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Proposed Registration Decision PRD2020-02

Stearic Acid and Related Fatty Acids and Rodents Away Odor Free

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Overview

Proposed Registration Decision for Stearic Acid and Related Fatty Acids

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 Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free, containing the technical grade active ingredient stearic acid and related fatty acids, for use as a mouse repellent in indoor spaces such as homes and recreational vehicles.

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 stearic acid and related fatty acids and Rodents Away Odor Free.

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 acceptable[1] 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 value[2] 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 the Canada.ca website at healthcanada.gc.ca/pmra.

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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 stearic acid and related fatty acids and Rodents Away Odor Free, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on stearic acid and related fatty acids and Rodents Away Odor Free, 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 Are Stearic Acid and Related Fatty Acids?

Stearic acid and related fatty acids is the active ingredient in the domestic class rodent repellent product, Rodents Away Odor Free, which reduces the presence and activity of house mice in indoor spaces including modes of transport. It is unknown how stearic acid and related fatty acids reduces the presence and activity of house mice.

Health Considerations

Stearic Acid and Related Fatty Acids are unlikely to affect human health when it is used according to label directions.

Potential exposure to stearic acid and related fatty acids may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where 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 where no effects are observed.

Based on available information, the technical grade active ingredient, Stearic Acid and Related Fatty Acids Technical, and the end-use product, Rodents Away Odor Free, were of low acute oral, dermal, and inhalation toxicity, non-irritating to the eyes and skin, and are not dermal sensitizers.

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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*.

Information from the published scientific literature was assessed for the potential of stearic acid and related fatty acids to cause short-term toxicity, developmental toxicity, and genotoxicity. Stearic acid and related fatty acids are naturally occurring fatty acids. Adverse effects in animals given repeated doses were not observed. There was no indication of prenatal developmental toxicity. There was no evidence that stearic acid and related fatty acids induced mutagenic or genotoxic effects.

Residues in Water and Food

Dietary risks from food and water are acceptable.

Rodents Away Odor Free is not proposed for food or feed uses. In addition, the likelihood of residues of stearic acid and related fatty acids in drinking water will be low. Consequently, health risks from dietary exposure 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.

Rodents Away Odor Free is proposed for use in indoor spaces including modes of transport (e.g., homes and recreational vehicles). Residential and non-occupational exposure to Rodents Away Odor Free is expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Occupational Risks From Handling Rodents Away Odor Free

Occupational risks are acceptable when Rodents Away Odor Free is used according to the label directions, which include protective measures.

Since Rodents Away Odor Free is a domestic product, occupational risks are not applicable.

Environmental Considerations

An environmental assessment was not required for Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free as they have no outdoor uses.

Value Considerations

What Is the Value of Rodents Away Odor Free?

Rodents Away Odor Free is a new domestic class product that reduces the presence and activity of house mice.

Rodents Away Odor Free reduces the presence and activity of house mice, which may reduce damage caused by house mice presence and/or activity.

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 labels of Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

The statements, 'KEEP OUT OF REACH OF CHILDREN' and 'Wash thoroughly with soap and water after handling' are required for the PRECAUTIONS section of the secondary display panel of the end-use product.

Next Steps

Before making a final registration decision on stearic acid and related fatty acids and Rodents Away Odor Free, 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

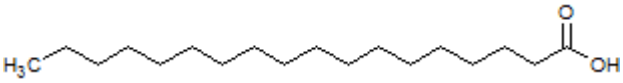
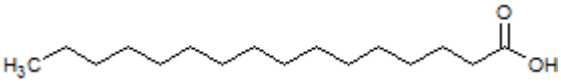
When the Health Canada makes its registration decision, it will publish a Registration Decision on stearic acid and related fatty acids and Rodents Away Odor Free (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Stearic Acid and Related Fatty Acids and Rodents Away Odor Free

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Stearic acid and related fatty acids
Function	Animal repellent
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Fatty acids, C14-20 and C18-unsaturated
2. Chemical Abstracts Service (CAS)	Fatty acids, C14-20 and C18-unsaturated
CAS number	98653-89-5
Molecular formula	$C_{18}H_{36}O_2$ and $C_{16}H_{32}O_2$ for the predominant C18 and C16 species
Molecular weight	284.5 and 256.4 for the predominant C18 and C16 species
Structural formula	C18  C16 
Purity of the active ingredient	99.7% stearic acid and related fatty acids

1.2 Physical and Chemical Properties of the Active Ingredient and End-Use Product

Technical Product—Stearic Acid and Related Fatty Acids Technical

Property	Result
Colour and physical state	White solid
Odour	Mild fatty odour
Melting range	55°C
Boiling point or range	205-225°C

Property	Result
Density	0.82-0.86 g/cm^3
Vapour pressure at 158°C	0.01 kPa
Ultraviolet (UV)-visible spectrum	λ_{max} = 210 nm (not expected to absorb in the visible range)
Solubility in water	Insoluble
Solubility in organic solvents	Soluble in many organic solvents
n-Octanol-water partition coefficient (K_{ow})	Log K_{ow} > 3 (estimated)
Dissociation constant (pK_a)	pK_a = 4.75 (estimated)
Stability (temperature, metals)	Stable under recommended storage conditions; incompatible with strong oxidizing agents.

End-Use Product—Rodents Away Odor Free

Property	Result
Colour	White and grey
Odour	Slight fatty acid (tallow) odour
Physical state	Solid
Formulation type	Particulate
Guarantee	99.7% stearic acid and related fatty acids
Container material and description	Sachets (nylon organza bags) packaged in a plastic foil bag
Density at 25°C	0.82-0.86 g/cm^3
pH of 1% dispersion in water	Not available (not readily soluble in water)
Oxidizing or reducing action	Not compatible with strong oxidizing agents
Storage stability	Stable when stored unopened between 5 and 30°C
Corrosion characteristics	Not expected to be corrosive to the packaging material
Explodability	Not expected to be explosive

1.3 Directions for Use

Rodents Away Odor Free contains stearic acid and related fatty acids at a guarantee of 99.7% to reduce the presence and activity of house mice in indoor spaces including modes of transport (for example, homes and recreational vehicles) within 3 m (or 114 L volume) for up to two weeks. Rodents Away Odor Free is formulated as a solid repellent packaged in cloth sachets containing 40 g of product. The sachets are placed on the floor or hung indoors and in vehicles.

1.4 Mode of Action

There is no known mode of action for stearic acid and related fatty acids in reducing house mouse presence or activity.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

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

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

No methods are required to quantify residues of stearic acid and related fatty acids due to their low toxicities (see Section 3.0 for additional details).

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological information in support of Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free. The data package for Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free is considered acceptable (Appendix I, Tables 1 and 2,) to assess the toxic effects that may result from exposure to stearic acid and related fatty acids. The data package consisted of acute toxicity information for the long-chain fatty acids in Stearic Acid and Related Fatty Acids Technical (acute oral and dermal toxicity, skin and eye irritation, and dermal sensitization), as well as information on short-term toxicity, prenatal developmental toxicity, and genotoxicity.

Stearic Acid and Related Fatty Acids Technical is of low acute oral and dermal toxicity, non-irritating to the eyes and skin, and is not a dermal sensitizer. Based on publicly available information and a long history of use in cosmetics and other consumer products, repeat exposure to the long-chain fatty acids in Stearic Acid and Related Fatty Acids Technical is not expected to result in any significant short-term toxicity, prenatal developmental toxicity, or genotoxicity.

The end-use product, Rodents Away Odor Free, is of low acute oral and dermal toxicity, not irritating to the eyes or skin, and is not a dermal sensitizer.

Incident Reports

Stearic acid and related fatty acids is a new active ingredient pending registration for use in Canada, and as of 2 October 2019, 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 on dermal absorption of stearic acid and related fatty acids in Rodents Away Odor Free was provided, however, dermal absorption is expected to be limited when the precautionary statements on the label are observed.

3.2.2 Use Description

Rodents Away Odor Free is applied throughout the area where rodents are present in indoor spaces including modes of transport (e.g., homes and recreational vehicles). Rodents Away Odor Free is contained in nylon mesh bags (sachets), which are, in turn, contained in re-sealable mylar stand-up pouches. Each pouch contains 3 or 6 sachets of 40 g of Rodents Away Odor Free per sachet. The end-use product is placed directly on the floor where rodents travel or 5 cm off the ground.

3.2.3 Mixer, Loader, and Applicator Exposure and Risk

When Rodents Away Odor Free is used according to label directions, exposure to individuals is characterized as short-term and intermediate-term in duration and is primarily by the dermal route.

Precautionary statements on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from any risk due to user exposure. Overall, risks to users are acceptable when the precautionary statements on the label are followed.

3.2.4 Postapplication Exposure and Risk

Postapplication activities include scouting for odours associated with the presence of rodents and removal of the spent sachets. Although individuals are expected to come in contact with the sachets containing the end-use product, the low toxicity of the active ingredient is such that the risk from postapplication exposure is considered to be acceptable.

3.2.5 Residential and Bystander Exposure and Risk

Rodents Away Odor Free is proposed for use in residential indoor spaces including modes of transport (for example, homes and recreational vehicles). Residential user exposure associated with the end-use product, Rodents Away Odor Free, is most likely to occur during application, clean-up, and removal of old sachets. Residential user exposure has been limited by the inclusion of appropriate precautionary statements on the label, such that the risk from residential user exposure is acceptable. In addition, the low toxicity and long history of use of stearic acid and

related fatty acids is such that exposure to humans and companion animals in residential areas is not a concern. Consequently, the health risks to individuals in residential areas are considered acceptable.

The use of Rodents Away Odor Free will not result in bystander exposure from drift. Consequently, the health risks to bystanders are considered acceptable.

3.3 Food Residue Exposure Assessment

3.3.1 Food

Rodents Away Odor Free is not proposed for food or feed use. Consequently, dietary exposure to stearic acid and related fatty acids from consumption of treated crops is not a concern.

3.3.2 Drinking Water

Dietary exposure from drinking water is expected to be negligible as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of Rodents Away Odor Free. Consequently, health risks from residues of stearic acid and related fatty acids in drinking water are acceptable.

3.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

As no dietary exposure is expected, acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for stearic acid and related fatty acids.

3.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of stearic acid and related fatty acids to the general population in Canada, including infants and children, when Rodents Away Odor Free is 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, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken. While stearic acid and related fatty acids may share a common moiety with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to stearic acid and related fatty acids, and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of stearic acid and related fatty acids.

3.3.6 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health.

This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Maximum residue limits for stearic acid and related fatty acids were not required for the proposed non-food use of Rodents Away Odor Free.

4.0 Value

The results from a laboratory efficacy trial conducted at the National Wildlife Research Center by the United States Department of Agriculture, Animal and Plant Health Inspection Service, demonstrated a reduction in house mice presence measured as daily occupation time and a reduction in house mice activity measured as daily feed consumption within 3 meters (or 114 L volume) of one 40 g sachet of Rodents Away Odor Free for up to two weeks.

5.0 Pest Control Product Policy Considerations

5.1 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, that is, 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, stearic acid and related fatty acids and their transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. Stearic acid and related fatty acids and their end-use product, Rodents Away Odor Free, did not meet TSMP criteria.

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

5.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical 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 Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- The technical grade active ingredient, Stearic Acid and Related Fatty Acids Technical, and its end-use product, Rodents Away Odor Free, 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.

6.0 Summary

6.1 Human Health and Safety

The available information for Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free is adequate to qualitatively identify the toxicological hazards that may result from human exposure to stearic acid and related fatty acids. The end-use product, Rodents Away Odor Free, is of low acute toxicity by oral and dermal routes, is expected to be non-irritating to the eyes and skin, and is not a dermal sensitizer. Short-term toxicity, prenatal developmental toxicity, and genotoxicity are not expected.

Rodents Away Odor Free is proposed for use in residential indoor spaces including modes of transport (for example, homes and recreational vehicles). Observing the label instructions will ensure minimal exposure to humans and companion animals. Consequently, the risks to individuals in residential areas are considered acceptable.

Dietary exposure to stearic acid and related fatty acids is not expected to occur as Rodents Away Odor Free is proposed for non-food uses only.

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6 SI/2005-114

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concernt.*

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

6.2 Value

The results from one efficacy trial and a letter of support supports the use of Rodents Away Odor Free for the reduction in presence and activity of house mice in indoor spaces including modes of transport within 3 m (or 114 L volume) of one 40 g sachet for up to two weeks.

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 Stearic Acid and Related Fatty Acids Technical and Rodents Away Odor Free, containing the technical grade active ingredient stearic acid and related fatty acids, for use as a mouse repellent in indoor spaces such as homes and recreational vehicles.

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.

List of Abbreviations

°C	degrees centigrade
λ_{max}	lambda max
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
g	gram
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LD_{50}	lethal dose 50%
mg	milligram
mL	millilitre
MRL	maximum residue limit
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Toxicity Profile of Rodents Away Odor Free Containing Stearic Acid and Related Fatty Acids

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Rat and mouse PMRA # 2658523, 3040406, 3040825, 3039992, 3040024, 3040005, 3040089, 3040260	Publicly available information notes that each component of Rodents Away Odor Free has an oral LD_{50} > 2000 mg/kg bw. Consequently, Rodents Away Odor Free is expected to have an oral LD_{50} > 2000 mg/kg bw. Low toxicity
Acute dermal toxicity Rabbit and Guinea Pig PMRA # 2658523, 3040406, 3040825, 3040024, 3040089	Publicly available information notes that the majority of the components of Rodents Away Odor Free have a dermal LD_{50} > 2000 mg/kg bw. Consequently, Rodents Away Odor Free is expected to have a dermal LD_{50} > 2000 mg/kg bw. Low toxicity
Acute inhalation toxicity	The vapour pressure of Rodents Away Odor Free is estimated to be below the value necessary for a review of the acute effects resulting from inhalation. Also, particles sufficiently small to be inhaled are not expected when handling the end-use product. Consequently, an assessment of the acute toxicity by the inhalation route is not necessary.

Eye irritation Rabbit PMRA # 3040407, 3040826, 3039992, 3040027, 3040302	Publicly available information states that the long-chain fatty acids and formulants in the end-use product are non-irritating to slightly irritating to the eyes. The proportions of the components responsible for any irritation is low. Consequently, Rodents Away Odor Free is expected to be non-irritating to the eyes.
Skin Irritation Rabbit and rat PMRA # 3040407, 3040826, 3039992, 3040027, 3040302	Publicly available information states that the long-chain fatty acids and formulants in the end-use product are non-irritating to slightly irritating to the skin. The proportions of the components responsible for any irritation is low. Consequently, Rodents Away Odor Free is expected to be non-irritating to the skin.
Dermal sensitization Guinea pigs 3039991, 3040028, 3040174. 3040302, 3040411, 3040424	Publicly available information states that the long-chain fatty acids and formulants in the end-use product are not dermal sensitizers. Consequently, Rodents Away Odor Free is not expected to be a dermal sensitizer.

Table 2 Toxicity Profile of Stearic Acid and Related Fatty Acids Technical

(Effects are known or assumed to occur in both sexes unless otherwise noted)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity Rat and mouse PMRA # 3040406, 3040825, 3039992, 3040024, 3040005, 3040089, 3040260	Publicly available information notes that long-chain fatty acids have an oral LD_{50} > 2000 mg/kg bw. Consequently, Stearic Acid and Related Fatty Acids Technical is expected to have an oral LD_{50} > 2000 mg/kg bw. Low toxicity
Acute dermal toxicity Rabbit and Guinea Pig PMRA # 3040406, 3040825, 3040024, 3040089	Publicly available information notes that long-chain fatty acids have a dermal LD_{50} > 2000 mg/kg bw. Consequently, Stearic Acid and Related Fatty Acids Technical is expected to have a dermal LD_{50} > 2000 mg/kg bw. Low toxicity

Acute inhalation toxicity	The vapour pressure of the long-chain fatty acids present in Stearic Acid and Related Fatty Acids Technical is estimated to be below the value necessary for a review of the acute effects resulting from inhalation. Consequently, an assessment of the acute toxicity by the inhalation route is not necessary.
Eye irritation Rabbit PMRA # 3040407, 3040826, 3039992, 3040027, 3040302	Publicly available information states that the long-chain fatty acids in the technical grade active ingredient are non-irritating to slightly irritating to the eyes. The proportions of the components responsible for any irritation is low. Consequently, Stearic Acid and Related Fatty Acids Technical is expected to be non-irritating to the eyes.
Skin Irritation Rabbit and rat PMRA # 3040407, 3040826, 3039992, 3040027, 3040302	Publicly available information states that the long-chain fatty acids in the technical grade active ingredient are non-irritating to slightly irritating to the skin. The proportions of the components responsible for any irritation is low. Consequently, Stearic Acid and Related Fatty Acids Technical is expected to be non-irritating to the skin.
Dermal sensitization Guinea pigs PMRA # 3039991, 3040028, 3040174. 3040302, 3040411, 3040424	Publicly available information states that the long-chain fatty acids in the technical grade active ingredient are not dermal sensitizers. Consequently, Stearic Acid and Related Fatty Acids Technical is not expected to be a dermal sensitizer.
Short-term oral toxicity Prenatal developmental toxicity Genotoxicity PMRA # 3040029, 3040147, 3040171, 3040172, 3040197, 3040341, 3040401, 3040403, 3040413, 3040417, 3040418, 3040425, 3040820, 3040824	Based on publicly available information and a long history of safe use in consumer products, repeat exposures to long-chain fatty acids are not expected to result in adverse effects. Consequently, the long-chain fatty acids in Stearic Acid and Related Fatty Acids Technical are not expected to elicit short-term, prenatal developmental, or genotoxic effects.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
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2521360	2015, DACO 2.14 Summary, DACO: 2.14, 2.14.1, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9 CBI
2542046	2015, Letter to address deficiency, DACO: 2.11,2.13,2.13.2,2.13.3 CBI
2632632	2016, Part A - Product Identity and Composition, DACO: 2.11, 2.11.1, 2.11.2, 2.11.3,2.11.4 CBI
2632633	2016, Part A - Preliminary Analysis, DACO: 2.12, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
2656220	2015, Certificate of Analysis for reference Material, DACO: 2.13.1 CBI
2656221	2015, CHI Standard Analytical Method, DACO: 2.13.1 CBI
2657678	2016, Chromatogram Runs for Standard G for Calibration, DACO: 2.13.1 CBI
2657679	2016, Two Lot Runs of Stearic Acid and Related Fatty Acids Technical, DACO: 2.13.1 CBI
2521568	2015, DACO Summary, DACO: 10.1, 10.2.1, 3.0, 3.1, 3.1.1, 3.1.2, 3.1.4, 3.2, 3.2.1,3.2.2,3.3.1,3.4,3.4.1,3.5,3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9,5.2 CBI
2521571	2015, Literature used for rationale and other data points addressed in the DACO requirements, DACO: 3.7
2656216	2016, Recommended Retest Date Documentation from Technical Supplier, DACO: 3.5.10 CBI

2.0 Human and Animal Health

PMRA Document Number	Reference
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3040013	2015, Rodents Odor Free, Rodents Odor Free Product Instructions, DACO: 5.2

3.0 Value

PMRA Document Number	Reference
3064112	2018, The Efficacy of Rodents Odour Free (ROF) Product for Inducing an Avoidant Defensive Phenotype in Rats and Mice, DACO: 10.2.3.2 CBI
2951913	2019, Value Dossier for Rodents Away Odor Free, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3,10.2.4,10.3,10.4,10.5,10.5.1,10.5.2,10.5.3,10.5.4,10.5.5
2951914	2018, Laboratory Efficacy of Rodents Odor Free Spatial Repellents, DACO: 10.2
3070248	2019, follow up letter, DACO: 10.1,10.2.3.1,10.7.1
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B. Additional Information Considered

Published Information

Human and Animal Health

PMRA Document Number	Reference
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3039992	Cosmetic Ingredient Review, 1987, , Final Report on the Safety Assessment of Oleic Acid, Lauric Acid, Palmitic Acid, Myristic Acid, and Stearic Acid., Journal of the American College of Toxicology Volume 6 Number 3, DACO: 4.2.1,4.2.2,4.2.4,4.2.5,4.2.6,4.3.1,4.5.2,4.5.4,4.5.5,4.8
3039995	HERA, 2002, Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Fatty Acid Salts Human Health Risk Assessment. https://www.heraproject.com/files/5-HH-04-HERA%20Fatty%20acid%20salts%20HH%20web%20wd.pdf, DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5,4.2.6,4.3.1,4.5.4,4.5.5,4.8
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3040029 European Chemical Agency, ECHA Icosanoic Acid Endpoint Summary - Repeat Dose Toxicity: via oral route - systemic effects, https://echa.europa.eu/registration-dossier/-/registered-dossier/11014/7/6/1 (accessed October 4, 2019) DACO: 12.5.4,4.3.1

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