 290 nm.
Solubility in water at 20°C	$< 10^{-17}$ mg/L

Solubility in organic solvents at 20 °C	Solvent	Solubility (g/L)
	n-heptane	14–20
	p-xylene	333–500
	1,2-dichloroethane	167–200
	2-propanol	< 10
	Acetone	< 10
	Ethyl acetate	< 10
<i>n</i> -Octanol-water partition coefficient (K_{ow})	Log K_{ow} : ≥ 18.7	
Dissociation constant (pK_a)	N/A	
Stability (temperature, metal)	The colour of the technical grade active ingredient changes from yellowish, non transparent to yellowish transparent when stored in a metallic container for 2 weeks at 54°C.	

End-use product— Trico

Property	Result
Colour	White
Odour	Slightly rancid
Physical state	Liquid
Formulation type	Suspension
Label concentration	6.40%
Container material and description	HDPE drums 5 to 1000 L
Density	1.0066 g/ml
pH of 1% dispersion in water	7.91
Oxidizing or reducing action	The end-use product does not exhibit oxidizing or reducing properties.
Storage stability	Waived
Corrosion characteristics	The product was not corrosive to the plastic can after storage for 24 months at 25°C.
Explosibility	Not expected to be explosive.

End-use product — Trico Garden

Property	Result
Colour	White
Odour	Slightly rancid
Physical state	Liquid
Formulation type	Suspension

Label concentration	6.40%
Container material and description	PET plastic bottles 0.25 to 10 L
Density	1.0066 g/ml
pH of 1% dispersion in water	7.91
Oxidizing or reducing action	The end-use product does not exhibit oxidizing or reducing properties.
Storage stability	Waived.
Corrosion characteristics	The product was not corrosive to the plastic can after storage for 24 months at 25 °C.
Explosibility	Not expected to be explosive.

1.3 Directions for use

Trico is for use both in commercial forestry and agriculture. It is applied by hand-held, backpack or garden sprayer with a flat fan or cone nozzle. In forestry, Trico is sprayed undiluted to the foliage, stems or trunks of young deciduous and coniferous trees and shrubs to prevent feeding damage (including bark stripping) or rubbing damage by deer, elk, or moose. The maximum application rate in forestry is 20 L of undiluted Trico/ha/application. A maximum of 4 applications per year may be made to the plants in forestry. In agriculture, Trico is applied as a foliar spray at 10 L product/ha diluted in 10 L of water/ha (1:1 dilution ratio) to apple trees and at 15 L product/ha diluted in 75 L of water/ha (1:5 dilution ratio) to grapevines to prevent feeding damage by deer. Application to fruit crops is limited to before flowering. A maximum of 2 applications per year may be made to the plants in agriculture. For complete use directions, refer to the registered product label.

Trico Garden is available to the general public to prevent feeding damage by deer to outdoor ornamentals, apple trees and grapevines. It is applied to plants by hand-held, backpack or garden sprayer with a flat fan or cone nozzle. Trico Garden is mixed at either 1 part concentrate in 3 parts water (1:3 dilution) for heavy browsing or 1 part concentrate in 5 parts water (1:5 dilution) for light to moderate browsing. A maximum of 2 ml Trico Garden concentrate/m² is permitted for all uses. Application to fruit crops is limited to before flowering. A maximum of 6 applications per year may be made to the plants. For complete use directions, refer to the registered product label.

1.4 Mode of action

The smell and taste of sheep fat repels deer, elk, or moose from treated plant material to prevent or reduce feeding or rubbing damage.

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of the active ingredient in the technical product has been validated and assessed to be acceptable.

2.2 Method for formulation analysis

Waived.

2.3 Methods for residue analysis

No methods are required to quantify residues of sheep fat due to its low toxicity (see section 3.0 for additional details).

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of the toxicological information was conducted in support of Sheep Fat Technical, Trico and Trico Garden. The data package for Sheep Fat Technical, Trico and Trico Garden is considered acceptable to assess the toxic effects that may result from exposure to sheep fat.

The data package consisted of publicly available toxicology information on the major fatty acid components in sheep fat as well as on surrogate fatty acids, and scientific rationales to waive acute oral, dermal and inhalation toxicity, primary skin and eye irritation, and dermal sensitization testing for Sheep Fat Technical, Trico and Trico Garden. Publicly available information and scientific rationales to waive short-term toxicity, developmental toxicity, genotoxicity, and various other effects for sheep fat were provided.

Sheep fat is produced from fat tissues of sheep. It has a long history of use in the human diet and is widely used in industry as an emulsifier, emollient, and lubricant in cosmetic creams, soaps, lotions, and pastes. Sheep fat is a triglyceride, consisting predominantly of glycerine esters (glycerol) with the following fatty acids: palmitic acid, stearic acid and oleic acid as well as smaller amounts of myristic, palmitoleic, heptadecanoic and linoleic acid.

The applicant provided information from a 5-batch analysis of sheep fat to specify the composition of fatty acids and to characterize the toxicity profile of sheep fat from those relevant components. However, the fatty acid composition of Sheep Fat Technical will vary slightly depending on the starting material.

Based on structure and similar toxicity observed in publicly available studies, the seven fatty acids from sheep fat can be used as surrogates for each other in the absence of data for one particular fatty acid.

In the absence of data for heptadecanoic and palmitoleic acids, publicly available studies on conjugated linoleic acid (CLA) are acceptable as surrogate information because CLA is a mixture of the cis/trans isomers of linoleic acid and is found in ruminant meat, including that of sheep. Also, tall oil fatty acid and olive oil are suitable surrogates for the seven fatty acid constituents of sheep fat.

Based on the available toxicology information, Sheep Fat Technical is considered to be of low acute toxicity by the oral, dermal, and inhalation routes, mildly irritating to eyes and skin, and is not considered to be a dermal sensitizer, but prolonged or frequently repeated skin contact to sheep fat may cause allergic reactions in some individuals.

In publicly available sensitization studies, oleic acid, linoleic acid, and olive oil tested positive in the local lymph node assays (LLNA), and oleic acid and olive oil tested positive for sensitization in the guinea pig maximization test. Publicly available results for linoleic acid were inconclusive in the maximization test. A rationale submitted by the Registrant was accepted to not classify sheep fat as a dermal sensitizer despite the positive dermal sensitization results for oleic and linoleic acid. The purity of the oleic acid and linoleic acid test substances evaluated in the two guideline studies from open literature was 99%, whereas the percent of oleic and linoleic acid that constitutes sheep fat is approximately 26% and 2%, respectively. Moreover, there is widespread exposure of humans to the fatty acids that comprise sheep fat, either endogenously or from food and cosmetics, and the overall weight-of-evidence from information on human exposure and the history of safe use does not support evidence for human skin sensitization potential for any of the fatty acids. However, based on the positive results from the dermal sensitization studies on some of the components, a precautionary label statement is required on the product labels indicating that prolonged or frequently repeated skin contact to sheep fat may cause allergic reactions in some individuals.

Information from the published literature and study summaries were assessed for the potential of sheep fat to cause short-term toxicity, developmental toxicity, and genotoxicity. Based on a weight-of-evidence of the available data for the major components of sheep fat, and taking into consideration the history of use of sheep fat in the human diet and fatty acids in consumer products, the low toxicity profile of sheep fat, and the anticipated limited human exposure based on the proposed use pattern, no short-term toxicity, developmental toxicity, genotoxicity and various other effects are anticipated for sheep fat.

In two short-term 90-day oral toxicity rat studies on CLA, there were no treatment-related adverse effects. The No-Observed-Adverse-Effect-Levels (NOAELs) were > 1970 mg/kg/day (highest dose tested; HDT) in one study and > 7299 mg/kg/day for males and 8184 mg/kg/day for females in the second study. In another study on tall oil fatty acids, there were no treatment-related effects and the NOAEL was > 12 500 mg/kg/day (HDT).

Isopropyl myristate showed no evidence of treatment-related systemic toxicity from repeated dermal exposure to rabbits or inhalation exposure to guinea pigs and monkeys.

In a dietary developmental toxicity study on CLA in rats, there were no treatment-related effects. The NOAEL for maternal and developmental toxicity was 250 mg/kg/day (HDT). In a developmental toxicity study on olive oil administered orally to rabbits, the maternal and developmental NOAEL was 910 mg/kg/day and the LOAEL was considered to be 2500 mg/kg/day based on reduced food consumption. In rats, dietary administration of tall oil fatty acid showed no treatment-related effects, and the parental and developmental NOAEL was considered to be >5000 mg/kg/day.

Based on publicly available mutagenicity data, there was no indication that oleic acid, myristic acid, stearic acid, linoleic acid, tall oil fatty acid, and conjugated linoleic acid were mutagenic. No data were available on the heptadecanoic, palmitic, or palmitoleic acids.

The scientific rationale to waive toxicology data requirements for the end-use products was accepted based on the low concentrations of the formulants (except the diluent), the low toxicity profile of sheep fat, and the toxicity profile of the formulants. Therefore, the toxicology profiles of Trico and Trico Garden are considered to be similar to the toxicology profile of Sheep Fat Technical.

Health incident reports

Sheep fat is a new active ingredient pending registration for use in Canada, and as of 7 December 2021, no incident reports had been submitted to the PMRA.

3.2 Occupational, residential and bystander exposure and risk assessment

3.2.1 Dermal absorption

No information was submitted on the potential dermal absorption of sheep fat. Based on the available information on long chain fatty acids (carbon chain length > 12), limited dermal uptake is expected.

3.2.2 Use description

Trico and Trico Garden are proposed for use as scent and taste repellents against deer, elk, and moose. Trico is a commercial-class product for use in forest nurseries and plantations (deciduous and coniferous trees and shrubs), apple orchards, and grapes (new and established plantations), while Trico Garden is a domestic-class product for use on outdoor ornamentals (flowers, trees, and shrubs), apple trees, and grapevines. The end-use products are to be applied using a hand-held, backpack or garden sprayer with a flat fan or cone nozzle.

For forestry use, Trico is to be applied as a foliar spray or trunk spray without any mixing or dilution at a maximum application rate of 20 L/ha (1.28 kg a.i.), up to four applications a year. To prevent browsing, an applicator working an 8-hr day and treating about 7500 trees in 3 ha would be exposed to about 0.74–3.84 kg a.i. of sheep fat.

For apple orchards, the maximum application rate of Trico is 10 L/ha diluted in 10 L of water/ha (1:1 dilution ratio) and up to two applications per year, with a minimum repeat interval of 28 days. For use on grapes, the maximum application rate of Trico is 15 L/ha diluted in 75 L of water/ha (1:5 dilution ratio) and up to two applications per year, with a minimum repeat interval of 28 days. The application timing for Trico for apple orchards and grapes is from three leaves unfolded stage until beginning of flowering.

For control of browsing, Trico Garden is to be applied as a foliar spray including to soil around the base of low-growing plants at a 1:3 dilution in water for heavy browsing pressure or at 1:5 dilution in water for moderate to light browsing pressure. The application rate is until run-off occurs or plants look wet (equivalent to 1 to 2 mL undiluted product/m²) and up to six applications per year, with a minimum repeat interval of 28 days.

Both Trico and Trico Garden labels specify that for treating apples and grapes, spraying is to be done only before flowering.

3.2.3 Mixer, loader, and applicator exposure and risk

When Trico is used according to label directions, occupational exposure is characterized as short- to intermediate-term in duration and is primarily by the dermal route, but incidental inhalation and ocular exposure is also possible, which is expected to be minimal, while mixing, loading, and applying the product, as well as during clean-up and repair. Sheep fat is not volatile; therefore, inhalation exposure if any would occur only if very fine droplets are formed during application and inhaled. Potential ocular exposure would only be during splashes when mixing/loading or if spray solution goes into the eye during application.

To protect workers from exposure to Trico, the proposed label requires workers to wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield) during mixing, loading, application, clean-up and repair. Health Canada considers this mitigation to be acceptable to protect against potential irritation and sensitization that is possible in some sensitive individuals from prolonged or repeated exposure, when handling Trico. In addition, the proposed label requires unprotected persons to remain out of the treated area until sprays have dried and spray advisory statements to minimize spray drift. Health Canada requires further label statements that if early entry is necessary before sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and protective eyewear (goggles or face shield).

Precautionary statements on the end-use product label, such as the wearing of personal protective equipment (PPE), aimed at mitigating exposure are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the label are followed which include PPE.

3.2.4 Postapplication exposure and risk

There is the potential for post-application exposure to workers re-entering areas treated with Trico. Trico is considered to be mildly irritating to eyes and skin, and may cause allergic reactions in some individuals from repeated and prolonged exposure. Given the nature of the post-application activities typically performed (for example, scouting treated areas), dermal contact with treated plants, soil, and surfaces is possible. Inhalation of suspended spray droplets is also possible if re-entry occurs immediately after application. Therefore, individuals must remain out of the treated area until sprays have dried. If early entry is required before sprays have dried, workers must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks, and protective eyewear (goggles or face shield). Precautionary (for example, wearing of PPE) statements on the end-use product label aimed at mitigating exposure are considered adequate to protect workers from risk due to postapplication exposure.

3.2.5 Residential and bystander exposure and risk

As Trico is a commercial-class end-use product, a residential handler exposure risk assessment is not required. However, a commercial applicator could apply the product in residential areas (for example, apple trees). If Trico is used in a residential area, similar considerations for post-application exposure and risk to residential populations would apply as was considered in the assessment for Trico Garden (see below). In addition, the commercial outdoor use of Trico in forests or orchards may result in bystander exposure due to drift. In the interest of promoting best management practices and to minimize human exposure from spray drift or from spray residues resulting from drift, a spray drift statement is required for the label.

Trico Garden is for domestic use. Trico Garden is considered to be mildly irritating to eyes and skin, and may cause allergic reactions in some individuals from repeated and prolonged exposure. When Trico Garden is used according to label directions, residential user exposure is characterized as short- to intermediate-term in duration and is primarily by the dermal route, but incidental inhalation and ocular exposure are also possible while mixing, loading, and applying the product, as well as during clean-up and repair. However, inhalation and ocular exposure are considered to be minimal. To minimize residential user exposure from Trico Garden, the proposed label instructs that users are required to wear rubber gloves and protective eyewear when handling, mixing, loading or applying the product, and during all clean-up and repair activities. Overall, risks to residential users from potential irritation and sensitization in some individuals from the use of Trico Garden are acceptable when the precautionary statements on the label are followed, which include PPE.

In addition, to minimize potential bystander exposure and residential exposure, Health Canada requires statements on the Trico Garden label that specifies that children, adults or pets are not permitted to enter the treated area until sprays have dried, and that the product is not to be applied in a way that will result in contact with other people or pets, either directly or through drift.

Health Canada considers this mitigation to be acceptable to protect against potential irritation and sensitization that is possible in some sensitive individuals from prolonged or repeated exposure, when handling Trico and Trico Garden. Consequently, the health risks to bystanders and individuals in residential areas to Trico and Trico Garden are considered acceptable.

3.3 Food residue exposure assessment

3.3.1 Food

The proposed use pattern is not expected to result in dietary exposure to sheep fat since Trico and Trico Garden will be applied only before flowering on fruit crops, such as apples and grapes. Moreover, sheep fat has long been part of the normal human diet. Sheep fat, Trico and Trico Garden are considered to be of low acute oral toxicity. Therefore, when the end-use products are applied as directed by the labels the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.3.2 Drinking water

Exposure to residues of sheep fat from drinking water is expected to be negligible because of the extremely low water solubility and low mobility in soil of the fatty acids in sheep fat, and their likely biodegradability in nature. Furthermore, the labels have the necessary mitigative measures to limit contamination of drinking water from the proposed uses of sheep fat. Health risks from residues of sheep fat in drinking water are acceptable due to the low toxicity profile and limited exposure following applications of Trico and Trico Garden.

3.3.3 Acute and chronic dietary risks for sensitive subpopulations

Calculations of acute reference doses and acceptable daily intakes are not required for sheep fat as it is part of the normal human diet. Based on all the available information and hazard data, sheep fat is considered to be of low toxicity. Thus, there are no threshold effects of concern. As a result, there is no need to apply uncertainty factors to account for intra- and interspecies variability, and no margin of exposure was determined.

In addition, consumption patterns among infants and children, special susceptibility in these subpopulations to the effects of sheep fat including developmental effects from pre- or post-natal exposures, and cumulative effects on infants and children of this active ingredient and other registered products containing it, does not apply to this active ingredient. As a result, the PMRA has used a qualitative approach to assess the risks of sheep fat to human health.

3.3.4 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, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

Sheep fat is considered to be of low acute oral, dermal, and inhalation toxicity, mildly irritating to eyes and skin, and is not considered as a dermal sensitizer, but prolonged or frequently repeated skin contact to sheep fat may cause allergic reactions in some individuals. Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of sheep fat to the general population in Canada, including infants and children, when Trico and Trico Garden are used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

3.3.5 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, a cumulative health assessment was undertaken. While components of sheep fat may share a common moiety with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to sheep fat and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of sheep fat.

3.3.6 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*.

Dietary risk to humans from the proposed use of sheep fat on agricultural crops is acceptable, given the history of use of sheep fat in the human diet, the low toxicity profile of sheep fat, and the timing of application of Trico and Trico Garden to fruit crops before flowering, which would result in negligible residues in the fruit. Consequently, the specification of MRLs, under the *Pest Control Products Act*, will not be required for sheep fat for the following reasons: 1) residues of sheep fat are not expected on foods; and 2) the fact that, although sheep fat will be registered as a pesticide, it is also considered a food, and MRLs are not specified for foods

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

Sheep fat consists predominantly of naturally occurring glycerin esters of palmitic acid, stearic acid and oleic acid, as well as smaller amounts of other fatty acids (myristic, palmitoleic, heptadecanoic and linoleic acid). Sheep fat has a low vapour pressure ($< 10^{-12}$ Pa at 25 °C), indicating it is not likely to volatilize. It is insoluble in water ($< 10^{-17}$ mg/L at 25 °C). It is soluble in non-polar solvents (n-heptane, p-xylene, 1,2-dichloroethane) and insoluble in polar solvents. Being a fat compound and based on a $\log K_{ow} \geq 18.7$ sheep fat is highly lipophilic; however, it is not expected to bioaccumulate in tissues or be of biological concern due to the natural source of this product and the ability of organisms to metabolize this compound. Sheep fat has low potential for direct phototransformation, based on the UV/Visible absorption spectra indicating no wavelength absorption maxima above 290 nm. Estimated DT₅₀ rates in air for the glycerol esters of palmitic, stearic and oleic acids were approximately 2.0, 1.8 and 0.5 hours, respectively, indicating that sheep fat will break down rapidly and, thus, not undergo long-range transport.

Sheep fat is not expected to be mobile in soil or volatilize from moist soil. Biodegradation is an important fate process in soil for sheep fat and its components. Hydrolysis is not expected to be an important environmental fate process for sheep fat under environmental conditions. Sheep fat is expected to adsorb to suspended solids and sediment if released to water, where it will be rapidly degraded by microorganisms.

4.2 Environmental risk characterization

Based upon lack of toxicity and the natural occurrence of sheep fat and its components, a qualitative risk assessment was conducted for terrestrial invertebrates, birds, wild mammals, fish, aquatic invertebrates and aquatic plants. Overall, risks to non-target organisms are acceptable when sheep fat and its associated end-use products are used in accordance with approved label directions.

4.2.1 Risks to terrestrial and aquatic organisms

Terrestrial species may be exposed to sheep fat following application. Birds and wild mammals may be exposed when consuming or coming into contact with soil, plants, seeds, and insects where sheep fat is present. Many rodents also live or burrow in the soil and may be exposed during application.

A summary of toxicity data are presented in Appendix I, Table 1. Available toxicity studies indicate sheep fat had no affect on survival of earthworms, adult honey bees or parasitoid wasps at the highest treatment levels tested. For terrestrial vascular plants, the most sensitive species was the dicot plant oilseed rape with a 25% reduction in dry weight at 17.40 L/ha (the calculated ER₂₅). This is higher than the proposed application rate of 15 L product/ha and thus adverse effects to terrestrial plants are not expected to occur at the site of application. Furthermore, based on the method of application (hand-held, backpack or garden sprayer), off-site exposure to non-

target plants is expected to be negligible. Risks to terrestrial invertebrates and plants are acceptable when sheep fat and its associated end-use products are used in accordance with approved label directions.

No toxicity data were available for birds and wild mammals. The PMRA agreed with the applicant's waiver request rationale that sheep fat is not of toxicological concern to these terrestrial organisms, as it is a natural product and its main components (glycerin esters of palmitic acid, stearic acid and oleic acid) are a part of the diet of many birds and mammals. Risks to wild birds and mammals are acceptable when sheep fat and its associated end-use products are used in accordance with approved label directions.

Due to the hand-held method of application, direct overspray, drift and run-off of products containing sheep fat into the aquatic environment are not expected to occur, thus preventing exposure to aquatic organisms including freshwater fish, invertebrates, algae and vascular plants. Sheep fat was practically non toxic to daphnia (*Daphnia magna*) and zebra fish (*Brachydanio rerio*) with respective EC₅₀ and LC₅₀ greater than 100 mg product/L (or 6 mg a.i./L), and no adverse effects were observed in these studies. Additionally, no adverse effects were observed for the freshwater algae, *Selenastrum capricornutum*, with an EC₅₀ greater than 100 mg product/L (or 6 mg a.i./L). No toxicity data were available for aquatic vascular plants, and the PMRA agreed with the applicant's waiver request rationale that the requirement for aquatic vascular plants be waived due to the lack of observed effects to algae. Risks to aquatic organisms are acceptable when sheep fat and its associated end-use products are used in accordance with approved label directions.

4.3 Environmental incident reports

Environmental incident reports are obtained from two main sources: the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments); and the USEPA Ecological Incident Information System (EIIS). Information on the reporting of incidents can be found on the [Pesticides](#) portion of the Canada.ca website.

The PMRA incident reporting database was searched for all human, domestic animal and environment incident reports involving the active ingredient sheep fat. As of 7 December 2021, no environment incident reports (including scientific studies) involving sheep fat or devices relevant to the use of this product were reported to the PMRA.

The USEPA Ecological Incident Information System (EIIS), which was last updated October 5, 2015, was searched and no environment incident reports related to sheep fat were found.

5.0 Value

The value of Trico was established based on 39 trials conducted in Europe or Canada examining the efficacy of Trico or an equivalent product to prevent deer, elk or moose damage on deciduous and coniferous tree species and on agricultural crops. The weight of evidence supports

the use of Trico on: 1) young deciduous and coniferous trees and shrubs in forestry to prevent winter and summer feeding damage by deer, elk, or moose; 2) deciduous and coniferous trees in forestry to reduce rubbing damage by deer; 3) deciduous and coniferous trees in forestry to prevent bark stripping by deer; and 4) apple orchards and grapevines to prevent browsing damage by deer.

In most of the submitted trials, no damage was observed on plants treated with Trico when applied according to the use directions. However, a white residue and some damage (for example, browning of leaf edges) was observed on plants in some trials. Label statements are present to identify and mitigate the impacts of treating plants with Trico.

There is a limited number of commercial-class repellents registered in Canada for use against deer, elk or moose. The registration of Trico will provide an additional repellent to prevent or reduce damage to trees and shrubs in forestry and certain agricultural crops.

Support for Trico Garden was based on a rationale to extrapolate from value information provided for Trico to support the value of Trico Garden. The weight of evidence supports the use of Trico Garden on outdoor ornamentals, apple trees and grapevines to prevent feeding damage by deer.

The registration of Trico Garden will provide the general public with a new repellent to prevent feeding damage by deer on outdoor ornamentals, apple trees, and grapevines.

6.0 Pest control product policy considerations

6.1 Toxic substances management policy considerations

The *Toxic Substances Management Policy* (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, sheep fat was assessed in accordance with the PMRA Regulatory Directive DIR99-03⁵ and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that sheep fat does not meet all of the TSMP Track 1 criteria.

⁵ DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁶ The list is used as described in the PMRA Science Policy Note SPN2020-01⁷ and is based on existing policies and regulations, including the *Toxic Substance Management Policy* and *Formulants Policy*,⁸ and taking into consideration the *Ozone-depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the *Montreal Protocol*).

The PMRA has reached the conclusion that sheep fat and its end-use products Trico and Trico Garden do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the [Pest Control Products Act](#), is proposing registration for the sale and use of Sheep Fat Technical, Trico and Trico Garden, containing the technical grade active ingredient sheep fat, as a repellent to deer, elk or moose from trees and shrubs in forestry, grapevines, apple trees and outdoor ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

⁶ SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

⁷ PMRA's Science Policy Note SPN2020-01, Policy on the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the *Pest Control Products Act*.

⁸ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

List of abbreviations

µg	micrograms
a.i.	active ingredient
CAS	Chemical Abstracts Service
CLA	conjugated linoleic acid
d	day(s)
DIR	Regulatory Directive
DT ₅₀	dissipation time 50% (the dose required to observe a 50% decline in concentration)
dw	dry weight
EC ₅₀	effective concentration on 50% of the population
EIIS	Ecological Incident Information System
ER ₂₅	effective rate 25%
ER ₅₀	effective rate 50%
EW	aqueous emulsion
g	gram
h	hour(s)
ha	hectare(s)
HDPE	high density polyethylene
HDT	highest dose tested
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
<i>K_{ow}</i>	<i>n</i> -octanol-water partition coefficient
L	litre
LC ₅₀	lethal concentration 50%
LD ₅₀	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LR ₅₀	lethal rate 50%
m	metres
mg	milligram
ml	millilitre
MRL	maximum residue limit
N/A	not applicable
nm	nanometers
NOAEL	no observed adverse effect level
NOER	no observed effect rate
Pa	Pascal
PET	polyethylene terephthalate
p <i>K</i> _a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
SD	standard deviation
SPN	Science Policy Note

TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight per weight

Appendix I Tables and figures

Figure 1 Structures of the key fatty acid components of sheep fat



Figure 1. Oleic Acid (C18)

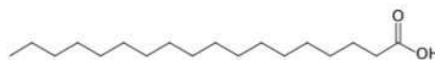


Figure 2. Stearic Acid (C18)

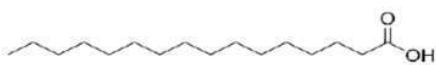


Figure 3. Palmitic Acid (C16)



Figure 4. Myristic Acid (C14)

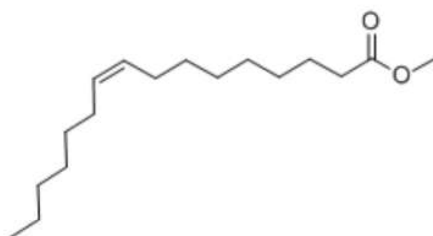


Figure 5. Palmitoleic acid methyl ester (C16)



Figure 6. Heptadecanoic acid (C17)

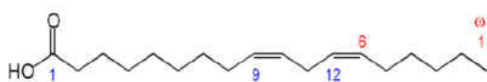


Figure 7. Linoleic Acid (C18)

Table 1 Toxicity of sheep fat to non-target species

Organism	Exposure	Test Substance	Toxicity Endpoint	Degree of Toxicity ^a	PMRA #
Terrestrial Species					
Earthworm (<i>Eisenia fetida</i>)	14 d	K 715-4 (Trico, 6% EW)	LC ₅₀ and NOER (mortality): > 1000 mg/kg dw soil (> 67.5 mg a.i./kg dw soil)	N/A	303287 1
Honey bee, adult (<i>Apis mellifera mellifera</i> L.)	96 h	K 715-4 (64 g/kg sheep fat)	Oral LD ₅₀ and NOER (mortality): > 63.063 µg a.i./bee Contact LD ₅₀ and NOER (mortality): > 63.063 µg a.i./bee	Relatively non-toxic	303287 2
Honey bee,	96 h	K 743-4	Oral LD ₅₀ and NOER	Relative	303287

Organism	Exposure	Test Substance	Toxicity Endpoint	Degree of Toxicity ^a	PMRA #
adult (<i>Apis mellifera mellifera</i> L.)		(250 g/kg sheep fat)	(mortality): > 100 µg a.i./bee Contact LD ₅₀ and NOER (mortality): > 100 µg a.i./bee	y non-toxic	2
Parasitoid wasp (<i>Aphidius rhopalosiphi</i>)	48 h	K 715-4 (Trico, 6% EW)	LR ₅₀ /ER ₅₀ and NOER (mortality): > 30 L/ha (> 2045 g a.i./ha)	N/A	3032873
Terrestrial plants (10 species)	28 d (vegetative vigour)	Trico (5.8% sheep fat w/w)	ER ₂₅ (oilseed rape weight): 17.4 L/ha (1020 g a.i./ha) ER ₂₅ (other species weight, height): > 60 L/ha (> 3518 g a.i./ha)	N/A	3032876
Aquatic Species (Freshwater)					
Daphnid (<i>Daphnia magna</i>)	48 h (static)	Trico Neu (K 715-4; 6% sheep fat w/w)	EC ₅₀ , NOER (signs of toxicity): > 100 mg/L (> 6 mg a.i./L) (nominal)	Practically non-toxic (based on EP)	3032874
Zebrafish (<i>Brachydanio rerio</i>)	96 h (semi-static, renewal)	Trico Neu (K 715-4; 6% sheep fat w/w)	LC ₅₀ , NOER (mortality): > 100 mg/L (> 6 mg a.i./L) (nominal)	Practically non-toxic (based on EP)	3032875
Algae (<i>Selenastrum capricornutum</i>)	72 h (static)	Trico Neu (K 715-4; 6.58% sheep fat w/w)	EC ₅₀ , NOER (biomass, growth rate): > 100 mg/L (> 6.58 mg a.i./L) (nominal)	N/A	3184451

^aAtkins et al. (1981) for bees and USEPA classification for others, where applicable; N/A = not applicable

References

A. List of studies/Information submitted by registrant

1.0 Chemistry

PMRA

Document

Number

Reference

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3032858	2019, Determination of Total Fat, the Main Component..., DACO: 2.13.3 CBI
3032859	2005, Sheep Fat Melting Temperature, DACO: 2.14.4 CBI
3032860	2019, Sheep Fat Technical and Trico color, ..., DACO: 2.14.1,2.14.2,2.14.3 CBI
3032861	2012, Relative Density of Sheep Fat, DACO: 2.14.6 CBI
3032862	2005, Sheep Fat: Estimation of the Water Solubility, DACO: 2.14.7 CBI
3032863	2005, Sheep Fat: Solubility in Organic Solvents, DACO: 2.14.8 CBI
3032864	2005, Sheep Fat: Vapour Pressure, DACO: 2.14.9 CBI
3032865	2019, Partition Coefficient of Sheep Fat, DACO: 2.14.11 CBI
3032866	2018, UV/VIS Absorption Spectrum of Sheep Fat, DACO: 2.14.12 CBI
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3190568	2018, Wareneingangsschein, DACO: 2.13.3 CBI
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3037617	2005, Trico: Relative Density, DACO: 3.5.6 CBI
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2.0 Human and animal health

PMRA

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| 3037623 | 2019, Trico: Waiver requests for acute toxicity studies, DACO 4.6.1, 4.6.2, 4.6.3, 4.6.4, 4.6.5, and 4.6.6 |
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- | Number | Reference |
|---------|---|
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PMRA

Document

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- 3037628 2014, Efficacy of Trico and Trico S against game browsing by red deer, DACO: 10.2.3.1
- 3037629 2015, Efficacy of Trico and Trico S against game browsing by red deer, DACO: 10.2.3.1
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- 3037636 2012, Trial Report 2012/Trico, DACO: 10.2.3.1
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B. Additional information considered**i) Published information****1.0 Human and animal health****PMRA****Document****Number****Reference**

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ii) Unpublished information**None**