Proposed Registration Decision PRD2012-13

Mint-X Super Perfume Blend

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Overview

Proposed Registration Decision for Mint-X Super Perfume Blend

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Mint-X Super Perfume Blend and Mint-X Treated Plastic, containing a mixture of the technical grade active ingredients methyl salicylate, cornmint oil, camphor oil and eucalyptus oil, to be used in the manufacture of trash bags with a claim of reducing the number of trash bags torn by Norway rats and racoons.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

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 Mint-X Super Perfume Blend and Mint-X Treated Plastic.

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 (for example, those most sensitive to environmental contaminants). 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 PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's 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 Mint-X Super Perfume Blend, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on Mint-X Super Perfume Blend, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA'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 Mint-X Super Perfume Blend?

Mint-X Super Perfume Blend, a mixture of the technical grade active ingredients methyl salicylate, cornmint oil, camphor oil and eucalyptus oil, is used in Mint-X Treated Plastic to be used in the manufacture of trash bags with a claim of reducing the number of trash bags torn by Norway rats and racoons.

Health Considerations

Can Approved Use of Mint-X Super Perfume Blend Affect Human Health?

Mint-X Super Perfume Blend is unlikely to affect human health when used according to label directions.

Potential exposure to Mint-X Super Perfume Blend may occur when domestic users handle the treated trash bags formulated with Mint-X Super Perfume Blend. 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 dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, Mint-X Super Perfume Blend, is a concentrated mixture containing essential oils and it is likely to be acutely toxic via the oral route and severely irritating. The Mint-X Super Perfume Blend label has signal words, precautionary and hygiene statements to protect occupational workers during the formulating process.

The treated plastic bags, manufactured using Mint-X Treated Plastic, are made by incorporating a low concentration of the technical grade active ingredient mixture (less than 1%) on to the polymer matrix, and it is not likely to be released from the matrix or significantly absorbed via skin contact. Due to the physical nature and the proposed use pattern of the treated bag, there is no health concern from the intended use.

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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*.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The treated plastic bags, manufactured using Mint-X Treated Plastic, have no food uses; therefore, there are no dietary risks from its intended use. No exposure to residues in drinking water is expected because of the nature of the product.

Risks in Residential and Other Non-Occupational Environments from the use of Mint-X Super Perfume Blend

Risks are not of concern from the intended use of trash bags manufactured with Mint-X Treated Plastic

The proposed manufacturing product is treated plastic, for use in the manufacture of trash bags for use in homes, formulated with a low concentration of Mint-X Super Perfume Blend (less than 1% w/w). Residential exposure is not expected to result in unacceptable risk.

Environmental Considerations

An environmental assessment was not required for this application.

Value Considerations

What Is the Value of Mint-X Treated Plastic?

Mint-X Treated Plastic, for use in the manufacture of trash bags, reduces the number of trash bags torn by Norway rats and raccoons.

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 Mint-X Super Perfume Blend to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Since Mint-X Super Perfume Blend is a concentrated mixture containing essential oils and the available information indicate one or more of the active ingredients are acutely toxic via the oral route of exposure and irritating, and there are no studies submitted to characterize Mint-X Super Perfume Blend, signal words are required on the manufacturing product label. The principal display panel of the technical product label must include the signal words: WARNING – POISON, WARNING – EYE IRRITANT, and WARNING – SKIN IRRITANT.

The additional precautionary statements required on the secondary display panel of Mint-X Super Perfume Blend include: "Harmful or Fatal if swallowed, May cause respiratory irritation, Avoid breathing vapors, Handle the product in a well-ventilated area, Causes eye and skin irritation, and DO NOT get in eyes, on skin or on clothing."

Next Steps

Before making a final registration decision on Mint-X Super Perfume Blend, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA 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). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

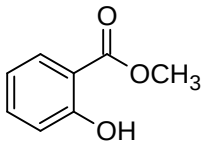
When the PMRA makes its registration decision, it will publish a Registration Decision on Mint-X Super Perfume Blend (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Mint-X Super Perfume Blend

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredients

Active substances	Methyl salicylate Cornmint oil Camphor oil Eucalyptus oil	
Function	Animal Repellent	
Chemical name		
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable	
2. Chemical Abstracts Service (CAS)	Not applicable	
CAS numbers	Methyl salicylate 119-36-8 Cornmint oil Camphor oil Eucalyptus oil	 68917-18-0 8008-51-3 8000-48-4
Molecular formulae	Methyl salicylate $C_8H_8O_3$ Cornmint oil Camphor oil Eucalpytus oil	 Not applicable Not applicable Not applicable
Molecular weights	Methyl salicylate 152.15 Cornmint oil Camphor oil Eucalpytus oil	 Not applicable Not applicable Not applicable
Structural formulae	 Methyl salicylate Cornmint oil Camphor oil Eucalyptus oil	 Not applicable Not applicable Not applicable
Purity of the active ingredients	Methyl salicylate ..... Cornmint oil …...…. Camphor oil …....… Eucalyptus oil ……..	36.0% 36.0% 23.0% 5.0%

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

Technical Product—Mint-X Super Perfume Blend

Property	Result
Colour and physical state	Not applicable; the product is a mixture of complex components
Odour	Not applicable; the product is a mixture of complex components
Melting range	Not applicable; the product is a liquid at room temperature
Boiling point or range	Not applicable; the product is a mixture of complex components
Density	Not provided
Vapour pressure at 20°C	Not applicable; the product is a mixture of complex components
Henry's law constant at 20°C	Not applicable
Ultraviolet (UV)-visible spectrum	No absorbance above 300 nm is expected from the respective active components
Solubility in water at 20°C	Not applicable
Solubility in organic solvents at 20°C (g/100 mL)	Not applicable; the product is a mixture of complex components
n-Octanol-water partition coefficient (K_{ow})	Not applicable; the product is a mixture of complex components
Dissociation constant (pK_a)	Not applicable; the product is a mixture of complex components
Stability (temperature, metal)	Not provided; however, the product is expected to be stable

End-Use Product—Mint-X Treated Plastic

Property	Result	
Colour	Black	
Odour	Minty odour	
Physical state	Solid	
Formulation type	Impregnated fabric	
Guarantee	Methyl salicylate	0.288%
	Cornmint oil	0.288%
	Camphor oil	0.184%
	Eucalyptus oil	0.04%

Property	Result
Container material and description	Low Density Polyethylene (LDPE) trash plastic in paper cartons (30-100 bags/carton)
Density	0.93-0.99 g/mL
pH of 1% dispersion in water	Not required; the product is treated plastic
Oxidizing or reducing action	The product does not contain reducing or oxidizing agents
Storage stability	Not provided; however, the product is expected to be stable under ambient storage conditions for at least 12 months
Corrosion characteristics	Not provided; however, the product is not expected to be corrosive under ambient storage conditions for at least 12 months
Explodability	The product does not contain explosive components

1.3 Directions for Use

Mint-X Treated Plastic is used in the manufacture of trash bags with the claim of reducing the number of trash bags torn by Norway rats and raccoons compared to standard trash bags. The performance of the product will depend on a variety of factors (for example, habituation by pest, availability of alternative food sources, contents of trash bag).

1.4 Mode of Action

Methyl salicylate, cornmint oil, camphor oil and eucalyptus oil are repellents.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

All the active ingredients except for methyl salicylate are mixtures of complex components; therefore, no analytical method to determine the composition of this product is required.

2.2 Method for Formulation Analysis

The active ingredients are a mixture of complex components impregnated in plastic bags and therefore no analytical enforcement method is required.

2.3 Methods for Residue Analysis

Not applicable

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for Mint-X Super Perfume Blend and its associated product, Mint-X Treated Plastic, was conducted by PMRA. The database consisted of an acute oral toxicity study and a dermal irritation study of Mint-X Treated Plastic and information submitted from published sources for the ingredients of the technical grade active ingredient mixture. The information submitted is acceptable and the database is sufficiently complete to define the majority of the toxic effects that may result from exposure to the treated plastic bags manufactured from Mint-X Treated Plastic.

Technical Grade Active Ingredient Mixture
The technical grade active ingredient (TGAI) mixture is a concentrated blend of methyl salicylate (36.0% w/w), cornmint oil (36.0% w/w), camphor oil (23% w/w), and eucalyptus oil (5% w/w).

Based on the toxicological profile of the ingredients of the mixture (summarized in Appendix I, Tables 1 - 4) and their most significant effects from animal studies, the mixture is anticipated to be moderately acutely toxic by the oral route and severely irritating to skin and eyes. Acute inhalation, eye-irritation, or skin sensitization studies were not identified for one or more ingredients of the mixture. Due to the irritation potential of one or more ingredients in the mixture, it is likely to cause irritation of the respiratory tract on inhalation.

There is limited information available on the sensitization potential of the ingredients of the TGAI mixture. Methyl salicylate is not a skin sensitizer in Guinea pigs. In the Fragrance Raw Materials Monographs (RIFM), maximization tests done with methyl salicylate, cornmint oil, camphor oil, and eucalyptus oil on human volunteers were reported to show no sensitization effects. Since these ingredients are used world-wide in consumer products, such as in ointments, liniments, or other preparations that are applied to human skin, and have a long history of safe use in these types of consumer products, they and Mint-X Super Perfume Blend are unlikely to be skin sensitizers.

The concentrated TGAI mixture is of toxicological concern mainly from occupational exposure during the formulating of Mint-X Treated Plastic, but such exposure can be minimized when workers follow label directions, which include precautionary and hygiene measures.

Due to the low concentration of the technical grade active ingredient mixture (0.8% w/w) used to formulate Mint-X Treated Plastic, which is a treated plastic bag, human exposure to the mixture is anticipated to be very low and not likely to result in adverse human health effects.

Due to the nature of the proposed product, no short-term and chronic toxicity studies with the active ingredient mixture were required to assess the human health risks.

End-use product
For the registration of Mint-X Treated Plastic, the applicant submitted acute oral toxicity and dermal irritation studies and data waiver requests for acute dermal toxicity, acute inhalation toxicity, eye irritation, and dermal sensitization studies. The waiver rationales were based on the composition of the product, its proposed use-pattern, and minimal human exposure from its proposed use.

Based on the submitted studies, Mint-X Treated Plastic is of low acute oral toxicity and is not a dermal irritant (summarized in Appendix I, Table 5).

As Mint-X Treated Plastic is formulated by incorporating a low concentration of Mint-X Super Perfume Blend (0.8% w/w) onto a polymer matrix during extrusion, the ingredients of Mint-X Super Perfume Blend are not likely to be released from the matrix, be significantly absorbed via skin contact, or be inhaled directly at a concentration that is detrimental to human health.

Human exposure to Mint-X Super Perfume Blend from handling and use of Mint-X Treated Plastic is expected to be minimal, and it is not likely to result in adverse human health effects. The data waiver requests were found to have merit and were accepted.

3.2 Occupational Exposure and Risk Assessment

The proposed manufacturing product is a treated plastic to be used in the manufacture of trash bags for domestic use; therefore, there is limited occupational exposure during the manufacturing process.

3.2.1 Use Description Scenario

The proposed manufacturing product is a treated plastic to be used in the manufacture of trash bags for domestic use for various indoor and outdoor sites (USC 31).

3.2.2 Residential Exposure and Risk Assessment

When handling the treated plastic for collecting trash, domestic users may be exposed dermally and from inhaling the fragrance emanating from the treated bag. Residential exposure is expected to be minimal as the duration of exposure is short-term while handling, and it is not likely that domestic users will remain in close vicinity of garbage bags for an extended period of time.

Mint-X Super Perfume Blend, consisting of plant essential oils, impregnated onto the plastic during extrusion to produce treated bags is not expected to rub off onto hands or to be inhaled directly at a concentration that is detrimental to human health.

3.2.3 Bystander Exposure and Risk Assessment

As the proposed manufacturing product is a treated plastic, containing 0.8% (w/w) Mint-X Super Perfume Blend, for use in the manufacture of domestic use trash bags, bystander exposure is minimal from the scent emanating from the bag from domestic use.

3.3 Dietary Exposure and Risk Assessment

3.3.1 Food

Mint-X Treated Plastic is a treated plastic for manufacturing trash bags; therefore, a dietary exposure assessment was not required.

3.3.2 Drinking Water

As Mint-X Treated Plastic, intended for the manufacture of plastic bags for trash disposal has a low concentration of Mint-X Super Perfume Blend (0.8% w/w), which is not likely to be persistent in the environment or leach to contaminate water bodies, there was no concern from drinking water exposure.

3.4 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Incidents from Canada and the United States were searched for pesticide products containing a mixture of the active ingredients: Methyl Salicylate, Cornmint Oil, Camphor Oil, and Eucalyptus Oil.

As of January 14, 2012, there were no health-related incident reports submitted to the PMRA, nor summarized by the US EPA or the California Department of Pesticide Regulation (CalDPR) for end-use products containing these active ingredients.

4.0 Impact on the Environment

An environmental assessment was not required for this application.

5.0 Value

5.1 Effectiveness Against Pests

One choice trial conducted under laboratory conditions demonstrated that trash bags manufactured with Mint-X Treated Plastic reduced the average amount of gnawing on the bags and feeding on the edible contents of the bag 76-81% and 88.5% in Norway rats compared to the untreated trash bags, respectively.

One choice trial conducted under laboratory conditions demonstrated that trash bags manufactured with Mint-X Treated Plastic reduced the amount of trash bags torn by raccoons by 100% compared to the untreated trash bags.

5.1.1 Acceptable Efficacy Claims

Mint-X Treated Plastic, used to manufacture trash bags, reduces the number of trash bags torn by Norway rats and raccoons.

5.2 Economics

No market analysis was conducted.

5.3 Sustainability

5.3.1 Survey of Alternatives

There are no other registered pest control products used to reduce the number of trash bags torn by Norway rats. There are other repellents containing oil of black pepper, piperine and capsaicin plus other capsaicinoids used to repel raccoons from trash bags. Non-chemical control methods include placing garbage bags in tamper resistant trash containers.

5.3.2 Compatibility with Current Management Practices Including Integrated Pest Management

Trash bags manufactured from Mint-X Treated Plastic are not intended to be used as a control method for Norway rats and raccoons. It is to be used to reduce the number of trash bags torn by Norway rats and raccoons. As such, it is expected that other methods (for example, sanitation, traps, registered rodenticide) would also be used to reduce problems caused by Norway rats and raccoons.

5.3.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Resistance is not expected to develop. However, Norway rats and raccoons may become habituated to the scent and the performance of trash bags made from Mint-X Treated Plastic is also dependent on a variety of external factors (for example, availability of alternative food sources, contents of trash bag).

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 [those that meet all four criteria outlined in the policy, i.e., 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 chemicals identified as having pesticidal activity are a mixture of methyl salicylate, cornmint oil, camphor oil and eucalyptus oil. Methyl salicylate, cornmint oil, camphor oil and eucalyptus oil are naturally present in the environment and are not expected to be persistent or bioaccumulative. Based on these considerations, TSMP Track1 criteria are not met.

6.2 Formulants and Contaminants of Health or Environmental Concern

Technical grade Mint-X Super Perfume Blend and Mint-X Treated Plastic do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

7.0 Summary

7.1 Human Health and Safety

The available information for the Mint-X Super Perfume Blend is adequate to qualitatively identify the toxicological hazards that may result from human exposure to Mint-X Treated Plastic. The TGAI mixture is anticipated to be moderately acutely toxic by the oral route and severely irritating to skin and eyes, and likely to be a respiratory irritant. Since the ingredients of the mixture are used world-wide in consumer products, such as in ointments, liniments, or other preparations that are applied to human skin, and have a long history of safe use in these types of consumer products, they and Mint-X Super Perfume Blend are unlikely to be skin sensitizers. The technical product label has adequate signal words, precautionary and hygiene measures to protect workers from exposure to Mint-X Super Perfume Blend.

Since a low concentration of the TGAI mixture is used to formulate Mint-X Treated Plastic, which is a treated plastic for the manufacture of trash bags, domestic exposure from the proposed use of the trash bag is anticipated to be very low and not likely to result in adverse human health effects.

7.2 Environmental Risk

An environmental assessment was not required for this application.

7.3 Value

Mint-X Treated Plastic, used to manufacture trash bags, reduces the number of trash bags torn by Norway rats and raccoons.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Mint-X Super Perfume Blend and Mint-X Treated Plastic, containing a mixture of the technical grade active ingredients methyl salicylate, cornmint oil, camphor oil and eucalyptus oil, to be used in the manufacture of trash bags with a claim of reducing the number of trash bags torn by Norway rats and racoons.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

bw	body weight
CalDPR	California Department of Pesticide Regulation
CAS	Chemical Abstracts Service
DACO	data code
g	gram
hr(s)	hour(s)
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	n-octanol-water partition coefficient
kg	kilogram
LD_{50}	lethal dose 50%
mg	milligram
MIS	maximum irritation score
mL	millilitre
nm	nanometres
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
RIFM	Research Institute for Fragrance Materials
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USC	Use Site Category
US EPA	United States Environmental Protection Agency
UV	ultraviolet
w/w	weight per weight

Appendix I Tables and Figures

Table 1 Toxicology profile of methyl salicylate

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Methyl Salicylate				
Oral Toxicity	Rats	LD_{50}: 887 mg/kg bw	Moderately acutely toxic WARNING - POISON	2002779, 2046219
Dermal Toxicity	Rabbits	LD_{50}: > 5000 mg/kg bw	Low acute toxicity	2002779, 2046219
Primary Eye Irritation	Guinea pigs	Highly irritating	WARNING – EYE IRRITANT	2002779, 2046219
Dermal Irritation	Guinea pigs	Highly irritating	WARNING – SKIN IRRITANT	2002779, 2046219
Dermal Sensitization	Guinea pigs (Freund's complete adjuvant test)	Negative	Not sensitizing	2002779, 2046219

Table 2 Toxicology profile of cornmint oil

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Corn Mint Oil				
Oral Toxicity	Rats	LD_{50}: 1240 mg/kg bw	Slightly acutely toxic CAUTION - POISON	2002780, 2162557
Dermal Toxicity	Rabbits	LD_{50}: > 5000 mg/kg bw	Low acute toxicity	2002780, 2162557
Dermal Irritation	Mice, swine, and rabbits Full strength	Not irritating	Not a dermal irritant	2002780, 2162557

Table 3 Toxicology profile of camphor oil

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Camphor Oil				
Oral Toxicity	Rat	LD_{50}: 3730 mg/kg bw	Low Toxicity	2046220, 2046221 2046224
Dermal Toxicity	Rabbit	LD_{50}: > 5000 mg/kg bw	Low toxicity	2046220, 2046221 2046224
Dermal Irritation	Rabbit (full strength)	Mildly irritating	CAUTION - SKIN IRRITANT	2046220, 2046221 2046224

Table 4 Toxicology profile of eucalyptus oil

STUDY	SPECIES/STRAIN AND DOSES	RESULT	SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Eucalyptus Oil				
Oral Toxicity	Rat	LD_{50}: 4400 mg/kg bw	Low Toxicity	2046222, 2046223
Dermal Toxicity	Rabbit	LD_{50} > 5000 mg/kg bw	Low Toxicity	2046222, 2046223
Dermal Irritation	Rabbit (full strength)	Moderately irritating	WARNING – SKIN IRRITANT	2046222, 2046223

Table 5 Toxicology profile of Mint-X Treated Plastic

STUDY	SPECIES/STRAIN AND DOSES	RESULT	TARGET ORGAN/ SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Oral Toxicity Up and Down Procedure	Rat – Sprague-Dawley (3 ♀) Dose: 5000 mg/kg bw of test substance[a] mixture (test material cut into pieces and mixed with peanut butter) for a period of 24 hrs	LD_{50} (♀) > 5000 mg/kg bw **Low Toxicity**	There were no treatment-related clinical findings, mortalities or gross necropsy findings.	2043915
Dermal Irritation 4-hr exposure Draize method	Rabbit - New Zealand albino (3 ♀) A 1-inch x 1-inch piece of the test substance[a] moistened with distilled water (0.4 mL) was applied to each site under semi-occlusive dressings.	Maximum average score (MAS) = 0/8. (at 24, 48, & 72 hrs). Maximum irritation score (MIS): 0/8 **Non-irritating based on MIS**	There was no dermal irritation at any of the treated sites.	2043924
DATA WAIVER REQUESTS				
Dermal toxicity	Rationale: Composition of the product (low levels of active ingredients embedded in a polymer matrix) and anticipated low dermal exposure from use-pattern No toxicological concern anticipated from low dermal exposure. Acceptable			2043916
Inhalation toxicity	Rationale: Composition of the product (low levels of active ingredients embedded in a polymer matrix) and limited exposure from the proposed use No toxicological concern from limited inhalational exposure. Acceptable			2043918

STUDY	SPECIES/STRAIN AND DOSES	RESULT	TARGET ORGAN/ SIGNIFICANT EFFECTS/ COMMENTS	REFERENCES (PMRA No.)
Eye Irritation	Rationale: Composition of the product (low levels of active ingredients embedded in a polymer matrix) and limited exposure from the proposed use No irritation anticipated from limited ocular exposure. Acceptable			2043920
Dermal Sensitization	Rationale: Composition of the product (low levels of active ingredients embedded in a polymer matrix) and the available dermal sensitization data for the components. No indication of skin sensitization from available data. The active ingredients bounded within the polymer matrix are not likely to cause skin sensitization. Acceptable.			2043925

[a] Test substance identified as Repell-X Bag

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Reference Document Number: 2002775
Reference: 2010, Chemistry Requirements, DACO: 2.1,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI

PMRA Reference Document Number: 2002776
Reference: 2010, Starting Material Food Grade Certificates and MSDS, DACO: 2.11.2,2.14.13,2.14.2,2.14.6,2.14.7,2.14.8 CBI

PMRA Reference Document Number: 2002777
Reference: 2010, Detailed Production Process, DACO: 2.11.3,2.12.1,2.13.2 CBI

PMRA Reference Document Number: 2002778
Reference: 2010, Certificates of Analysis, DACO: 2.13.3 CBI

PMRA Reference Document Number: 2064149
Reference: Camphor Food Grade Certificate, DACO: 2.16 CBI

PMRA Reference Document Number: 2064323
Reference: 2011, Eucalyptus Species Information and rationale for reduced requirements, DACO: 2.11.2,2.16 CBI

PMRA Reference Document Number: 2003199
Reference: 2010, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI

PMRA Reference Document Number: 2003200
Reference: 2010, Physical Properties, DACO: 3.5.4,3.5.5,3.5.8,3.5.9 CBI

PMRA Reference Document Number: 2003212
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2.0 Human and Animal Health

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B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

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