Proposed Registration Decision PRD2022-07

# 98Sumithrin, MGK 3145 MUP, and MGK Formula 31451

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# Overview

## Proposed registration decision for 98Sumithrin

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 S1-183 Technical Grade, containing the technical grade active ingredient 98Sumithrin, and the manufacturing product MGK 3145 MUP and the end-use product MGK Formula 31451, containing the active ingredients 98Sumithrin and N-octyl bicycloheptene dicarboxide (MGK-264). MGK Formula 31451 is a pressurized spray that is applied indoors as a crack-and-crevice and spot treatment, and to furniture, including mattresses, to control bed bugs and bed bug eggs.

The co-active ingredient, MGK-264, is an insecticide synergist that is always co-formulated with one or more active ingredients belonging to the synthetic pyrethroids and pyrethrins group. It enhances the pesticide properties of other insecticides and is registered for a wide spectrum of insect pests in or on stored food and feed, structures, companion animals, human habitat and recreational areas, human skin, clothing and proximal sites, and outdoor residential areas. For details see the Re-evaluation Decision RVD2019-10, *N-Octyl Bicycloheptene Dicarboximide (MGK-264) And Its Associated End-use Products* and the Proposed Re-evaluation Decision PRVD2017-15, *N-Octyl Bicycloheptene Dicarboximide (MGK-264) And Its Associated End-use Products*.

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 98Sumithrin, MGK 3145 MUP and MGK Formula 31451.

## 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.

[1] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

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 Canada.ca.

Before making a final registration decision on 98Sumithrin, MGK 3145 MUP and MGK Formula 31451, 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 98Sumithrin, MGK 3145 MUP and MGK Formula 31451, 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 98Sumithrin?

98Sumithrin is a pyrethroid insecticide used to kill bed bugs and bed bug eggs. It is combined with the synergist N-octyl bicycloheptene dicarboximide in the commercial-class product, MGK Formula 31451. 98Sumithrin affects the insect nervous system causing paralysis and death. 98Sumithrin is used to control bed bugs and bed bug eggs indoors including on mattresses and upholstered furniture.

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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."

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*.

## Health considerations

### Can approved uses of 98Sumithrin affect human health?

**MGK 3145 MUP and MGK Formula 31451, containing 98Sumithrin and co-formulated with N-octyl bicycloheptene dicarboxide, are unlikely to affect your health when used according to proposed label directions.**

Potential exposure to 98Sumithrin may occur when handling and applying the end-use product or when coming into contact with treated surfaces. 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 dose 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 level at which no effects are observed. The health effects noted in animals occur at dose levels more than 100-fold higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, the technical grade active ingredient 98Sumithrin was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. 98Sumithrin was non-irritating to the eyes and skin, and did not cause an allergic skin reaction.

The manufacturing concentrate MGK 3145 MUP was of low acute toxicity by the oral, dermal, and inhalation routes of exposure. MGK 3145 MUP was minimally irritating to the eyes; however, it was moderately irritating to the skin and caused an allergic skin reaction. Consequently, the signal word “WARNING” and the hazard statements “SKIN IRRITANT” and “POTENTIAL SKIN SENSITIZER” are required on the label.

The end-use product MGK Formula 31451 was considered to be of low acute toxicity by the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eyes but was considered mildly irritating to the skin; consequently, the signal word and hazard statement “CAUTION – SKIN IRRITANT” are required on the label. MGK Formula 31451 is not considered to cause an allergic skin reaction.

Registrant-supplied short- and long-term (lifetime) animal toxicity tests, as well as information from the published scientific literature, were assessed for the potential of 98Sumithrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were effects on the liver, pituitary, adrenals, epididymides, and nasal cavity.

There was an indication that the young were more sensitive than the adult animal. The risk assessment protects against the effects noted above and other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

**Residues in water and food**

As MGK Formula 31451 is proposed to be applied indoors as a crack-and-crevice and spot treatment, and to furniture, including mattresses, to control bed bugs and bed bug eggs, dietary exposure to residues of 98Sumithrin in water and food is not expected.

**Health risks to workers**

**Occupational risks are not of health concern when MGK Formula 31451 is used according to the proposed label directions, which include protective measures.**

Workers applying MGK Formula 31451 and entering recently treated sites can come in direct contact with 98Sumithrin residues. Therefore, the label specifies that anyone applying MGK Formula 31451 must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. In addition, taking into consideration the label statements and the duration of exposure for handlers and postapplication workers, the risks to these individuals are not of health concern.

**Health risks in residential and other non-occupational environments**

**Risks in residential and other non-occupational environments are not of health concern when MGK Formula 31451 is used according to the proposed label directions and restrictions are observed.**

Adults, youth and children may be exposed to 98Sumithrin by dermal contact, while performing activities in residential areas treated by commercial applicators. Children may also be exposed to 98Sumithrin when playing on treated surfaces, and subsequently ingesting the product as a result of hand- or object-to-mouth transfer. No risks of concern were identified.

**Health risks to bystanders**

**Bystander risks are not of health concern when MGK Formula 31451 is used according to the proposed label directions and restrictions are observed.**

With the restrictions on the label, that prohibit people (other than the applicator) and animals from being in treatment areas during application, bystander exposure is expected to be minimal. Therefore, health risks to bystanders are not of concern.

## Environmental considerations

As MGK Formula 31451 is proposed to be applied indoors as a crack-and-crevice and spot treatment, and to furniture, including mattresses, to control bed bugs and bed bug eggs, an environmental assessment was not required.

## Value considerations

### What is the value of MGK Formula 31451?

**MGK Formula 31451 has value in killing bed bugs and bed bug eggs when applied as a crack-and-crevice and spot treatment indoors, including to sites such as mattresses and upholstered furniture.**

Bed bugs are a pest of public health concern that feed on the blood of humans and animals and can have substantial impacts on the well-being of Canadians. Bed bugs are difficult to control, and resistance to many registered control products is present in bed bug populations across Canada. MGK Formula 31451 will provide a new tool for use against bed bugs and bed bug eggs.

## 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 S1-183 Technical Grade, MGK 3145 MUP and MGK Formula 31451 to address the potential risks identified in this assessment are as follows.

### Key risk-reduction measures

### Human health

To reduce the potential of workers coming into direct contact with 98Sumithrin dermally or through inhalation, workers applying MGK Formula 31451 and performing cleaning and repair activities must wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Risks to workers are not of health concern when MGK Formula 31451 is used according to the proposed label directions. Standard label statements are on the label to provide directions for proper ventilation prior to entering treated sites, and to minimize postapplication exposure to residents and domestic animals. Furthermore, label statements prohibiting people and animals from being in treatment areas during application are present on the label.

## Next steps

Before making a final registration decision on 98Sumithrin, MGK 3145 MUP and MGK Formula 31451, 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

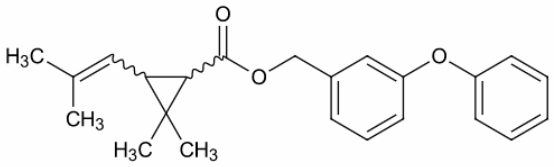
When Health Canada makes its registration decision, it will publish a Registration Decision on 98Sumithrin, MGK 3145 MUP and MGK Formula 31451 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

# Science evaluation

## 98Sumithrin

## 1.0 The active ingredient, its properties and uses

### 1.1 Identity of the active ingredient

| | |
|---|---|
| **Active substance** | 98Sumithrin (1*R*-isomers of phenothrin, *trans:cis* ratio 96:4 minimum) |
| **Function** | Insecticide |
| **Chemical name** | |
| **1. International Union of Pure and Applied Chemistry (IUPAC)** | 3-phenoxybenzyl (1*R*)-*cis*-*trans*-2, 2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate<br>or<br>3-phenoxybenzyl (1*R*)-*cis*,*trans*-chrysanthemate |
| **2. Chemical Abstracts Service (CAS)** | (3-phenoxyphenyl)methyl (1*R*)-*cis*-*trans*-2, 2-dimethyl-3-(2-methyl-1-propenyl)cyclopropanecarboxylate |
| **CAS number** | 188023-86-1 (combined 1*R* isomers) |
| **Molecular formula** | $C_{23}H_{26}O_3$ |
| **Molecular weight** | 350.46 |
| **Structural formula** | racemic phenothrin:<br>  |
| **Purity of the active ingredient** | 92.6% |

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

**Technical product—98Sumithrin Technical**

| Property | Result |
|---|---|
| Colour and physical state | Pale yellow, oily liquid |
| Odour | Slight petrol odour |
| Melting range | N/A |
| Boiling point or range | >301°C |
| Density | 1.0–1.1 g/mL |
| Vapour pressure at 20–25°C | $2.4 – 4.2 \times 10^{-5}$ Pa |
| Ultraviolet (UV)-visible spectrum | $\lambda_{max}$ = 202–203 nm in acidic and neutral media, 217 nm in alkaline media |
| Solubility in water at 21°C | 2 µg/L |
| Solubility in organic solvents at 25°C | >250 g/L for methanol, acetone, ethyl acetate, 1, 2-dichloroethane, m-xylene and heptane |
| *n*-Octanol-water partition coefficient ($K_{ow}$) | log $K_{ow}$ = 6.8 |
| Dissociation constant (p$K_a$) | No dissociable moiety |
| Stability (temperature, metal) | Stable at 54°C for 14 days. Incompatible with strong oxidizers. Not expected to decompose under sunlight. |

**Manufacturing concentrate— MGK 3145 MUP**

| Property | Result |
|---|---|
| Colour | Transparent yellow |
| Odour | Hydrocarbon solvent odour |
| Physical state | Liquid |
| Formulation type | Solution |

| Property | Result |
|---|---|
| Label concentration | 98Sumithrin … 7.65%<br>N-octyl bicycloheptene dicarboximide … 30.63% |
| Container material and description | Plastic, 3.8 – 209 L |
| Density | 0.8–0.9 g/cm$^3$ at 22.8°C |
| pH of 1% dispersion in water | 5.58 |
| Oxidizing or reducing action | Incompatible with strong oxidizers. |
| Storage stability | Stable after storage for 14 days at 54°C in amber glass and fluorinated HDPE. |
| Corrosion characteristics | Not corrosive to commercial packaging. |
| Explodability | Not explosive. |

**End-use product— MGK Formula 31451**

| Property | Result |
|---|---|
| Colour | Transparent white |
| Odour | Oily hydrocarbon solvent odour |
| Physical state | Liquid |
| Formulation type | Pressurized product |
| Label concentration | 98Sumithrin … 0.38%<br>N-octyl bicycloheptene dicarboximide … 1.53% |
| Container material and description | Metal can, 1–500 g |
| Density | 0.9–1.0 g/cm$^3$ at 22.8°C |
| pH of 1% dispersion in water | 6.68 |
| Oxidizing or reducing action | Incompatible with strong oxidizers. |
| Storage stability | Stable after storage for 14 days at 54°C and for 12 months at room temperature in metal cans. |
| Corrosion characteristics | Not corrosive to commercial packaging. |
| Explodability | As a pressurized product, product bears “Caution – Explosive” labelling. |

## 1.3 Directions for use

MGK Formula 31451 is a commercial-class product containing the insecticide 98Sumithrin and the synergist N-octyl bicycloheptene dicroboximide, for use indoors in homes and non-food areas of restaurants, schools, nursing homes, warehouses, offices, apartments, hotels, motels, kennels, and hospitals. MGK Formula 31451 is a pressurized spray product applied as a spot treatment or crack-and-crevice spray in structures and on human-proximal sites such as mattresses and furniture. MGK Formula 31451 is applied as a crack and crevice treatment on and

around baseboards, floorboards, bed frames, wall hangings, headboards, furniture, door and window frames, millwork and walls. MGK Formula 31451 is applied as a spot treatment to carpet, mattresses, box springs, walls, furniture, floor and floor coverings, closets (remove clothing and other articles before treatment) and window treatment hardware such as curtain rods. Treatments are applied to areas that may harbour bed bugs or their eggs, especially tufts, folds, seams, and edges of mattresses. MGK Formula 31451 is sprayed until the surface is damp, after which, treatments must be allowed to dry.

### 1.4 Mode of action

98Sumitrhin is a trans-isomer-enriched version of the pyrethroid d-phenothrin. The trans-isomer is the more active isomer of d-phenothrin, which affects the insect nervous system, causing paralysis and death. 98Sumithrin belongs to Insect Resistance Action Committee Group 3A insecticides (sodium channel modulators). N-octyl bicycloheptene dicarboximide is a synergist that enhances the potency of 98Sumithrin by affecting the detoxification mechanisms of insects.

## 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 methods provided for the analysis of the active ingredients in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

## 3.0 Impact on human and animal health

### 3.1 Toxicology summary

98Sumithrin, also referred to as 1R-trans phenothrin, is a Type I synthetic pyrethroid insecticide comprised of two isomers, cis and trans, at a ratio of 2:98, respectively. It differs from d-phenothrin in terms of the isomeric ratio in that d-phenothrin is comprised of cis and trans isomers at a ratio of 20:80, respectively. Synthetic pyrethroids induce neurotoxic effects primarily by binding to voltage-dependent channels in neurons, thereby delaying the closing of sodium channels and causing the depolarization of neurons. This interferes with the ability of the nervous system to relay nerve transmissions and may result in downstream clinical effects.

The applicant requested to fulfill the toxicology data requirements for 98Sumithrin with toxicology data for d-phenothrin. This request was supported with bridging information consisting of acute toxicity data and a 90-day dietary toxicity study in rats that incorporated an assessment of neurotoxicity endpoints as well as a comparison of toxicokinetic parameters. Based on the results of the available toxicology studies, similar effects and effect levels were

identified for 98Sumithrin and d-phenothrin. In addition, a comparison of toxicokinetic parameters indicated that the trans-isomer of d-phenothrin is eliminated more quickly from the body and accumulates in tissues to a lesser extent than the cis-isomer, suggesting lower bioavailability of the trans-isomer. Based on the available information, the trans-isomer-enriched 98Sumithrin is considered toxicologically equivalent to, or of lower toxicity than, d-phenothrin, and the request to bridge to the d-phenothrin toxicology database was supported.

A detailed review of the toxicology database for d-phenothrin was conducted previously and is summarized in the Proposed Re-evaluation Decision PRVD2015-05, *d-Phenothrin*. An extensive toxicology database is available for the assessment of human health hazards of d-phenothrin and the data quality is considered adequate to define the majority of the toxic effects that may result from exposure to d-phenothrin. Target organs identified in laboratory animals following repeated oral exposure to d-phenothrin included the liver, pituitary gland, adrenal gland, and epididymides. The dog appeared to be the most sensitive species following oral dosing. The most sensitive endpoints following repeated inhalation exposure of rats to d-phenothrin included eosinophilic inclusions in the olfactory epithelial cells of the nasal turbinates. The d-phenothrin toxicity database as a whole showed little to no evidence of neurological signs typically associated with pyrethroids. There was no evidence to suggest that d-phenothrin damaged genetic material and it is not considered to be a potential human carcinogen. Although evidence of increased sensitivity of the young was noted in the 2-generation reproductive toxicity study with d-phenothrin, based on decreased pup weight that was observed in the absence of maternal toxicity, there was a low level of concern for this finding.

In acute toxicity testing, 98Sumithrin technical was of low acute toxicity in rats by the oral, dermal, and inhalation routes of exposure. 98Sumithrin was non-irritating to the eyes and skin of rabbits, and was not a dermal sensitizer in guinea pigs when tested via the Maximization method.

The manufacturing concentrate MGK 3145 MUP, containing 98Sumithrin and co-formulated with N-octyl bicycloheptene dicarboximide, was of low acute toxicity in rats by the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eyes and moderately irritating to the skin of rabbits. MGK 3145 MUP was a dermal sensitizer in guinea pigs when tested via the Buehler method.

The end-use product MGK Formula 31451, containing 98Sumithrin and co-formulated with N-octyl bicycloheptene dicarboximide, was considered to be of low acute toxicity in rats by the oral, dermal, and inhalation routes of exposure. It was minimally irritating to the eyes but was considered mildly irritating to the skin of rabbits. MGK Formula 31451 was not considered to be a dermal sensitizer based on the results of testing in guinea pigs via the Buehler method.

The 90-day dietary toxicity study in rats conducted with 98Sumithrin was also designed to assess neurotoxicity endpoints through inclusion of a functional observational battery, motor activity assessments, and histopathological examination of nervous tissues. Results of the study did not reveal any evidence of neurotoxicity, which is consistent with findings in the d-phenothrin toxicology database.

Treatment-related effects were confined to the highest dose level tested and consisted of decreases in body weight, body weight gain and food consumption, as well as increased liver weight and decreased triglyceride levels observed in both sexes. Increased prothrombin time was additionally observed in males at this dose level.

A supplemental in vitro study summarized in the published literature investigated the effects of d-trans-phenothrin on human peripheral blood lymphocytes and human hepatocytes. Results indicated that d-trans-phenothrin induced DNA damage in the absence of marked cytotoxicity but at relatively high concentrations. These findings are in contrast to those of the in vitro and in vivo mutagenicity studies previously evaluated for d-phenothrin. Overall concern for the findings in this study was low.

Given that the available data support the toxicological equivalence of 98Sumithrin and d-phenothrin, the toxicology reference values established previously for d-phenothrin, and summarized in Appendix III, Table 2 of PRVD2015-05 *d-Phenothrin*, are relevant to the assessment of 98Sumithrin.

Results of the toxicology studies conducted on laboratory animals with d-phenothrin are summarized in Appendix III, Table 1 of PRVD2015-05 *d-Phenothrin*. Results of the submitted toxicology studies conducted with 98Sumithrin, as well as the identified published literature study assessed subsequent to PRVD2015-05 *d-Phenothrin*, are summarized in Appendix I, Table 1 of this document. Appendix I, Tables 2 and 3 of this document summarize the results of the acute toxicity studies for the associated manufacturing concentrate MGK 3145 MUP and end-use product MGK Formula 31451, respectively.

## 3.2 Dermal absorption

An in vivo rat dermal absorption study for d-phenothrin was previously reviewed. This study demonstrated differential dermal absorption for the cis- and trans-isomers of 17% and 11% respectively, and a value of 17% was selected (PRVD2015-05, *d-Phenothrin*) for the long-term risk assessment of d-phenothrin. Dermal absorption was not required for short- to intermediate-term exposure risk assessments of d-phenothrin as the toxicological endpoint selected is based on a dermal toxicity study. A dermal absorption value of 17% is not expected to underestimate the dermal absorption of 98Sumithrin.

## 3.3 Occupational and residential exposure assessment

### 3.4.1 Acute hazards of MGK Formula 31451 and mitigation measures

The acute hazard assessment indicated that MGK Formula 31451 is of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is considered minimally irritating to the eyes and mildly irritating to the skin and is not considered to be a dermal sensitizer. Based on these acute hazards, a long-sleeved shirt, long pants, socks, shoes and chemical-resistant gloves are required for workers during application, clean-up and repair.

### 3.4.2 Occupational exposure and risk assessment

The use pattern of 98Sumithrin is the same as the registered use of commercial d-phenothrin products to control bed bugs and bed bug eggs. The toxicology reference values established previously for d-phenothrin are relevant to the assessment of 98Sumithrin. As such, the occupational risk assessment for d-phenothrin, as presented in PRVD2015-05, *d-Phenothrin*, is adequate to assess the risks associated with the use of 98Sumithrin.

### 3.4.3 Residential exposure and risk assessment

The residential risk assessment for d-phenothrin, as presented in PRVD2015-05, *d-Phenothrin*, is adequate to assess the risks associated with the use of 98Sumithrin.

### 3.4.4 Bystander exposure and risk assessment

With the restrictions on the label, that prohibit people (other than the applicator) and animals from being in treatment areas during application, bystander exposure is expected to be minimal. Therefore, health risks to bystanders are not of concern.

## 3.5 Aggregate exposure and risk assessment

There is potential for individuals to be exposed to 98Sumithrin via different routes of exposure concurrently. The aggregate risk assessment for d-phenothrin, as presented in PRVD2015-05, *d-Phenothrin*, is adequate to assess the aggregate risks associated with the use of 98Sumithrin.

## 3.6 Cumulative assessment

The *Pest Control Products Act* requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. 98Sumithrin belongs to a group of insecticides commonly known as the pyrethroids. Pyrethroids and pyrethrins have a common mechanism of toxicity wherein they possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, cumulative risk will be assessed as a separate exercise, incorporating all relevant members of the common mechanism group(s).

## 3.7 Health incident reports

As of 18 October 2021, no incident reports have been submitted to the PMRA for 98Sumithrin.

Based on the high number of human and domestic animal incidents involving re-entry or contact with treated surfaces following indoor residential treatment with d-phenothrin (which is considered to be toxicologically similar to 98Sumithrin) and/or N-Octyl bicycloheptene dicarboximide (MGK), a co-formulant in two proposed 98Sumithrin products, the label statements on the end-use product label must include directions for proper ventilation prior to entering treated sites, to minimize postapplication exposure to residents and domestic animals.

## 4.0 Value

Bed bugs are a difficult to control structural pest of public health concern, which feed on the blood of humans and animals. Bed bugs have a significant impact on the well-being of Canadians exposed to or living in infested structures. Bed bug populations in Canada also have widespread resistance to many registered active ingredients.

Value data reviewed in support of MGK Formula 31451 consisted of trials conducted on bed bugs and bed bug eggs using Bedlam Insecticide (PCP Registration number 30075). Bedlam Insecticide contains the active ingredient d-phenothrin at the same rate in the formulation as the rate of 98Sumithrin in MGK Formula 31451. The scientific rationale that justified extrapolation of efficacy using data from studies conducted on the registered product Bedlam Insecticide was that MGK Formula 31451 is expected to provide a similar or higher level of control of bed bugs and bed bug eggs compared to Bedlam Insecticide because 98Sumithrin has a higher ratio of active isomer than the d-phenothrin in Bedlam Insecticide.

Based on this rationale, the efficacy trials support the use of MGK Formula 31451 to kill bed bugs and bed bug eggs when applied as a spot or crack-and-crevice treatment indoors and on furniture, including mattresses, when applied until damp.

MGK Formula 31451 can be used in an integrated pest management program using physical and cultural control methods and other registered bed bug control products formulated with active ingredients such as beta-cyfluthrin, lambda-cyhalothrin, permethrin, pyrethrin, d-phenothrin, dinotefuran, imidacloprid, boric acid, *Beauveria bassiana* and diatomaceous earth. While MGK Formula 31451 does not represent a new mode of action in Canada to kill bed bugs and bed bug eggs, it has value as it provides a new isomerically-enriched active ingredient that provides an additional tool for controlling this pest.

## 5.0 Impact on the environment

It was determined that an environmental assessment was not required for indoor use to control bedbugs.

## 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, 98Sumithrin was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the conclusion that 98Sumithrin does not meet all of the TSMP Track 1 criteria.

## 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 SPN2020-01[7] 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 98Sumithrin, MGK 3145 MUP and MGK Formula 31451 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.

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

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*.

## 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 S1-183 Technical Grade, containing the technical grade active ingredient 98Sumithrin, and the manufacturing product MGK 3145 MUP and the end-use product MGK Formula 31451, containing the active ingredients 98Sumithrin and N-octyl bicycloheptene dicarboxide applied indoors as a crack-and-crevice and spot treatment, and to furniture, including mattresses, to control bed bugs and bed bug eggs.

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

| | |
|---|---|
| ↑ | increased |
| ↓ | decreased |
| ♂ | male |
| ♀ | female |
| °C | degree Celsius |
| µM | micromolar |
| µg | micrograms |
| bw | body weight |
| bwg | bodyweight gain |
| CAS | Chemical Abstracts Service |
| cm | centimetres |
| DNA | deoxyribonucleic acid |
| fc | food consumption |
| g | gram |
| HDT | highest dose tested |
| HDPE | high-density polyethylene |
| hr(s) | hour(s) |
| IUPAC | International Union of Pure and Applied Chemistry |
| kg | kilogram |
| $K_{ow}$ | *n*–octanol-water partition coefficient |
| L | litre |
| $LC_{50}$ | lethal concentration 50% |
| $LD_{50}$ | lethal dose 50% |
| LOAEL | lowest observed adverse effect level |
| MAS | maximum average score |
| mg | milligram |
| MGK-264 | n-octyl bicycloheptene dicarboximide |
| MIS | maximum irritation score |
| ml | millilitre |
| nm | nanometre |
| NOAEL | no observed adverse effect level |
| N/A | not applicable |
| Pa | Pascal |
| p*K*a | dissociation constant |
| PMRA | Pest Management Regulatory Agency |
| PT | prothrombin time |
| REI | restricted-entry intervals |
| s.s. | statistically significant |
| TSMP | Toxic Substances Management Policy |
| UV | ultraviolet |
| wt | weight |

# Appendix I Tables and figures

## Table 1 Summary of toxicity data with 98Sumithrin

Effects observed in both sexes are presented first followed by sex-specific effects in males, then females, each separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted.

| Study Type/Animal/PMRA# | Study results |
|---|---|
| **Acute Toxicity Studies** | |
| Acute oral toxicity<br><br>Sprague Dawley rats<br><br>PMRA# 3034602 | $LD_{50}$ >5000 mg/kg bw (♂/♀)<br><br>No treatment-related clinical signs.<br><br>Low acute oral toxicity |
| Acute dermal toxicity<br><br>Sprague-Dawley rats<br><br>PMRA# 3034598 | $LD_{50}$ >2000 mg/kg bw (♂/♀)<br><br>No treatment-related dermal or clinical signs.<br><br>Low acute dermal toxicity |
| Acute inhalation toxicity<br><br>Sprague-Dawley rats<br><br>PMRA# 3034600 | $LC_{50}$ >5.24 mg/L (♂/♀)<br><br>No treatment-related clinical signs.<br><br>Low acute inhalation toxicity |
| Eye irritation<br><br>New Zealand White rabbits<br><br>PMRA# 3034604 | MAS = 0/110<br>MIS =0/110<br><br>Non-irritating |
| Dermal irritation<br><br>New Zealand White rabbits<br><br>PMRA# 3034606 | MAS = 0/8<br>MIS = 0/8<br><br>Non-irritating |
| Dermal sensitization (Maximization method)<br><br>Hartley guinea pigs<br><br>PMRA# 3034608 | Negative |

| | |
|---|---|
| **Short-Term Toxicity Studies** | |
| 90-day oral toxicity (dietary)<br><br>Fischer rats<br><br>PMRA# 3034596 | NOAEL = 191/198 mg/kg bw/day (♂/♀)<br>LOAEL = 643/658 mg/kg bw/day (HDT)<br><br>Effects at the LOAEL: ↓ bw, ↓ bwg, ↓ fc, ↓ triglycerides, ↑ liver wt (♂/♀); ↑ PT (♂). |
| **Published Literature** | |
| DNA damage in vitro in human peripheral blood lymphocytes and human hepatocytes exposed to d-trans-phenothrin.<br><br>(Including modified Comet assay for detection of oxidative-based damage in DNA)<br><br>PMRA# 3297187 | Supplemental<br><br>Cells exposed to 20, 50, 100, or 1000 µM d-trans-phenothrin for 1 hr.<br><br>d-trans-phenothrin induced statistically significant, dose-dependent DNA damage in the absence of marked cytotoxicity at concentrations higher than 20 µM and 50 µM in human blood peripheral lymphocytes and hepatocytes, respectively.<br><br>Dose-dependent increase in oxidative DNA damage in both cell types (not s.s.).<br><br>Higher level of damage observed in lymphocytes.<br><br>Study Limitations: Non-guideline, limited reporting |

**Table 2 Toxicity Profile of MGK 3145 MUP, containing 98Sumithrin and N-octyl bicycloheptene dicarboximide**

| Study Type/Animal/PMRA# | Study results |
|---|---|
| Acute oral toxicity (Up-and-down procedure)<br><br>Sprague-Dawley rats<br><br>PMRA# 3052227 | $LD_{50}$ >5000 mg/kg bw (♀)<br><br>One rat hypoactive with irregular respiration and ↓ fecal volume (recovered by Day 2).<br><br>Low acute oral toxicity |
| Acute dermal toxicity<br><br>Sprague-Dawley rats<br><br>PMRA# 3052228 | $LD_{50}$ >5000 mg/kg bw (♂/♀)<br><br>No treatment-related clinical signs. Dermal irritation observed at all dose sites (various days between Days 1-9).<br><br>Low acute dermal toxicity |

| Study Type/Animal/PMRA# | Study results |
|---|---|
| Acute inhalation toxicity<br><br>Sprague-Dawley rats<br><br>PMRA# 3052229 | $LC_{50}$ >5.39 mg/L (♂/♀)<br><br>Hypoactivity, abnormal respiration, anogenital staining and moist rales observed in all rats following exposure. Facial staining, nasal discharge and gasping also observed in some animals. Recovery of most animals by Day 12.<br><br>Low acute inhalation toxicity |
| Eye irritation<br><br>New Zealand White rabbits<br><br>PMRA# 3052230 | MAS = 2.44/110<br>MIS = 10/110 (1 hr)<br><br>Minimally irritating |
| Dermal irritation<br><br>New Zealand White rabbits<br><br>PMRA# 3052231 | MAS = 4.44/8<br>MIS = 4.67/8 (24 and 48 hrs)<br><br>Moderately irritating |
| Dermal sensitization (Buehler method)<br><br>Hartley guinea pigs<br><br>PMRA# 3052232 | Positive<br><br>Potential dermal sensitizer |

**Table 3 Toxicity Profile of MGK Formula 31451, containing 98Sumithrin and N-octyl bicycloheptene dicarboximide**

| Study Type/Animal/PMRA # | Study results |
|---|---|
| Acute oral toxicity<br><br>Conducted with a surrogate formulation<br><br>Sprague-Dawley rats<br><br>PMRA# 3052471 | $LD_{50}$ >5000 mg/kg bw (♂/♀)<br><br>Piloerection, hypoactivity, facial/anogenital staining, ↓ fecal volume and soft feces observed in all rats (recovery by Day 4).<br><br>Low acute oral toxicity |

| Study Type/Animal/PMRA # | Study results |
|---|---|
| Acute dermal toxicity<br><br>Conducted with a surrogate formulation<br><br>Sprague-Dawley rats<br><br>PMRA# 3052470 | $LD_{50}$ > 5000 mg/kg bw (♂/♀)<br><br>No treatment-related dermal or clinical signs.<br><br>Low acute dermal toxicity |
| Acute inhalation toxicity<br><br>Conducted with a surrogate formulation<br><br>Sprague-Dawley rats<br><br>PMRA# 3052469 | $LC_{50}$ > 2.07 mg/L (♂/♀)<br><br>Ocular and nasal discharge, irregular respiration, dyspnea, hunched posture and/or hypoactivity observed during exposure. Irregular respiration, hunched posture and hypoactivity observed in a few animals upon removal from chamber (recovery by Day 1).<br><br>Low acute inhalation toxicity |
| Eye irritation<br><br>New Zealand White rabbits<br><br>PMRA# 3052468 | Un-rinsed eyes:<br>MAS = 0.67/110<br>MIS = 2.67/110 (1 hr)<br><br>Rinsed eyes:<br>MAS = 0/110<br>MIS = 2.0/110 (1 hr)<br><br>Minimally irritating |
| Dermal irritation<br><br>Conducted with a surrogate formulation<br><br>New Zealand White rabbits<br><br>PMRA# 3052467 | MAS = 2.13/8<br>MIS = 3.0/8 (24 hrs)<br><br>Mildly irritating |
| Dermal sensitization (Buehler method)<br><br>Conducted with a surrogate formulation<br><br>Hartley guinea pigs<br><br>PMRA# 3052466 | Negative |

# References

## A. List of studies/Information submitted by registrant

### 1.0 Chemistry


| PMRA document number | Reference |
|---|---|
| 3034593 | 2018, Product Chemistry for SI-183 - Group A, DACO: 10.2.1, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.12.2, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.15, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.3.2, 3.4.1, 3.4.2, 3.6, 830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750, 830.1800, 830.1900 CBI |
| 3034594 | 2018, Product Properties of SI-183 - Group B, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 3.5.1, 3.5.10, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 8.2.3.2, 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7370, 830.7550, 830.7560, 830.7570, 830.7840, 830.7950 CBI |
| 3034671 | 2018, Waiver Request for Dissociation Constant in Water on Sumithrin Technical Grade (d-Phenothrin), DACO: 2.14.10, 8.2.3.2, 830.7370 |
| 3144958 | 2020, Confirmation of Identities of Ingredients in IR-trans-Phenothrin Technical Grade, DACO: 2.13.2 CBI |
| 3144959 | 2020, Confirmation of Identity of [CBI REMOVED] in lR-trans-Phenothrin Technical Grade, DACO: 2.13.2 CBI |
| 3156690 | 2020, Position Paper for Quantification of [CBI REMOVED] in 1R-trans-Phenothrin, DACO: 2.13.2 CBI |
| 3052219 | 2019, 3.1.1-3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI |
| 3052220 | 2018, Formulation Process Description for MGK Formula 3145, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI |
| 3052221 | 2018, Product Chemistry of MGK FORMULA 3145, DACO: 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI |
| 3052222 | 2018, Accelerated Storage Stability Evaluation of MGK Formula 3145, DACO: 3.5.10, 3.5.14 CBI |
| 3052223 | 2019, DACO 3.5.4_Formulation Type, DACO: 3.5.4 CBI |
| 3052225 | 2019, DACO 3.5.5_Container Material and Description, DACO: 3.5.5 CBI |
| 3052474 | 2019, Appendix 1: Product Chemistry of Multicide Lice and Dust Mite Spray 27911, DACO: 3.5.13, 3.5.6, 3.5.7, 3.5.9 CBI |

3052475 2019, Container Material and Description, DACO: 3.5.5 CBI

3052476 2019, Formulation Type, DACO: 3.5.4 CBI

3052477 2018, Accelerated Storage Stability Evaluation of MGK Formula 31451, DACO: 3.5.10, 3.5.14 CBI

3052481 2018, Product Chemistry of MGK Formula 31451, DACO: 3.4.1, 3.5.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI

3052484 2018, Formulation Process Description for MGK Formula 31451, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI

3052485 2019, 3.1.1-3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI

3181447 2018, Storage Stability Evaluation of MGK Formula 31451, DACO: 3.5.10, 3.5.14


## 2.0 Human and animal health


| PMRA document number | Reference |
|---|---|
| 3034596 | 2018, A 90-Day Oral (Dietary) Study of 1R-trans-Phenothrin in Fischer Rats with Functional Observational Battery and Motor Activity Determinations, DACO: 4.3.1,4.7.1, 870.3100 |
| 3034598 | 2015, Acute Dermal Toxicity Study of IR-trans-phenothrin in Rats, DACO: 4.2.2,4.6.2, 870.1200 |
| 3034600 | 2015, Acute Inhalation Toxicity Study of IR-trans-phenothrin in Rats, DACO: 4.2.3,4.6.3, 870.1300 |
| 3034602 | 1997, Acute oral toxicity study of S-1712 in rats, DACO: 4.2.1,4.6.1, 870.1100 |
| 3034604 | 2015, Primary eye irritation test of IR-trans-phenothrin in rabbits, DACO: 4.2.4,4.6.4, 870.2400 |
| 3034606 | 2015, Primary skin irritation test of IR-trans-phenothrin in rabbits, DACO: 4.2.5,4.6.5, 870.2500,M4.5.2 |
| 3034608 | 2015, Skin sensitization test of IR-trans-phenothrin in guinea pigs (Maximization Test), DACO: 4.2.6,4.6.6, 870.2600 |
| 3034610 | 2018, Rationale Bridging the Toxicology of 80Sumithrin to the Isomerically-Enriched 98Sumithrin (SI-183 and S-1712), DACO: 4.3.1, 4.3.2, 4.3.5, 4.3.6, 4.4.1, 4.4.2, 4.4.3, 4.5.1, 4.5.12, 4.5.13, 4.5.2, 4.5.3, 4.5.4, 4.5.5, 4.5.6, 4.5.7, 4.5.9, 4.7.1, 4.7.2, 4.7.4, 4.7.6, 4.8 |
| 3052227 | 2018, MGK Formula 3145: Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1 |

3052228 2018, MGK Formula 3145: Acute Dermal Toxicity in Rats, DACO: 4.6.2

3052229 2018, MGK Formula 3145: Acute Inhalation Toxicity in Rats , DACO: 4.6.3

3052230 2018, MGK Formula 3145: Primary Eye Irritation in Rabbits, DACO: 4.6.4

3052231 2019, MGK Formula 3145: Primary Skin Irritation in Rabbits, DACO: 4.6.5

3052232 2018, MGK Formula 3145: Dermal Sensitization Test in Guinea Pigs-Buehler Method, DACO: 4.6.6

3052466 2001, Dermal Sensitization Study in Guinea Pigs (Buehler Method), DACO: 4.6.6

3052467 2000, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5

3052468 2000, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4

3052469 2000, Acute Inhalation Toxicity Study in Rats-Limit Test, DACO: 4.6.3

3052470 2011, Acute Dermal Toxicity Study in Rats, DACO: 4.6.2

3052471 2000, Acute Oral Toxicity Study in Rats-Limit Test, DACO: 4.6.1

3112486 2020, Clarification Response: DACO 4 Rationale, DACO: 4.1 CBI

3266735 2021, Subject: Recent positive control validation studies for motor activity assessment DACO 4.3.1 90-day oral toxicity study in rats (PMRA 3034596), DACO: 4.3.1


## 3.0 Value


**PMRA document number** **Reference**

3052488 2002, Evaluation of Three Products against Bed Bugs, DACO: 10.2.3.2(C),10.3.2(B)

3052489 2007, Laboratory bioassay to determine the efficacy of Bedlam against a standard laboratory susceptible and an alpha-cypermethrin resistant strain of bed bug eggs, DACO: 10.2.3.2(C),10.3.2(B)

3052490 2007, Laboratory bioassay to determine the efficacy of treatments against an alpha-cypermethrin resistant strain of bed bug eggs, *Cimex lectularius*, DACO: 10.2.3.2(C),10.3.2(B)

3052491 2006, Laboratory Trial to evaluate an aerosol for residual efficacy against bed bugs, *Cimex lectularius*, DACO: 10.2.3.2(C),10.3.2(B)

## B. Additional information considered

### i) Published information

#### 1.0 Human and animal health

| PMRA document number | Reference |
|---|---|
| 3297187 | Nagy, K., Rácz, G., Matsumoto, T., Ádány, R., Ádám, B., 2014, Evaluation of the genotoxicity of the pyrethroid insecticide phenothrin. Mutation Research 770 (2014): 1-5, DACO: 4.5.5 |