Proposed Registration Decision PRD2016-06

Propoxycarbazone-sodium

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Overview

Proposed Registration Decision for Propoxycarbazone-sodium

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 Propoxycarbazone-sodium Technical Herbicide and MKH 6561 70WG Herbicide, containing the technical grade active ingredient propoxycarbazone-sodium, for control or suppression of the grassy weeds downy brome and Japanese brome, and specific broadleaf weeds in winter wheat in western Canada.

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 Propoxycarbazone-sodium Technical Herbicide and MKH 6561 70WG Herbicide.

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 PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada'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 propoxycarbazone-sodium, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on propoxycarbazone-sodium, which will include the decision, the reasons for it, a summary of comments received on the proposed 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 Propoxycarbazone-sodium?

Propoxycarbazone-sodium is a new conventional herbicide active ingredient that provides control or suppression of the grassy weeds downy brome and Japanese brome and specific annual broadleaf weeds in winter wheat grown in western Canada.

Health Considerations

Can Approved Uses of Propycarbazone-sodium Affect Human Health?

Products containing propoxycarbazone-sodium are unlikely to affect your health when used according to the label directions.

Potential exposure to propoxycarbazone-sodium may occur through the diet (food and water) or 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 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.

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. The health effects noted in laboratory animals occur at doses more than 100-times 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 propoxycarbazone-sodium was of low acute oral, dermal and inhalation toxicity. It was minimally irritating to the eye and skin and did not cause an allergic skin reaction. The acute toxicity of the end-use product MKH 6561 70WG Herbicide was low via the oral, dermal and inhalation routes of exposure. It was non-irritating to the eye and skin and did not cause an allergic skin reaction.

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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*.

Short- and long-term (lifetime) animal toxicity tests were assessed for the potential of propoxycarbazone-sodium to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment were decreased body weight gain and gastrointestinal irritation. There was no indication that the young were more sensitive than the adult animal.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal studies.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Chronic aggregate dietary intake estimates (food plus drinking water) revealed that the general population and infants less than one year old, the subpopulation which would ingest the most propoxycarbazone-sodium relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from propoxycarbazone-sodium is not of health concern for all population subgroups.

Propoxycarbazone-sodium is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of propoxycarbazone-sodium is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

The MRLs for this active ingredient can be found in the Science Evaluation section of this Consultation Document.

Occupational Risks From Handling MKH 6561 70WG Herbicide

Occupational risks are not of concern when MKH 6561 70WG Herbicide is used according to the label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply MKH 6561 70WG Herbicide, as well as field workers re-entering freshly treated fields, can come in direct contact with propoxycarbazone-sodium residues on the skin or through inhalation of spray mists. Therefore, the label of MKH 6561 70WG Herbicide specifies to wear a long-sleeved shirt, long pants, shoes and socks during all activities, including application. In addition, workers mixing and loading the product, or involved in equipment clean-up and repairs, must wear chemical-resistant gloves, rubber boots and protective eyewear. The label also requires that workers do not enter treated

fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the health risk to these individuals are not expected to be of concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Propoxycarbazone-Sodium is Introduced Into the Environment?

When used according to the label directions, propoxycarbazone-sodium is not expected to pose an unacceptable risk to the environment.

Propoxycarbazone-sodium can enter the environment when it is used to control select grass and broadleaf weeds in winter wheat. Propoxycarbazone-sodium breaks down in soil and water and is not expected to persist for long periods of time, nor is it expected to move downward through the soil and enter groundwater. Propoxycarbazone-sodium is unlikely to enter the atmosphere and be transported to areas far removed from where it was applied. Propoxycarbazone-sodium is not expected to accumulate in the tissues of organisms.

When used according to the label directions, propoxycarbazone-sodium does not present an unacceptable risk to birds, small mammals, fish, algae, earthworms, bees and invertebrates. The use of the end-use product, MKH 6561 70WG Herbicide, may pose a risk to non-target terrestrial and aquatic plants. Buffer zones are specified on the product label to protect terrestrial and freshwater habitats adjacent to treated areas and specific instructions are provided to prevent runoff into aquatic habitats. Toxicity statements are also specified on the product label to protect terrestrial and aquatic plants.

Value Considerations

What Is the Value of MKH 6561 70WG Herbicide?

MKH 6561 70WG Herbicide contains a new active ingredient, propoxycarbazone-sodium, which will control or suppress the grassy weeds downy brome and Japanese brome, two difficult to control grassy weed species for which post-emergent chemical control options are limited in winter wheat, and specific annual broadleaf weeds.

The registration of MKH 6561 70WG Herbicide will provide winter wheat producers in western Canada with a viable option for the chemical control of downy brome and Japanese brome. Additionally, MKH 6561 70WG Herbicide will provide control or suppression of specific annual broadleaf weeds that are often found in winter wheat that is grown in western Canada.

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 MKH 6561 70WG Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with the active ingredient propoxycarbazone-sodium on the skin or through inhalation of spray mists, all workers handling MKH 6561 70WG Herbicide, including applicators, must wear a long-sleeved shirt, long pants, shoes and socks. In addition, workers mixing and loading the product, or involved in equipment clean-up and repairs, must wear chemical-resistant gloves, rubber boots and protective eyewear. Furthermore, standard label statements to protect against drift during application have been added to the label and workers re-entering freshly treated wheat fields to perform postapplication activities, such as scouting, are required to respect the restricted-entry interval (REI) of 12 hours.

Environment

To minimize potential risks to non-target terrestrial and aquatic plants, label statements and buffer zones to protect sensitive terrestrial and aquatic habitats are to be specified on the end-use product label.

To mitigate potential exposures via spray drift, buffer zones of 1 metre are required on the end-use product label to protect sensitive terrestrial and aquatic habitats.

Next Steps

Before making a final registration decision on propoxycarbazone-sodium, the PMRA will consider any 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 note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. 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

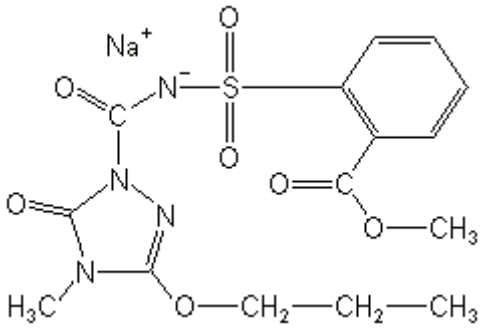
When the PMRA makes its registration decision, it will publish a Registration Decision on Propoxycarbazone-sodium (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon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

Science Evaluation

Propoxycarbazone-sodium

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Propoxycarbazone-sodium
Function	Herbicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	sodium [2-(methoxycarbonyl)benzenesulfonyl](4-methyl-5-oxo-3-propoxy-4,5-dihydro-1*H*-1,2,4-triazole-1-carbonyl)azanide
2. Chemical Abstracts Service (CAS)	Benzoic acid, 2-[[[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]-, methyl ester, sodium salt (1:1)
CAS number	181274-15-7
Molecular formula	$C_{15}H_{17}N_4NaO_7S$
Molecular weight	420.37
Structural formula	
Purity of the active ingredient	95.3%

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

Technical Product—Propoxycarbazone-sodium Technical

Property	Result
Colour and physical state	Colourless crystalline powder
Odour	Odourless
Melting range	230-240°C (under decomposition)
Boiling point or range	Not available
Density	1.42 g/cm^3 at 20°C
Vapour pressure	<1 × 10^{-8} Pa at 20°C <9 × 10^{-8} Pa at 70°C
Ultraviolet (UV)-visible spectrum	pH λ (nm) absorbance ε (cm^{-1} mol^{-1} L) 4 201 1.096 4.37 × 10^4 7 204 0.476 1.90 × 10^4 9 207 0.289 1.15 × 10^4 not expected to absorb at λ > 300 nm
Solubility in water at 20°C	42 g/L
Solubility in organic solvents at 20°C	Solvent — Solubility (g/L) n-Heptane <0.1 xylene <0.1 dichloromethane 1.5 1-octanol <0.1 1-paropanol <0.1 Polyethylene glycol 5.2 acetone 0.50 ethyl acetate <0.1 acetonitrile 0.90 dimethylsulfoxide 190
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 7 -1.55
Dissociation constant (pK_a)	2.1
Stability (temperature, metal)	Thermally stable at ambient temperature when exposed to air

End-Use Product—MKH 6561 70WG Herbicide

Property	Result
Colour	Medium brown
Odour	Unpleasant odour
Physical state	Solid
Formulation type	WG (wettable granule)
Guarantee	70.0%
Container material and description	HDPE bottles, 0.25-20 kg
Density	0.59 g/cm^3
pH of 10% dispersion in water	7.8
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.

Storage stability	The product is stable for 2 years stored at ambient temperature.
Corrosion characteristics	No corrosion to HDPE bottles was observed at 50°C for two weeks. No corrosion was observed to HDPE containers during 2-year storage at ambient temperature.
Explodability	The product is not explosive.

1.3 Directions for Use

MKH 6561 70WG Herbicide

MKH 6561 70WG Herbicide, containing propoxycarbazone-sodium at 70% w/w, is a selective post-emergent herbicide that will provide control of the grassy weeds downy brome and Japanese brome as well as other specific annual broadleaf weeds in winter wheat grown in western Canada (refer to Table 19 of Appendix I). MKH 6561 70WG Herbicide may be applied once per crop cycle (in the fall or spring) at a rate of 30 to 45 g ai/ha (equivalent to 42 to 63 g product per ha) with ground application equipment, and must be applied in tank mix with a non-ionic surfactant at 0.25% v/v.

1.4 Mode of Action

Propoxycarbazone-sodium, which belongs to the sulfonylaminocarbonyl-triazolinones class of chemistry, inhibits the normal function of the enzyme acetolactate synthase. This enzyme is essential in amino acid and protein synthesis. Based on its mode of action, propoxycarbazone-sodium is classified as a Group 2 herbicide, one of a number of herbicides registered for use in western Canada for grassy and broadleaf weed control in winter, spring and durum wheat.

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 for the determinations.

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

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in environmental media. Methods for residue analysis are summarized in Table 1 Appendix I.

Please refer to the Evaluation Report for Application Number 2008-4377 available in the Pesticides and Pest Management section of Health Canada's website (http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php), under Public Registry, Pesticide Product Information Database for a summary of the previously reviewed analytical methods used for data generation and enforcement purposes.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for propoxycarbazone-sodium. The database consists of an array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is acceptable, and the database is considered adequate to characterize the toxicity of propoxycarbazone-sodium.

Laboratory studies in the rat demonstrated that the absorption of radiolabelled propoxycarbazone-sodium was rapid but incomplete following oral administration. Peak plasma concentrations were seen about 1 h after exposure. Within 48 hours, approximately 21-31% of the administered dose (AD) was absorbed and eventually excreted in the urine, while the majority of the AD was excreted unchanged in the feces. Negligible propoxycarbazone-sodium residues were detected in expired air. Tissue distribution of propoxycarbazone-sodium residues was limited to the gastrointestinal (GI) tract, liver, and kidneys at low concentrations. The total propoxycarbazone-sodium residue remaining in tissues was low and there was no evidence of bioaccumulation for all dose levels tested. Metabolism of propoxycarbazone-sodium in the rat was limited. Analysis of the metabolites indicated that only a small number of minor metabolites, each accounting for less than 3% of the AD, were detected in the urine and feces, with the exception of a fecal metabolite which accounted for 2-9% of the AD. There were no notable gender differences in the metabolic profile of propoxycarbazone-sodium in the rat.

Propoxycarbazone-sodium was of low acute oral, dermal and inhalation toxicity in rats. It was minimally irritating to the eye and skin of rabbits and was not a skin sensitizer in guinea pigs (Maximization test). The acute toxicity of the end-use product, MKH 6561 70WG Herbicide, was low via the oral, dermal and inhalation routes of exposure in rats. It was non-irritating to the eye and skin of rabbits and was not a dermal sensitizer in the guinea pig (Buehler test).

Short-term toxicity studies in laboratory animals (mouse, rat, and dog) demonstrated that propoxycarbazone-sodium induced systemic toxicity only at very high dose levels. The effects included lower food consumption and body-weight gains, increased water intake, and in the rat only, irritation of the forestomach. Gross and histopathology changes in other tissues were not evident.

In a 28-day dermal study, neither systemic nor local skin effects were noted at the limit dose.

Due to study limitations (for example, limited histopathology), this study was considered supplemental.

In vivo/in vitro genotoxicity studies of propoxycarbazone-sodium assessing gene mutation, chromosome aberration, and unscheduled DNA synthesis showed negative genotoxic findings.

Long-term studies of propoxycarbazone-sodium in mice and rats showed toxic effects similar to those observed in shorter-term studies. Sufficiently high dose levels were tested in these rodent species and there was no evidence of oncogenic potential.

A reproductive toxicity study in rats demonstrated slight changes in the estrous cycle at a high dose that also induced maternal toxicity (decreased food efficiency, epithelial vacuolation of forestomach). However, there was no evidence of offspring toxicity. Developmental toxicity studies in the rat and rabbit did not demonstrate any evidence of teratogenicity. In rats tested at the limit dose, there was no evidence of maternal or developmental toxicity. In the rabbit, oral exposure to propoxycarbazone-sodium resulted in maternal toxicity (decreased food and water intake, body-weight gain, and GI tract effects) and abortions. A single abortion occurred at the maternal LOAEL with more animals affected at the highest dose tested. Growth and development of the fetuses were also delayed at the highest dose.

Acute and short-term neurotoxicity studies indicated that propoxycarbazone-sodium was not neurotoxic and there were no triggers for the requirement of a developmental neurotoxicity study.

The plant metabolite, KTS 9061, and the soil metabolites, 4-OH-saccharine and MKH 8394, were of low acute toxicity by the oral route in rats and were not mutagenic when tested in in vitro mutation assays. The soil metabolite KTS 9304 was also negative in a bacterial reverse mutation assay. No effects were observed in a 28-day dietary study in rats with KTS 9061, up to the highest dose tested. Select impurities of propoxycarbazone-sodium (methylthio analogue free acid-MKH 6561, bissulforylurea-MKH 6561) were of low acute toxicity by the oral route and were not mutagenic when tested in in vitro microbial mutation assays. Overall, these metabolites and impurities were not considered to be more toxic than the parent, propoxycarbazone-sodium.

The results of the toxicity tests conducted on laboratory animals with propoxycarbazone-sodium are summarized in Tables 2 (End-use product), Table 3 (TGAI, metabolites/impurities), and the toxicology endpoints for use in the human health risk assessment are listed in Appendix I, Table 4.

3.1.1 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website.

Incidents from Canada and the United States were searched for propoxycarbazone-sodium. As of 06 May 2015, no incidents involving adverse effects resulting from exposure to propxycarbazone-sodium have been reported to the PMRA from other jurisdictions. Since propoxycarbazone-sodium is a new active ingredient pending registration for use in Canada, there are no Canadian incident reports and the applicant did not provide additional information relevant to incidents.

3.1.2 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects. This factor should take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children and potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database, as it pertains to the toxicity to infants and children, the standard complement of required studies are available for propoxycarbazone-sodium, including developmental toxicity studies in rats and rabbits and reproductive toxicity studies in rats.

With respect to prenatal and postnatal toxicity, no evidence of increased susceptibility was seen following in utero exposure to rats or rabbits in the developmental toxicity studies. In the rat developmental toxicity study, there were no maternal or developmental effects at the limit dose. In the rabbit developmental toxicity study, the abortions seen at high doses occurred late in gestation and were associated with maternal toxicity (decreased food and water consumption, decreased body-weight gain, and GI tract pathology). In the rat reproductive toxicity study, adverse offspring effects were not identified. Based on these data, there is a low level of concern for pre- or post-natal toxicity associated with propoxycarbazone-sodium exposure. In light of these findings and the completeness of the database, the *Pest Control Products Act* factor was reduced from 10-fold to 1-fold.

3.2 Human Risk Assessment

3.2.1 Determination of Acute Reference Dose (ARfD)

There were no effects in the database warranting the establishment of an acute reference dose.

3.2.2 Determination of Acceptable Daily Intake (ADI)

To estimate dietary risk from long-term repeated exposure, the 2-generation dietary reproductive toxicity study in the rat is considered relevant for the establishment of the ADI. Systemic toxicity in the parents was demonstrated at the LOAEL of 297 mg/kg bw/d based on epithelial vacuolation in the forestomach. The NOAEL for parental toxicity was 75 mg/kg bw/d. Although a lower NOAEL (34 mg/kg bw/d) was observed in the 2-year dietary study in the rat, the effect at the LOAEL of 459 mg/kg bw/d was a marginal decrease in body weight gain. Therefore, the highest NOAEL below the lowest LOAEL was selected. For ADI determination, the standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies

variability were applied. For the reasons outlined in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor was reduced to 1-fold. The composite assessment factor (CAF) is therefore 100. This ADI is considered to be protective of all sub-populations including women of child-bearing age and nursing infants.

The ADI, calculated according to the following formula, is 0.8 mg/kg bw/d:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{75 \text{ mg/kg bw/d}}{100} = 0.8 \text{ mg/kg bw/d}$$

3.3 Occupational and Residential Risk Assessment

3.3.1 Toxicological Endpoints

Short-Term Dermal and Inhalation

For short-term dermal and inhalation exposure, the rabbit developmental study was selected. The existing short-term dermal toxicity study was considered supplemental and no repeat dose inhalation study was available. Maternal toxicity was demonstrated at the LOAEL of 500 mg/kg bw/d based on GI tract toxicity (enlarged cecum) and light coloured feces. The NOAEL was 100 mg/kg bw/d.

For occupational scenarios, the target margin of exposure (MOE) selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. This target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Intermediate-Term Dermal and Inhalation

For intermediate-term dermal and inhalation risk assessment, the 2-generation reproductive toxicity study in rats was selected. Systemic toxicity in the parents was demonstrated at the LOAEL of 297 mg/kg bw/d based on epithelial vacuolation in the forestomach. The NOAEL for parental toxicity was 75 mg/kg bw/d. A repeat dose inhalation study was not available and the short-term dermal study was considered supplemental.

For occupational scenarios, the target MOE selected for this endpoint is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. This target MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

Occupational exposure to MKH 70WG Herbicide is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation routes.

3.3.1.1 Dermal Absorption

No dermal absorption study was submitted to the PMRA by the applicant. As such, the default dermal absorption factor of 100% was used in the occupational exposure and risk assessments.

3.3.2 Occupational Exposure and Risk

In order to determine the acceptability for registration of the proposed end-use product, MKH 70WG Herbicide, quantitative exposure and risk assessments for occupational handlers and postapplication workers were conducted as described below.

3.3.2.1 Mixer/loader/applicator Exposure and Risk Assessment

MKH 6561 70WG Herbicide is a water dispersible granular formulation. It will be mixed with water and applied to winter wheat using a tractor pulled groundboom sprayer. Hence, individuals have potential for dermal and inhalation exposure to propoxycarbazone-sodium during mixing, loading and application. Chemical handler exposure is expected to be of short-term duration for farmers and potentially intermediate-term duration for custom applicators since only one application of MKH 6561 70WG Herbicide is recommended during the growing season when wheat is at the 1-leaf stage of growth up to just prior to jointing (approximately 30 days).

As chemical-specific data for assessing human exposures during pesticide handling activities were not submitted, dermal and inhalation exposures for workers involved in mixing and loading the water dispersible granular formulation, as well as applying the liquid mixture with an open-cab groundboom sprayer, were estimated using the Pesticide Handlers Exposure Database (PHED), version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. The exposure estimates are based on the personal protective equipment (PPE) described on the product label, which consists of a long-sleeved shirt, long pants, shoes and socks for all workers handling the product during any type of activity, including application. In addition, workers involved in mixing, loading, clean-up and repairs must wear chemical-resistant gloves, rubber boots and protective eyewear. PHED unit exposure values applicable for mixing, loading and applying MKH 6561 70WG Herbicide are summarized in Table 3.3.2.1.1 below.

Table 3.3.2.1.1 Unit Exposure Estimates for Mixers, Loaders and Applicators Handling MKH 6561 70WG Herbicide

Exposure Scenarios and PPE[1]		Unit Exposure (µg/kg a.i. handled)[2]		
		Dermal	Inhalation[3]	Total
Open mixing/loading water dispersible granules				
A_1	Single layer, CR[1] gloves	163.77	1.02	164.79
Open-cab groundboom application				
B_1	Single layer, no gloves	32.98	0.96	33.94

Exposure Scenarios and PPE[1]		Unit Exposure (µg/kg a.i. handled)[2]		
		Dermal	Inhalation[3]	Total
Total of open mixing/loading water dispersible granules + open-cab groundboom application				
$A_1 + B_1$	Single layer, CR[1] gloves for mixing/loading and no gloves for applying	196.75	1.98	198.73

[1] PPE = personal protective equipment; CR = chemical-resistant
[2] Unit exposure values are from the PHED Tables (Version 1.1, February 2002)
[3] Light inhalation rate

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and 100% dermal absorption as no chemical-specific dermal absorption studies were submitted by the applicant. Similarly, inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day and 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight. The amount of product handled per day was calculated using the maximum application rate of 0.0441 kg a.i./ha and the default areas treated per day (ATPD) of 107 ha for farmers and 360 ha for commercial applicators.

For short-term exposure and intermediate-term exposure, dermal and inhalation unit exposure estimates were combined since the no observed adverse effects levels (NOAELs), adverse effects and target margins of exposure (MOEs) are the same. Hence, the total unit exposure estimate was compared to the toxicological endpoints to obtain the calculated MOE as presented in Table 3.3.2.1.2. The target MOE is 100 for both dermal and inhalation exposures.

Table 3.3.2.1.2 Mixer/Loader/Applicator Risk Assessment for Workers Handling MKH 6561 70WG Herbicide

Exposure Scenario and PPE[1]		Total Unit Exposure[2] (µg/kg a.i. handled)	Max. App. Rate (kg a.i./ha)	ATPD[3] (ha/day)	Daily Exposure[4] (mg/kg bw/day)	Calculated MOE[5]	
						Short[6]	Intermediate[6]
Open mixing/loading water dispersible granules & open-cab groundboom application							
$A_1 + B_1$	Single layer, CR[1] gloves for mixing/loading, no gloves for applying	198.73	0.0441	107	0.01172	8.53×10^3	6.40×10^3
				360	0.03944	2.54×10^3	1.90×10^3

[1] PPE = personal protective equipment; CR= chemical-resistant
[2] Sum of the dermal and inhalation unit exposure estimates
[3] ATPD: Area Treated per Day; default values for groundboom application by farmers and commercial applicators
[4] Daily exposure = (Total unit exposure × ATPD × rate) / (80 kg bw × 1000 µg/mg)
[5] MOE = NOAEL / Daily exposure
[6] Based on the short-term oral NOAEL of 100 mg/kg bw/day, the intermediate-term oral NOAEL of 75 mg/kg bw/day and target MOEs of 100; assuming 100% dermal absorption and 100% inhalation in the absence of dermal absorption data.

As shown above, the proposed exposure scenario ($A_1 + B_1$; open mixing/loading water dispersible granules and open-cab groundboom application for a worker wearing a single layer of clothing with chemical-resistant gloves during mixing and loading) resulted in calculated MOEs for short- and intermediate-term exposure of farmers and commercial applicators that are significantly above the target MOEs of 100. As such, the PPE described on the label of MKH 6561 70WG Herbicide is adequate to protect mixers, loaders and/or applicators from the exposure to propoxycarbazone-sodium while handling this product.

Furthermore, the acute toxicity studies for MKH 6561 70WG Herbicide have demonstrated that this product has a very low toxicity via the oral, dermal and inhalation routes of exposure, as well as not being an eye or a skin irritant/sensitizer. Thus, no additional PPE is required based on these results.

3.3.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering winter wheat fields treated with MKH 6561 70WG Herbicide. Re-entry activity would consist of scouting which would typically occur within the first week of application and require limited contact with treated foliage. As such, the potential postapplication exposure to workers is expected to be of short-term duration and the primary route of exposure would be through the dermal route.

Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route since the active ingredient propoxycarbazone-sodium is non-volatile ($<1 \times 10^{-11}$ kPa at 20°C) according to NAFTA criteria for outdoor use (i.e. $<1 \times 10^{-4}$ kPa at 20-30°C), and as such, an inhalation risk assessment was not required.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue (DFR) values with activity-specific transfer coefficients (TCs). Activity transfer coefficients are based on data from the Agricultural Re-entry Task Force (ARTF), of which the applicant is a member. For scouting in winter wheat (low height & full foliage), the default TC is 1100 cm^2/hr. Given that chemical-specific DFR data were not submitted, default DFR residue values were used in the exposure assessment, i.e. 25% of the application rate dislodgeable on the application day (Day 0) and 10% dissipation per day. In addition, the maximum application rate of 0.0441 kg a.i./ha, an exposure duration of 8 hours per day, the default dermal absorption factor of 100% and the default adult body weight of 80 kg were used. The postapplication dermal exposure of workers to propoxycarbazone-sodium was calculated for the day of the application, immediately after the spray has dried (Day 0). Postapplication risk was then obtained by comparing the dermal exposure with the short-term dermal toxicological endpoint of 100 mg/kg bw/day.

Table 3.3.2.2.1 Postapplication Exposure and Risk Estimate for MKH 6561 70WG Herbicide on the Application Day (Day 0)

Crop	Max. App. Rate (kg a.i./ha)	No. of App./Year	Peak DFR ($\mu g/cm^2$)[1]	Re-Entry Activity	Transfer Coefficient (cm^2/hr)[2]	Dermal Exposure (mg/kg bw/day)[3]	Calculated MOE[4]
Winter wheat	0.0441	1	0.1103	Scouting	1100	0.0121	8.26×10^3

[1] Dislodgeable foliar residues (DFR) were calculated using 25% dislodgeable on Day 0 and 10% dissipation per day; peak DFR is the DFR on Day 0.
[2] The TC for scouting was based on ARTF studies.
[3] Dermal exposure = (Peak DFR [$\mu g/cm^2$] × TC [cm^2/hr] × 8 hours) / (80 kg bw × 1000 µg/mg)
[4] MOE = Dermal NOAEL / Dermal Exposure; based on the short-term oral NOAEL of 100 mg/kg bw/day and a target MOE of 100; assuming 100% dermal absorption in the absence of dermal absorption data.

The calculated MOE on Day 0 for scouting in winter wheat treated with MKH 6561 70WG Herbicide is 8.26×10^3, which is well above the target MOE of 100. Therefore, the restricted entry interval (REI) of 12 hours is adequate to protect workers.

3.3.3 Residential Exposure and Risk Assessment

There are no residential uses for MKH 6561 70SG Herbicide, and as such, a residential risk assessment was not required.

3.3.4 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.4 Food Residues Exposure Assessment

3.4.1 Residues in Plant and Animal Foodstuffs

Please refer to the Evaluation Report for Application Number 2008-4377 available in the Pesticides and Pest Management section of Health Canada's website (http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php), under Public Registry, Pesticide Product Information Database for a summary of the previously reviewed residue data for propoxycarbazone-sodium in/on plant matrices, as well as the rationale for the previous regulatory decision (MRL of 0.02 ppm on wheat).

The information captured herein for the domestic registration of Propoxycarbazone-sodium Technical Herbicide and the end-use product MKH 6561 70WG Herbicide relates to new confined and field crop rotation studies, a cattle feeding study, and a freezer storage stability study provided to support the domestic registration on winter wheat, and to changes in dietary exposure due to the update of the dietary exposure assessments to include livestock commodities.

The previously determined residue definition for both enforcement and risk assessment purposes in wheat is propoxycarbazone and the 2-hydroxypropoxy metabolite (Pr-2-OH MKH 6561). Adequate confined and field crop rotation studies were performed on three distinct crop types (cereal, leafy and root crops) treated separately with phenyl and triazolinone radio-labelled propoxycarbazone. The nature of the residues was adequately characterized and a separate residue definition was not required for rotational crops. The plant-back interval of 10 months for spring wheat and winter wheat is supported.

Radio-labelled residues of propoxycarbazone and the 2-hydroxypropoxy metabolite were demonstrated to be stable in turnip tops, turnip roots and mustard greens for up to 12 months when stored frozen at < -15 °C.

Adequate feeding studies were carried out in a lactating ruminant to assess the anticipated residues in edible matrices resulting from the current use. A hen feeding study is not available and is not currently required given that results from the poultry metabolism study demonstrated that residues are not expected in edible poultry matrices in birds fed treated grain. Based on previously reviewed data, a residue definition for enforcement and dietary exposure purposes was determined to be propoxycarbazone in livestock matrices.

3.4.2 Exposure from Drinking Water

3.4.2.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of propoxycarbazone-sodium in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. An overview of how the EECs are estimated is provided in the PMRA's Science Policy Notice SPN2004-01, *Estimating the Water Component of a Dietary Exposure Assessment*. EECs of propoxycarbazone-sodium in groundwater were calculated using the PRZM-GW model to simulate leaching through a layered soil profile over a 50-year period. EECs of propoxycarbazone-sodium in surface water were calculated using the SWCC model, which simulates pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a vulnerable drinking water source, a small reservoir.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. The Level 1 EECs are expected to allow for future use expansion into other crops at this application rate and application method. Table 3.4.2.1-1 lists the application information and main environmental fate characteristics used in the simulations. A combined residue of the parent and five transformation products (M04, M05, M06, M09, and M10) was modelled for drinking water. Approximately twenty initial application dates from early April through early June for spring applications, and from mid-October through mid-November for fall applications were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Table 3.4.2.1-2. Details of water modelling inputs and calculations are available upon request.

Table 3.4.2.1-1 Major groundwater and surface water model inputs for Level 1 assessment of propoxycarbazone-sodium

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Wheat
	Maximum allowable application rate per year (g a.i./ha)	45
	Maximum rate each application (g a.i./ha)	45
	Maximum number of applications per year	1
	Minimum interval between applications (days)	NA
	Method of application	Ground foliar
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable
	Photolysis half-life in water (days)	Stable
	Adsorption K_{OC} or K_d (mL/g)	Surface Water: 0.244 (20^{th} percentile of five K_d values for parent) Groundwater: 0.003 (K_d of M06) for phenyl-label degradation, and 0.11 (K_d of M04) for triazolinone-label degradation Ecoscenario: 0.244 (20^{th} percentile of five K_d values for parent)
	Aerobic soil biotransformation half-life (days)	Drinking Water: 151 (90^{th} percentile confidence bound on mean of four half-lives adjusted to 25ºC) for phenyl-label degradation, and 1013 (90^{th} percentile confidence bound on mean of four half-lives adjusted to 25ºC) for triazolinone-label degradation Ecoscenario: 125 (90^{th} percentile confidence bound on mean of four half-lives at 20ºC)
	Aerobic aquatic biotransformation half-life (days)	Drinking Water: 327 (longest of two half-lives) for phenyl-label degradation, and 440 (longest of two half-lives) for triazolinone-label degradation Ecoscenario: 198 (longest of two half-lives for two labels)
	Anaerobic aquatic biotransformation half-life (days)	Drinking Water: Stable Ecoscenario: 27 (average of two values for two labels)

Table 3.4.2.1-2 Level 1 estimated environmental concentrations of propoxycarbazone-sodium+M04+M05+M06+M09+M10 in potential drinking water sources

Crop/use pattern	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Wheat (1x45 g a.i./ha, yearly total of 45 g a.i./ha)	88	88	7.8	1.4

1 90th percentile of daily average concentrations
2 90th percentile of 365 day moving average concentrations
3 90th percentile of the peak concentrations from each year
4 90th percentile of yearly average concentrations

3.4.3 Dietary Risk Assessment

A chronic non-cancer dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 4.02), which uses 2005-2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey (NHANES).

3.4.3.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic non-cancer analysis for propoxycarbazone-sodium: 100% crop treated, default processing factors, residues of wheat based on established MRL values and the recommended MRL values for animal commodities. The chronic dietary exposure from all supported propoxycarbazone-sodium food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than or equal to 0.2% of the acceptable daily intake (ADI). Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to propoxycarbazone-sodium from food and drinking water is 0.3% (0.0024 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year) at 0.9% (0.0072 mg/kg bw/day) of the ADI.

Propoxycarbazone-sodium is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

3.4.3.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.4.4 Aggregate Exposure and Risk

The aggregate risk for propoxycarbazone-sodium consists of exposure from food and drinking water sources only; there are no residential uses.

3.4.5 Maximum Residue Limits

Table 3.4.5-1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Fat, meat, meat byproducts (except kidney) of cattle, goat, horse and sheep	0.05
Kidney of cattle, goat, horse and sheep	0.07
Milk	0.01

For additional information on Maximum Residue Limits (MRLs) in terms of the international situation and trade implications, refer to Appendix II.

The confined crop and field rotational data, the freezer storage stability study data, the ruminant feeding study data and chronic dietary risk estimates are summarized in Appendix I, Tables 5 and 6.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

In the terrestrial environment, hydrolysis and phototransformation are not important routes of dissipation for propoxycarbazone-sodium. Propoxycarbazone-sodium can be transformed by aerobic and anaerobic microorganisms and can span the full range of pesticide persistence classifications from non-persistent to persistent in aerobic and anaerobic terrestrial systems, depending primarily on organic carbon content. Faster degradation correlated well with increasing organic carbon content. Eight transformation products (all major) were detected in laboratory studies: MKH 7018 (M04), STJ 4934 (M05), MKH 7283 (M06), MKH 7284 (M07), KTS 9357 (M08), KTS 9304 (M09), MKH 7017 (M10) and 4-methoxy saccharin. The laboratory results on the transformation of the major transformation products in soil showed that depending on the chemical structure and soil type investigated these transformation products are non-persistent to moderately persistent in soil, with the exception of KTS 9357 (M08), which is persistent.

The mobility data and the comparison of propoxycarbazone-sodium with the Cohen et al. (1984) criteria and the groundwater ubiquity score (GUS; Gustafson, 1989), which both characterize leaching potential based on physico-chemical properties and laboratory data, indicate propoxycarbazone-sodium has the potential to leach under certain circumstances. Under field conditions; however, terrestrial field dissipation and lysimeter studies demonstrated relatively quick dissipation and little vertical movement of propoxycarbazone-sodium and its transformation products down the soil profile. The concern for leaching of propoxycarbazone-sodium is low under the proposed use pattern.

Propoxycarbazone-sodium may enter into the aquatic environment through spray drift or run-off. In aquatic environments, propoxycarbazone-sodium is not expected to partition to sediment or bioaccumulate in aquatic organisms. Phototransformation is not an important route of dissipation

for propoxycarbazone-sodium in the aquatic environment. Propoxycarbazone-sodium can be transformed by aerobic and anaerobic microorganisms in aquatic environments and can span the full range of pesticide persistence classifications from non-persistent to persistent. Propoxycarbazone-sodium is not expected to volatilize from water or moist soils.

Environmental fate data for propoxycarbazone-sodium are summarized in Appendix I, Tables 7 and 8 (fate and behaviour of propoxycarbazone-sodium in terrestrial and aquatic environments, respectively). The chemical names and structures of propoxycarbazone-sodium transformation products formed in the environment, as well as a summary of their occurrence in environmental fate studies, are presented in Appendix I, Table 9.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats, including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1 for most species, 0.4 for pollinators and 2 for beneficial arthropods). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A risk assessment for propoxycarbazone-sodium and its transformation products (based on available toxicity data for transformation products) was conducted for terrestrial organisms. For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for terrestrial invertebrates, birds and mammals when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. Risk quotients for propoxycarbazone-sodium and its transformation products were calculated based on the highest maximum seasonal application rate of 45 g a.i./ha. A summary of terrestrial toxicity data for propoxycarbazone-sodium is presented in Appendix I, Table 4 and the accompanying risk assessment is presented in Appendix I, Table 11 for terrestrial organisms other than birds and mammals, and Appendix I, Table 12 for birds and mammals. The assessment of potential risk from spray drift is presented in Appendix I, Table 15.

As multiple EC_{50} values were available for terrestrial vascular plants, the program ETX 2.0 was used to generate species sensitivity distributions (SSDs) based on normally distributed toxicity data. The hazardous concentration to 5% of the species (HC_5) was then calculated for both vegetative vigour and seedling emergence from their respective SSDs. The HC_5 is the concentration that is theoretically protective for 95% of species. At the HC_5 exposure level, 5% of all species will be exposed to a concentration which exceeds their LC_{50} toxicity value. The variability around the fraction of species affected value is indicated by the lower and upper confidence limits, which indicates the minimum and maximum percent of species that may be affected at the HC_5 value. The HC_5 values were used to calculate the risk quotients for terrestrial vascular plants instead of the most sensitive species tested. This provides a more scientifically robust endpoint, which uses all of the data.

Earthworms: The risk quotient for earthworms resulting from acute and chronic exposure to propoxycarbazone-sodium and its transformation products do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose an acute or chronic risk to earthworms.

Bees: The risk quotients for both acute contact and oral exposure routes were all below the LOC, indicating propoxycarbazone-sodium is not expected to pose a risk to pollinators. Bee larval toxicity studies are not required as larval bee toxicity is not expected from exposure to propoxycarbazone-sodium based on; the mode of action, a lack of effects observed in adult bees, and minimal effects observed for beneficial arthropods at environmentally relevant concentrations.

Beneficial arthropods: The risk quotients for predatory and parasitic arthropods resulting from exposure to propoxycarbazone-sodium do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to predatory and parasitic arthropods.

Birds: The risk quotients for birds resulting from acute and reproductive exposure to propoxycarbazone-sodium do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to birds.

Mammals: The risk quotients for mammals resulting from acute and reproductive exposure to propoxycarbazone-sodium do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to mammals.

Vascular plants: Using the HC_5 values from the SSDs for seedling emergence and vegetative vigour, the calculated risk quotients exceed the LOC at the screening level. The risk to terrestrial vascular plants was further characterized by looking at off-field exposure from drift. Based on the risk quotients using the off-field EECs from drift, the LOC for terrestrial vascular plants was still exceeded. A buffer zone of 1 metre will be required on the propoxycarbazone end-use product label to protect non-target terrestrial vascular plants.

4.2.2 Risks to Aquatic Organisms

A risk assessment for propoxycarbazone-sodium and its transformation products (based on available toxicity data for transformation products) was conducted for freshwater and marine aquatic organisms. A summary of aquatic toxicity data for propoxycarbazone-sodium and its transformation products is presented in Appendix I, Table 13.

For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used for aquatic plants and invertebrates, and fish species, respectively, when calculating risk quotients (RQs). No uncertainty factors are applied to chronic NOEC endpoints. For groups where the level of concern (LOC) is exceeded (i.e. RQ $\geq$1), a refined Tier 1 assessment is conducted to determine risk resulting from spray drift and runoff separately. Risk quotients for propoxycarbazone-sodium and its transformation products were calculated based on the highest maximum seasonal application rate of 45 g a.i./ha. The calculated risk quotients for propoxycarbazone-sodium are summarized in Appendix I, Table 14 (screening level), Table 15 (spray drift) and Table 16 (runoff).

Invertebrates: The risk quotients for freshwater and marine invertebrates resulting from exposure to propoxycarbazone-sodium and its transformation products do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to freshwater and marine aquatic invertebrates.

Fish and amphibians: The risk quotients for freshwater and marine fish resulting from exposure to propoxycarbazone-sodium and its transformation products do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to fish.

The risk quotients for amphibians do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to amphibians.

Algae: The risk quotients for algae resulting from exposure to propoxycarbazone-sodium and its transformation products do not exceed the LOC at the screening level. The use of propoxycarbazone-sodium is not expected to pose a risk to algae.

Aquatic vascular plants: The screening level risk quotient for aquatic vascular plants resulting from exposure to propoxycarbazone-sodium slightly exceeds the LOC at the screening level. The risk to aquatic vascular plants was further characterized by looking at exposure from spray drift

and runoff. Based on the risk quotients using the off-field EECs from drift, the LOC for aquatic vascular plants is not exceeded. A default buffer zone of 1 metre will be required on the propoxycarbazone end-use product label to protect non-target aquatic vascular plants. Based on the risk quotients using the EECs from runoff, the LOC for aquatic vascular plants was exceeded. Label statements to mitigate risk from runoff into aquatic habitats will be required on the end-use product label for propoxycarbazone-sodium.

4.2.3 Incident Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the USEPA Ecological Incident Information System (EIIS). Specific information regarding the mandatory reporting system regulations that came into force April 26, 2007 under the *Pest Control Products Act* can be found at http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

Propoxycarbazone-sodium is a new active ingredient pending registration for use in Canada, hence, there were no environment incidents involving this active ingredient in the PMRA database, as of 24 June 2015. The USEPA's Ecological Incident Information System (EIIS) was also queried for environmental incidents. There were 30 incident reports available in the EIIS database for the active propoxycarbazone-sodium, from 2005 to 2012. All incidents in the EIIS database related to crop injury to wheat. No environmentally relevant incident reports were found for propoxycarbazone-sodium. When products containing propoxycarbazone-sodium are registered in Canada, the PMRA will monitor for incident reports.

5.0 Value

5.1 Consideration of Benefits

Wheat (winter, spring and durum combined) is Canada's most economically important field crop, individually out-producing all other cereal, pulse, oilseed and hay crops. Downy brome and Japanese brome are both winter annual members of the grass family that typically germinate in late summer or fall following precipitation and overwinter in a vegetative state. Given the biology of these two brome species, they can be problematic for winter wheat producers since they can compete effectively against winter wheat by resuming growth in the early spring before the winter wheat does, using soil moisture at shallow depths, and blooming early in the growing season prior to the winter wheat, giving them a competitive advantage.

At present, four herbicide active ingredients are registered for use in western Canada for the post-emergent (to the crop) control or suppression of downy brome and Japanese brome in winter wheat (refer to Appendix I, Table 18) for a list of active ingredients / products that are currently registered for the control of these weeds). However, there are limitations associated with each of these alternatives, as described below:

- Metribuzin: may only be applied to the Norstar variety of winter wheat, and controls only downy brome.

- Pyroxsulam: controls Japanese brome and suppresses downy brome in spring and durum wheat; in winter wheat it only controls (fall application) or suppresses (spring application) downy brome.
- Imazamox: may only be used in Clearfield (imazamox-tolerant) wheat varieties, and suppresses only Japanese brome.
- Thiencarbazone-methyl: suppresses or controls only Japanese brome.

Propoxycarbazone-sodium, the active ingredient of MKH6561 70WG Herbicide, provides an additional choice within the Group 2 herbicides for downy brome and Japanese brome control. The use of MKH6561 70WG Herbicide will not restrict the sequential use of other chemicals of alternate modes of action for control of weeds not controlled by the product alone. Propoxycarbazone-sodium is compatible with integrated pest management practices, including chemical and non-chemical options.

Propoxycarbazone-sodium is an ALS inhibitor belonging to the chemical family of sulfonylaminocarbonyl-triazolinones, and is classified as a Group 2 herbicide active ingredient. While Group 2 resistant weed biotypes have been well documented across Canada, managing the development and spread of these resistant biotypes is possible. To date, there has only been one documented case globally of downy brome having resistance to Group 2 herbicides. For Japanese brome, there has been only one documented case globally for resistance to Group 2 herbicides.

To mitigate the development / spread of Group 2 resistant weed biotypes, a number of methods can be employed, including the use of non-Group 2 herbicides, tank mixing with herbicides from a different herbicide Group (i.e. different mode of action), implementing integrated pest management practices and preventing the movement of resistant weed seeds to other fields.

5.2 Effectiveness Against Pests

Value information submitted for review included efficacy data from 41 small-scale field trials conducted in Canada and in the USA between 1993 and 2010, as well as rationales and use history information. The provided information demonstrated that acceptable control or suppression of the grassy weeds Japanese brome and downy brome as well as all labelled broadleaf weeds would be expected when MKH 6561 70WG Herbicide is applied as per the label directions in the fall or spring to winter wheat grown in western Canada.

5.3 Non-Safety Adverse Effects

Value information submitted for review included host crop tolerance data from 21 small scale field trials (five of which had yield measurements taken) conducted in the USA between 1994 and 1998, as well as use history information. The provided information demonstrated that acceptable winter wheat tolerance would be expected when MKH 6561 70WG Herbicide is applied as per the label directions in the fall or spring.

Value information submitted for review included rotational crop tolerance data from 6 small scale field trials (two of which had yield measurements taken) conducted in the USA between 1999 and 2006, as well as use history information. The provided information demonstrated that acceptable rotational crop (i.e. winter wheat and spring wheat) tolerance would be expected when planted 10 months after a MKH 6561 70WG Herbicide application.

5.4 Supported Uses

The claims of control or suppression of downy brome, Japanese brome and select annual broadleaf weeds in winter wheat grown in western Canada, with either a spring or fall application, are supported. Refer to Appendix I, Table 19 for details of the supported uses.

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*].

During the review process, propoxycarbazone-sodium and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria (Table 17 of Appendix I). The PMRA has reached the following conclusions:

- Propoxycarbazone-sodium does not meet TSMP Track 1 criteria, and is not considered a TSMP Track 1 substance. See Table 17 of Appendix I for comparison with Track 1 criteria.
- The major transformation products of propoxycarbazone-sodium do not meet TSMP Track 1 criteria, and are not considered TSMP Track 1 substances.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and 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* maintained in the *Canada Gazette*.[6] The list

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

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette,* Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

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* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade propoxycarbazone-sodium does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*
- The end-use product, MKH 6561 70WG Herbicide, does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

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

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for propoxycarbazone-sodium is adequate to define the majority of toxic effects that may result from exposure. In short- and long-term studies on laboratory animals, general systemic toxicity was observed. The effects included lower food consumption and body-weight gains, increased water intake, and, in the rat, irritation of the forestomach epithelium. There was no evidence of genotoxicity or, in rats and mice, carcinogenicity. There was no evidence of developmental toxicity in the rat. In the rabbit, abortions occurred at high doses and late in the gestation period, which were associated with maternal toxicity. The rat reproductive toxicity study demonstrated slight effects on reproductive parameters with an alteration the estrous cycle. Propoxycarbazone-sodium was not neurotoxic.

The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Provided that the required PPE is worn and that all label restrictions are followed, mixers, loaders and applicators handling MKH 6561 70WG Herbicide, as well as workers re-entering treated winter wheat fields to do scouting, are not expected to be exposed to levels of propoxycarbazone-sodium that will result in health risks of concern. Bystander exposures are expected to be negligible.

The nature of the residues in plants and animals is adequately understood. The residue definition is propoxycarbazone and the 2-hydroxypropoxy metabolite in plant matrices and the residue

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7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

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

definition is propoxycarbazone in animal matrices. The proposed use of propoxycarbazone-sodium on winter wheat does not constitute a health risk of concern for chronic dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient residue data have been reviewed to recommend MRLs. The PMRA recommends that the following MRLs be specified for residues of propoxycarbazone.

Commodity	Recommended MRL (ppm)
Fat, meat, meat byproducts (except kidney) of cattle, goat, horse and sheep	0.05
Kidney of cattle, goat, horse and sheep	0.07
Milk	0.01

7.2 Environmental Risk

The use of MKH 6561 70WG Herbicide, containing the active ingredient, propoxycarbazone-sodium, may pose a risk to non-target terrestrial and aquatic vascular plants. As a result, buffer zones to protect sensitive terrestrial and aquatic habitats from spray drift and label statements to inform users of potential risks to the environment are required.

7.3 Value

The registration of propoxycarbazone-sodium will provide winter wheat growers in western Canada a chemical control option for two difficult to control grassy weeds, downy brome and Japanese brome, as well as a number of specific annual broadleaf weed species. It offers flexibility in terms of application timing (i.e. fall vs. spring application), and will not restrict the sequential use of other herbicide products for the control of weeds not controlled by propoxycarbazone-sodium alone.

8.0 Proposed Regulatory Decision

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 Propoxycarbazone-sodium Technical Herbicide and MKH 6561 70WG Herbicide, containing the technical grade active ingredient propoxycarbazone-sodium, to control specific broadleaf weeds, including downy brome and Japanese brome in winter wheat in western Canada.

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.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with the active ingredient propoxycarbazone-sodium on the skin or through inhalation of spray mists, all workers handling MKH 6561 70WG Herbicide, including applicators, must wear a long-sleeved shirt, long pants, shoes and socks. In addition, workers mixing and loading the product, or involved in equipment clean-up and repairs, must wear chemical-resistant gloves, rubber boots and protective eyewear. Furthermore, standard label statements to protect against drift during application have been added to the label and workers re-entering freshly treated wheat fields to perform postapplication activities, such as scouting, are required to respect the restricted-entry interval (REI) of 12 hours

Environment

To minimize potential risks to non-target terrestrial and aquatic plants, label statements and no-spray buffer zones to protect sensitive terrestrial and aquatic habitats are to be specified on the end-use product label.

To mitigate potential exposures via spray drift, buffer zones of 1 metre are required on the end-use product label to protect sensitive terrestrial and aquatic habitats.

List of Abbreviations

µg	micrograms
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
DF	dry flowable
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ER_{25}	effective rate for 25% of the population
g	gram
ha	hectare(s)
HDT	highest dose tested
Hg	mercury
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
km	kilometre
K_{oc}	organic-carbon partition coefficient
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
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
mg	milligram
mL	millilitre
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
N/R	not required
NZW	New Zealand white
OC	organic carbon content
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
RSD	relative standard deviation
SC	soluble concentrate
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference (PMRA #)
Plant	N/A	Reviewed by Exposure Assessment Food of HED			
Animal	N/A	Reviewed by Exposure Assessment Food of HED			
Soil	N/A	Parent	HPLC-MS	1 ppb	2375455, 2375456
soil	N/A	II, III, IV, V, VI, VII, VIII	HPLC-MS	1 ppb	2375455, 2375456
Sediment	N/A	The soil method can be accepted for sediment.			2375457
Drinking water	N/A	Parent	HPLC-UV	0.05 µg/L	2375460
Surface water	N/A	Parent	HPLC-UV	1.0 µg/L	2375460

Table 2 Toxicity Profile of MKH 6561 70WG Herbicide

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

Acute toxicity	Study Results
Acute Oral LD_{50} Rat PMRA# 2376426	LD_{50} >2000 mg/kg bw **Low toxicity**
Acute Dermal LD_{50} Rat PMRA# 2376428	LD_{50} >2000 mg/kg bw **Low toxicity**
Acute Inhalation LC_{50} Rat PMRA# 2376431	LC_{50} > 4995 mg/L **Low toxicity**
Eye Irritation Rabbit PMRA# 2376433	MAS (24-72 hours) = 0.0/110 **Non-Irritating**
Dermal Irritation Rabbit PMRA# 2376435	MAS (24-72 hours) = 0.0/8.0 **Non-Irritating**
Skin Sensitization (Buehler patch test) Guinea Pig PMRA# 2376438	No dermal reaction for test and naïve control Positive control, 55% of test animals exhibited dermal reactions. **Non-Sensitizer**

Table 3 Toxicity of Propoxycarbazone (MKH 6561) and Metabolites/Impurities

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

Species, strain (test compound)	Study Results
Metabolism/Toxicokinetics – TGAI (MKH 6561)	
Metabolism Rat, Wistar PMRA# 1654848, 1653836, 1653857 Triazolinon-3-^{14}C]MKH 6561 or [Phenyl-UL-^{14}C]MKH 6561. Triazole-labelled MKH 6561	**Absorption:** rapid but incomplete (~21-31%); plasma peak concentrations at 1h post-dosing; T_{max} = 0.33 - 0.81 h **Distribution:** rapid, biphasic (~1 and 11 h post-dosing), mainly in gut, liver, and kidneys; but the level declined rapidly; no evidence of bioaccumulation. **Excretion:** rapid; mainly in feces (64-83%); urinary elimination secondary (~21-31%); negligible via expired air (<0.15%). **Metabolism:** minimal; unchanged parent compound the main compound excreted.
Acute toxicity – TGAI (MKH 6561)	
Acute Oral LD_{50} Rat, Wistar PMRA# 1654546	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute Dermal LD_{50} Rat, Wistar PMRA# 2375419	LD_{50} >5000 mg/kg bw **Low toxicity**
Acute Inhalation LC_{50} Rat, Wistar PMRA# 2375419	LC_{50} > 5030 mg/L **Low toxicity**
Eye Irritation Rabbit, New Zealand White PMRA# 2375424	MAS (24-72 hours) = 0.22/110 **Minimally Irritating**
Skin Irritation Rabbit, New Zealand White PMRA# 2375424	MAS (24-72 hours) = 0.3/8.0 **Minimally Irritating**
Skin Sensitization (Maximization test of Magnusson and Kligman) Guinea Pig, Dunkin Hartley PMRA# 2375427	No dermal reaction for test and naïve control **Non-Sensitizer**
Short-term toxicity – TGAI (MKH 6561)	
28-Day dietary Rat, Wistar PMRA# 1654563	A NOAEL was not established in this range-finding study. No effects observed
28-Day dermal Rat, Wistar PMRA# 2375438	A NOAELwas not established in this supplemental study. Only one dose was examined, only minimal organ histopathology was conducted. Epididymides, ovary and uterus weights were missing, and the age of the animals used were outside the range of the guideline recommendation.

5-week dietary Mouse, B6C3F$_1$ PMRA# 1654560	A NOAEL was not established in this range-finding study. 10000 ppm (5579.4 mg/kg bw/d): ↑ food consumption, ↓ bwg (♂)
64-Day dietary Dog, Beagle PMRA# 1654595	A NOAEL was not established in this range-finding study. 4000 ppm (mg/kg bw/d equivalent not reported): ↑ hepatic cytochrome P-450 activity (♂) ↑ hepatic N-demethylase activity considered adaptive response not adverse (♀)
14-Week dietary Mouse, B6C3F$_1$ PMRA# 1654579	NOAEL: ♂ = 625 ppm (205 mg/kg bw/d) ♀ = 2500 ppm (1159 mg/kg bw/d) LOAEL: ♂ = 2500 ppm (860 mg/kg bw/d). Effects included ↓ bw and ↑ food consumption ♀ = 10000 ppm or 5109 mg/kg bw/d. Effects included ↓ bw.
14-Week dietary with 4-week recovery Rat, Wistar PMRA# 1654568	NOAEL = 4000 ppm ♂= 286, ♀ = 351 mg/kg bw/d LOAEL: 20000 ppm ♂ = 1508, ♀ = 1770 mg/kg bw/d. Effects included forestomach irritation.
1-Year dietary Dog, Beagle PMRA# 1654604	NOAEL: 10000 ppm ♂ = 258, ♀ = 236 mg/kg bw/d LOAEL: 25000 ppm ♂ = 631, ♀ = 605 mg/kg bw/d. Effects included ↓ food efficiency.
Chronic toxicity and oncogenicity – TGAI (MKH 6561)	
107-Week dietary oncogenicity Mouse, B6C3F$_1$ PMRA# 1654621	NOAEL = 1400 ppm ♂ = 369; ♀ = 627 mg/kg bw/d LOAEL = 7000 ppm ♂ = 1881; ♀ = 3106 mg/kg bw/d. Effects included ↓ bw and bwg No evidence of oncogenicity
2-Year dietary/oncogenicity Rat, Fischer 344 PMRA# 1654648	NOAEL = 1000 ppm ♂ = 34; ♀ = 49 mg/kg bw/d LOAEL = 10000 ppm ♂ = 459; ♀ = 525 mg/kg bw/d. Effects included ↓ bwg No evidence of oncogenicity
Reproduction and developmental toxicity – TGAI (MKH 6561)	
1-Generation reproductive toxicity Rat, Wistar PMRA# 1654751	NOAELs were not established in this range-finding study. Parental systemic toxicity: 20000 ppm (1229.7 mg/kg bw/d): ♂ - Effects included ↓ bwg (wk 0-1), ↑ bwg (wk 1-2) Offspring toxicity: No effects observed Reproductive toxicity: 20000 ppm (1542.2 mg/kg bw/d): Effects included ↓ litter size, ↓ ♂ pups
2-Generation reproductive toxicity Rat, Wistar PMRA# 1654755	Parental systemic toxicity: NOAEL ♂ = 1000 ppm (75 mg/kg bw/d); ♀ = 4000 ppm (374 mg/kg bw/d) LOAEL: ♂ = 4000 ppm (297 mg/kg bw/d). Effects included microscopic lesions in forestomach; ♀ = 16000 ppm (1605 mg/kg bw/d). Effects included ↑ food intake, ↓ food efficiency Offspring toxicity: NOAEL = 16000 ppm; ♂ = 1231, ♀ = 1605 mg/kg bw/d (HDT) LOAEL Not established. Reproductive toxicity: NOAEL ♂ = 16000 ppm (1231 mg/kg bw/d) (HDT); ♀ = 4000 ppm (374 mg/kg bw/d) LOAEL ♂ Not established / 16000 ppm (1605 mg/kg bw/d) ♀ -Effect included ↑ metestrous/diestrous

Developmental toxicity Rat, Wistar PMRA# 1654774	Maternal and developmental toxicity NOAEL = 1000 mg/kg bw/d (HDT) LOAEL Not established No evidence of teratogenicity
Developmental toxicity Rabbit, Himalayan PMRA# 1654787	Maternal and developmental toxicity NOAEL = 100 mg/kg bw/d LOAEL = 500 mg/kg bw/d. Effects included ↑ abortion, ↓ bw and GI tract effects. Developmental toxicity: NOAEL = 100 mg/kg bw/d LOAEL = 500 mg/kg bw/d. Effects included delayed fetal growth, ↑ abortion. No evidence of teratogenicity
Neurotoxicity – TGAI (MKH 6561)	
Acute oral Rat, Wistar PMRA# 2375440	NOAEL: Systemic ♂ = 2000, ♀ = 800 mg/kg bw Neurotoxicity ♂♀ = 2000 mg/kg bw LOAEL: ♂ Not established; ♀ =2000 mg/kg bw. Effect included ↓ bwg.
Subchronic neurotoxicity (90-Day) Rat, Wistar PMRA# 2375442	NOAEL: Systemic and neurotoxicity ♂♀ = 20000 ppm. ♂ = 1321 mg/kg bw/d ♀ = 1651 mg/kg bw/d LOAEL: Systemic ♂♀ = not established No evidence of neurotoxicity
Immunotoxicity – TGAI (MKH 6561)	
Plaque-Forming-Cell Assay Rat, Wistar ♂ PMRA#2375447	NOAEL = 20000 ppm (2144 mg/kg bw/d) (HDT) LOAEL Not established. No effects were observed.
Genotoxicity – TGAI (MKH 6561)	
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 PMRA# 1654801	Cytotoxicity: ≥200 µg/plate **Negative**
Gene mutations in mammalian cells *in vitro* Chinese hamster V79 cells (HGPRT locus) /forward mutation in mammalian cells PMRA# 1654826	Cytotoxicity: nil **Negative**
Chromosome aberrations *in vitro* Chinese hamster V79 cells PMRA# 1654821	Cytotoxicity: nil **Negative**
In vitro unscheduled DNA synthesis Primary rat hepatocyte cultures PMRA# 1654824	Cytotoxicity: 75.3 and 48.2% relative survival at 2000 and 4000 µg/mL, respectively **Negative**

Genotoxicity - Metabolites /Impurities	
In vivo mouse micronucleus assay Mouse, CD-1 2500 mg/kg bw (intraperitoneal injection) **MKH 6561** PMRA# 1654828	**Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **MKH 8394** PMRA# 1654813	Cytotoxicity: weakly ≥ 50 µg/plate; more significant at 5000 µg/plate **Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **bissulfonylurea - MKH 6561**, a byproduct of MKH 6561 PMRA# 1654819	Cytotoxicity: ≥ 1581 µg/plate **Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **Methylthio analogue free acid - MKH 6561** PMRA# 1654807	Cytotoxicity: ≥ 4 µg/plate **Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **4-OH-saccharine** PMRA# 1654815	Cytotoxicity: ≥500 µg/plate; ≥158 µg/plate (TA102) **Negative**
Chromosome aberrations *in vitro* Chinese hamster V79 cells / **KTS 9061** PMRA# 1654828	Cytotoxicity: nil **Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **KTS 9061** PMRA# 1654804	Cytotoxicity: 1581 and 5000 µg/plate, all strains ≥ 500 µg/plate with TA102 and TA1535 **Negative**
Bacterial reverse mutation *Salmonella typhimurium* strains TA98, TA100, TA102, TA1535, TA1537 / **KTS 9304** PMRA# 1654810	**Negative**
Acute toxicity - Metabolites/impurities	
Acute oral Rat, Wistar (**bissulfonylurea-MKH 6561**) PMRA# 1654548	LD_{50} > 5000 mg/kg bw **Low toxicity**

Acute oral Rat, Wistar (**KTS 9061**) PMRA# 1654550	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute oral Rat, Wistar (**MKH 8394**) PMRA# 1654553	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute oral Rat, Wistar (**4-OH-saccharine**) PMRA# 1654555	LD_{50} > 5000 mg/kg bw **Low toxicity**
Acute oral Rat, Wistar (**methylthio analogue free acid – MKH 6561**) PMRA# 1654558	LD_{50} > 5000 mg/kg bw **Low toxicity**
Short-term Toxicity - Metabolite/impurities	
28-Day dietary Rat, Wistar / **KTS 9061** PMRA# 1654589	A NOAEL was not established in this supplemental study. No effects on clinical signs, food and water intake, bw, bwg, FOB, hematology, clinical chemistry, urinalysis, organ weights, gross and histopathology at 880 mg/kg bw/d ♀, 905 mg/kg bw/d ♂ (HDT)

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for propoxycarbazone

Exposure scenario	NOAEL, mg/kg bw/d	Study	Endpoint	CAF[1]	MOE[2]
Acute dietary (ARfD), all population	Not required. No endpoint of concern attributed to a single exposure.				
Chronic dietary (ADI), all population	75	Rat, 2 generation reproductive toxicity study	LOAEL = 297 mg/kg bw/d Epithelial vacuolation of fore-stomach (stomach irritation)	100	-
ADI = 0.8 mg/kg bw/d					
Short-term dermal and inhalation	100	Rabbit developmental toxicity	LOAEL = 500 mg/kg bw/d GIT toxicity (enlarged cecum) and light coloured feces.	100	100
Intermediate-term dermal and inhalation	75	Rat, 2 generation reproductive toxicity study	LOAEL = 297 mg/kg bw/d Epithelial vacuolation of fore-stomach (stomach irritation)	100	100
Cancer	A cancer risk assessment was not required as there was no evidence of oncogenicity				

[1] CAF (Composite Assessment Factor) refers to the total uncertainty and *Pest Control Products Act* factors for dietary risk assessment.
[2] MOE refers to a target MOE for occupational assessment.
Since an oral NOAEL was selected a dermal absorption factor of 100% (default value) was used in a route-to-route extrapolation

Table 5 Integrated Food Residue Chemistry Summary

Only the relevant parts of this table are presented herein. i.e. DACO 7.3 (Storage Stability [Plants and Plant Products]), DACO 7.4.3 (Confined accumulation in rotational crops), and DACO 7.4.4 (Field crop rotational trials). For all other DACO parts, please refer to the Evaluation Report for Application Number 2008-4377 available in the Pesticides and Pest Management section of Health Canada's website (http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php), under Public Registry, Pesticide Product Information Database.

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Kale, Turnips and Wheat		**PMRA # 2376473**	
Radiolabel Position		[phenyl-UL-^{14}C] propoxycarbazone and [triazolinone-3-^{14}C] propoxycarbazone	
Test site		Outdoor and indoor above ground confined plots	
Formulation		Propoxycarbazone – formulation type not indicated	
Application rate and timing		Bare soil was treated at 45 g a.i./ha, and aged for 30, 120 and 365 days prior to planting spring wheat, turnip and kale seeds. Raw agricultural commodities (RACs) were harvested from each crop for each time interval except at the 30-day interval where kale and turnips failed to germinate.	
Metabolites Identified		**Total Radioactive Residues (TRRs) (ppm)**	
Matrices	**PBI (days)**	**[phenyl-UL-^{14}C]**	**[triazolinone-3-^{14}C]**
Wheat grain	30	0.007	0.006
	120	0.004	0.002
	365	0.005	0.005
Wheat forage	30	0.055	0.050
	120	0.011	0.016
	365	0.013	0.028
Wheat hay	30	0.105	0.129
	120	0.026	0.063
	365	0.046	0.106
Wheat straw	30	0.051	0.096
	120	0.045	0.073
	365	0.023	0.087
Turnip roots	120	<0.002	0.002
	365	<0.002	0.002
Turnip tops	120	0.004	0.018
	365	0.003	0.013
Kale	120	0.003	0.010
	365	0.007	0.014

Metabolites Identified		Major Metabolites (>10% of the TRRs)	Minor Metabolites (<10% of the TRRs)	Major Metabolites (>10% of the TRRs)	Minor Metabolites (<10% of the TRRs)
Matrices	**PBI (days)**	**[phenyl-UL-^{14}C]**		**[triazolinone-3-^{14}C]**	
Wheat grain	30	Pr-2-OH MKH 6561 (62%)	--	--	--
	120	--	--	--	--
	365	Not analysed			
Wheat forage	30	Pr-2-OH MKH 6561 (51%), saccharin (18%), saccharin conjugates (20%)	Unknown peak P2 (4%)	Pr-2-OH MKH 6561 (26%), Pr-2-OH NMT (22%), Pr-2-OH NMT Conjugates (32%)	Unknown peak T1 (4%), Unknown peak T4 (4%)
	120	Pr-2-OH MKH 6561 (46%), saccharin (37%)	--	Pr-2-OH MKH 6561 (13%), Pr-2-OH NMT (42%), Pr-2-OH NMT Conjugates (27%)	--
	365	Pr-2-OH MKH 6561 (48%), saccharin (40%)	--	Pr-2-OH MKH 6561 (10%), Pr-2-OH NMT (37%), Pr-2-OH NMT Conjugates (32%)	--
Wheat hay	30	Pr-2-OH MKH 6561 (65%), saccharin (15%), saccharin conjugates (10%)	--	Pr-2-OH MKH 6561 (18%), Pr-2-OH NMT (26%), Pr-2-OH NMT Conjugates (38%)	Unknown peak T1 (3%)
	120	Pr-2-OH MKH 6561 (57%), saccharin (17%), saccharin conjugates (15%)	--	Pr-2-OH MKH 6561 (13%), Pr-2-OH NMT (37%), Pr-2-OH NMT Conjugates (32%)	Unknown peak T1 (4%)
	365	Pr-2-OH MKH 6561 (43%), saccharin (26%)	Saccharin conjugates (9%), unknown peak P1 (2%)	Pr-2-OH NMT (30%), Pr-2-OH NMT Conjugates (43%)	Pr-2-OH MKH 6561 (9%), unknown peak T1 (4%)
Wheat straw	30	Pr-2-OH MKH 6561 (58%), saccharin conjugates (16%)	--	Pr-2-OH MKH 6561 (12%), Pr-2-OH NMT (10%)	Pr-2-OH NMT Conjugates (7%), unknown peak T1 (2%), Unknown peak T4 (4%)
	120	Pr-2-OH MKH 6561 (53%), saccharin (24%), saccharin conjugates (14%)	--	Pr-2-OH NMT (44%), Pr-2-OH NMT Conjugates (34%)	Pr-2-OH MKH 6561 (4%), unknown peak T1 (5%)
	365	Pr-2-OH MKH 6561 (32%), saccharin (29%)	--	Pr-2-OH MKH 6561 (14%), Pr-2-OH NMT (38%), Pr-2-OH NMT Conjugates (19%)	Unknown peak T1 (4%)
Turnip roots	120	--	--	--	--
	365	Not analysed.			
Turnip tops	120	Saccharin (21%), saccharin conjugates (19%), unknown peak P2 (16%)	--	--	--
	365	--	--	Pr-2-OH MKH 6561 (39%), unknown peak T4 (36%)	Pr-2-OH NMT (8%)

Kale	120	Propoxycarbazone (24%), saccharin (18%), unknown peak P2 (34%)	--	Pr-2-OH MKH 6561 (28%), Pr-2-OH NMT Conjugates (12%), unknown peak T4 (24%)	--
	365	--	--	Pr-2-OH MKH 6561 (48%), unknown peak T4 (36%)	--

FREEZER STORAGE STABILITY | **PMRA # 2420678**

Plant matrices: Turnips (tops and roots) and mustard greens

The freezer storage stability data indicate that residues of propoxycarbazone and the 2-hydroxypropoxy metabolite are stable at <-15°C for 12 months.

RESIDUE DATA IN ROTATIONAL CROPS | **PMRA # 2376475**

Wheat, Turnips and Mustard greens

Three field trials on turnips, mustard greens and wheat were conducted during the 1997-1999 growing seasons in NAFTA Growing Regions 2, 5 and 10. At each trial location, a single broadcast soil application of MKH 6561 70WG (a wettable granule formulation) was made at a rate of 45 g a.i./ha. A cover crop was planted just before application in most of the trials. The cover crop was disced and tilled into the soil prior to planting the rotational crops, at 1, 4, 8 and 12 months following the application of MKH 6561 70WG to the soil. Raw agricultural commodities (RACs) of all rotational crops were harvested at earliest maturity. Total propoxycarbazone residues were <0.01 ppm in all matrices at all PBIs. Mustard green samples were not available for the 1-month plant-back interval due to phytotoxicity.

Commodity	Total Application Rate (g a.i./ha)	PBI (mths)	Total Residue Levels (ppm)					
			n	LAFT *	HAFT *	Median *	Mean *	SD *
Propoxycarbazone-sodium + Pr-2-OH MKH 6561 (expressed as propoxycarbazone equivalents)								
Turnip tops and roots, mustard greens, and wheat forage, hay, grain and straw	45	1 - 12	2	<0.01	<0.01	<0.01	<0.01	n/a

* Values based on per-trial averages. LAFT = Lowest Average Field Trial, HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ. n = number of field trials.

Based on the fact that certain crops failed to germinate both in the confined and the field accumulation studies, plant-back intervals of 30 days for cereal and root crops, and of 120 days for leafy vegetables are recommended.

LIVESTOCK FEEDING – Dairy cattle | **PMRA #1654958**

Lactating dairy cows were orally administered propoxycarbazone-sodium via capsule at a dose level of 0.703, 2.07, 7.23 or 36.0 mg/kg (ppm) for 29 consecutive days. The dose levels of 0.703, 2.07, 7.23 and 36.0 ppm represent 0.2X, 0.6X, 2.0x and 10x, respectively, the estimated dietary burden for dairy cattle.

Matrix	Feeding Level (ppm)	n	Min	Max	Median	Mean	Standard Deviation
Whole milk*	0.703	3	<0.002	<0.002	<0.002	<0.002	n/a
	2.07	3	<0.002	<0.002	<0.002	<0.002	n/a
	7.23	3	<0.002	0.0044	0.0025	0.00293	0.000784
	36.0	3	0.0075	0.0255	0.0146	0.0148	0.00442
Liver	7.23	3	<0.05	<0.05	<0.05	<0.05	n/a
	36.0	3	<0.05	0.051	<0.05	0.0503	0.00058
Kidney	2.07	3	<0.05	<0.05	<0.05	<0.05	n/a
	7.23	3	<0.05	0.053	<0.05	0.051	0.00173
	36.0	3	0.135	0.288	0.176	0.200	0.0792

Muscle	7.23	3	<0.05	<0.05	<0.05	<0.05	n/a
	36.0	3	<0.05	<0.05	<0.05	<0.05	n/a
Fat	7.23	3	<0.05	<0.05	<0.05	<0.05	n/a
	36.0	3	<0.05	<0.05	<0.05	<0.05	n/a

* Data from 0.703 and 2.07 ppm are from Day 28 milk. Data for 7.23 and 36 ppm are from Days 4 – 28 when residues had plateaued.

Commodity	Feeding Level (ppm)	Highest Propoxycarbazone Residues (ppm)	MBD (ppm)	Anticipated Residues at MBD (ppm)
			Dairy	
Whole milk	36.0	0.0166	8.82	0.005
Whey	36.0	0.0163		n/a
Cream	36.0	0.0079		n/a
Fat	36.0	<0.05		0.05
Liver	36.0	0.051		0.05
Kidney	36.0	0.288		0.07
Muscle	36.0	<0.05		0.05

LIVESTOCK FEEDING – Laying hens	**PMRA # 2376480**

A hen feeding study waiver was supplied given that results from the poultry metabolism study demonstrated that residues would not be expected in edible poultry matrices in birds fed treated grain.

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (wheat)** **Rotational crops**	Propoxycarbazone and the 2-hydroxypropoxy metabolite [Pr-2-OH MKH 6561]		
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops** **Rotational crops**	Propoxycarbazone and the 2-hydroxypropoxy metabolite [Pr-2-OH MKH 6561]		
METABOLIC PROFILE IN DIVERSE CROPS	The profile in diverse crops cannot be determined, because only wheat was investigated.		
ANIMAL STUDIES			
ANIMALS	**Ruminant and Poultry**		
RESIDUE DEFINITION FOR ENFORCEMENT	Propoxycarbazone		
RESIDUE DEFINITION FOR RISK ASSESSMENT	Propoxycarbazone		
DIETARY RISK FROM FOOD AND WATER			
Basic chronic non-cancer dietary exposure analysis **ADI = 0.8 mg/kg bw/day** **Estimated chronic drinking water concentration = 0.088 mg/L [Level 1, groundwater]**	**POPULATION**	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone (%)	**Food and Drinking Water (%)**
	All infants < 1 year	<0.1	0.9
	Children 1–2 years	0.2	0.5

	Children 3 to 5 years	0.1	0.4
	Children 6–12 years	0.1	0.3
	Youth 13–19 years	<0.1	0.2
	Adults 20–49 years	<0.1	0.2
	Adults 50+ years	<0.1	0.2
	Females 13-49 years	<0.1	0.2
	Total population	<0.1	0.3

Table 7 Fate and Behaviour of Propoxycarbazone-sodium in the Terrestrial Environment

Study type	Test material/test system	Value	Transformation products	Comments	Reference (PMRA#)
Abiotic transformation					
Phototrans-formation on soil	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] pH 7; 20 ºC	Half-life (continuous irradiation) = 51 days Half-life (environmental at 40ºN latitude) = 70 days	Major: None Minor: STJ 4934 (M05), MKH 7284 (M07), CO_2	Phototransfor-mation is not an important route of dissipation for propoxycarbazone-sodium.	2375468
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] pH 7; 20 ºC	Half-life (continuous irradiation) = 22 days Half-life (environmental at 40ºN latitude) = 38 days	Major: None Minor: MKH 7017 (M10), CO_2	Phototransfor-mation is not an important route of dissipation for propoxycarbazone-sodium.	2375467
Phototrans-formation in air	Propoxycarbazone-sodium is not expected to be volatile under field conditions based on vapour pressure, Henry's law constant and the volatility study. Transformation products of propoxycarbazone-sodium are not expected to be volatile under field conditions based on low detection of volatile organics in soil biotransformation studies. A phototransformation study in air is not required.				

Biotransformation					
Biotrans-formation in aerobic soil	**Propoxycarbazone-sodium**				
	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] Soil: Quincy loamy sand (Ephrata, Washington) 0.81% OM; pH 6.4; 20°C; 361 d	DT_{50} = 83.1 days ($t_{R\ IORE}$) DT_{90} = 276 days	Major: KTS 9357 (M08), CO_2 Minor: MKH 7018 (M04), STJ 4934 (M05), MKH 7284 (M07)	Propoxycarbazone-sodium is moderately persistent. Up to 20% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 49% and volatile organics averaged a total of 0.1%.	2375477
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] Soil: Quincy loamy sand (Ephrata, Washington) 0.86% OM; pH 6.8; 20°C; 365 d	DT_{50} = 103 days (SFO) DT_{90} = 344 days	Major: KTS 9304 (M09), MKH 7017 (M10), CO_2 Minor: None	Propoxycarbazone-sodium is moderately persistent. Up to 29% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 9% and volatile organics averaged a total of 0.2%.	2375480
	Propoxycarbazone-sodium [phenyl-^{14}C-labelled]	DT_{50} = 8.7 days (SFO) DT_{90} = 28.9 days	Major: STJ 4934 (M05), MKH 7284 (M07), KTS 9357 (M08), CO_2	Propoxycarbazone-sodium is non-persistent.	2375479

	Soil: Höfchen am Hohenseh silt (Germany) 2.62% OC; pH 7.2; 20°C; 184 d		Minor: MKH 7018 (M04), MKH 7283 (M06)	Up to 28% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 44%. Volatile organics were not detected.	
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] Soil: Höfchen am Hohenseh silt (Germany) 2.62% OC; pH 7.2; 20°C; 182 d	DT_{50} = 21 days (SFO) DT_{90} = 69.8 days	Major: MKH 7017 (M10), CO_2 Minor: MKH 7018 (M04), KTS 9304 (M09)	Propoxycarbazone-sodium is slightly persistent. Up to 66% of the applied radioactivity was not extracted from the soils by the final sampling interval. At study termination, CO_2 averaged a total of 13%. Volatile organics were not detected.	2375478
	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] Soil: Laacherhof Axxa loamy sand (Germany) 1.8% OC; pH 6.4; 20°C; 183 d	DT_{50} = 46.5 days (SFO) DT_{90} = 154 days	Major: STJ 4934 (M05), MKH 7284 (M07), KTS 9357 (M08), CO_2 Minor: MKH 7018 (M04), MKH 7283 (M06)	Propoxycarbazone-sodium is slightly persistent. Up to 20% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study	2375479

				termination, CO_2 averaged a total of 26%. Volatile organics were not detected.	
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] Soil: Laacherhof Axxa loamy sand (Germany) 1.8% OC; pH 6.4; 20°C; 182 d	DT_{50} = 16.1 days (SFO) DT_{90} = 53.5 days	Major: MKH 7017 (M10) Minor: MKH 7018 (M04), KTS 9304 (M09), CO_2	Propoxycarbazone-sodium is slightly persistent. Up to 62% of the applied radioactivity was not extracted from the soils by the final sampling interval. At study termination, CO_2 averaged a total of 9%. Volatile organics were not detected.	2375478
	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] Soil: Loamy sand standard BBA 2.2 (Germany) 2.48% OC; pH 6.3; 20°C; 184 d	DT_{50} = 223 days (SFO) DT_{90} = 742 days	Major: CO_2 Minor: MKH 7018 (M04), STJ 4934 (M05), MKH 7283 (M06), MKH 7284 (M07), KTS 9357 (M08)	Propoxycarbazone-sodium is persistent. Up to 8% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 22%. Volatile organics were not detected.	2375479
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled]	DT_{50} = 82.7 days (SFO) DT_{90} = 275 days	Major: MKH 7017 (M10) Minor: MKH 7018 (M04), KTS	Propoxycarbazone-sodium is moderately persistent.	2375478

	Soil: Loamy sand standard BBA 2.2 (Germany) 2.48% OC; pH 6.3; 20°C; 182 d		9304 (M09), CO_2	Up to 18% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 3%. Volatile organics were not detected.	
	Transformation Products				
	MKH 7284 (M07) [phenyl-^{14}C-labelled] Soil: Quincy loamy sand (Ephrata, Washington) 0.81% OM; pH 6.4; 20°C; 121 d	DT_{50} = 27.3 days (SFO)	M08 (max 37.0% AR, day 121)	MKH 7248 is slightly persistent. Up to 28% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 21% and volatile organics averaged a total of 0.3%.	2375475
	KTS 9357 (M08) [phenyl-^{14}C-labelled] Soils: Höfchen am Hohenseh silt (Germany) 2.62% OC; pH 7.8; 20°C; 123 d	Half-life for Höfchen and Laacherhof = 173 days, Quincy = stable	Höfchen M07 (max 16.6% AR, day 62) Laacherhof M07 (maximum 31.2% AR, day 62) Quincy M07 (max 5.7% AR, day 30)	KTS 9357 is persistent. Up to 7-13% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study	2375476

	Laacherhof Axxa loamy sand (Germany) 1.8% OC; pH 7.0; 20°C; 123 d Quincy loamy sand (Ephrata, Washington) 0.47% OC; pH 6.4; 20°C; 123 d			termination, CO_2 averaged a total of 2-7% and volatile organics averaged a total of 0.2%.	
	KTS 9304 (M09) [triazolinone-^{14}C-labelled] Soils: Höfchen am Hohenseh silt (Germany) 2.62% OC; pH 7.8; 20°C; 120 d Laacherhof Axxa loamy sand (Germany) 1.8% OC; pH 7.0; 20°C; 120 d Quincy loamy sand (Ephrata, Washington) 0.47% OC; pH 6.4; 20°C; 120 d	Half-life for Höfchen = 75 days, Laacherhof = 62 days, Quincy = stable	Laacherhof M10 (maximum 47.9% AR, day 62) Höfchen M10 (max 37.6% AR, day 62) Quincy M10 (max 14.6% AR, day 90)	KTS 9304 is moderately persistent to persistent. Up to 5-28% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination, CO_2 averaged a total of 0.2-5% and volatile organics averaged a total of 0.1%.	2375473
	MKH 7017 (M10) [triazolinone-^{14}C-labelled] Soil: Quincy loamy sand (Ephrata, Washington) 0.47% OC; pH 6.4; 20°C; 121 d	Half-life = 59 days	None	MKH 7017 is moderately persistent. Up to 51% of the applied radioactivity was not extracted from the soil by the final sampling interval. At study termination,	2375474

				CO_2 averaged a total of 9% and volatile organics averaged a total of 0.1%.	
	STJ 4934 (M05) [phenyl-^{14}C-labelled]	Höfchen DT_{50} = 3.1 days (SFO) Laacherhof DT_{50} = 22.3 days (SFO) Quincy DT_{50} = 3.0 days (SFO)	N/A	STJ 4934 is non-persistent to slightly persistent. Data from the studies of Ripperger *et al*., 1999 and Helfrich *et al*., 1999 were used to estimate the degradation rate of M05.	2375483
	MKH 7284 (M07) [phenyl-^{14}C-labelled]	Höfchen DT_{50} = 5.0 days (SFO) Laacherhof DT_{50} = 57.0 days (SFO)	N/A	MKH 7284 is non-persistent to slightly persistent. Data from the studies of Ripperger *et al*., 1999 were used to estimate the degradation rate of M07.	2375483
	MKH 7017 (M10) [triazolinone-^{14}C-labelled]	Höfchen DT_{50} = 38.7 days Laacherhof DT_{50} = 51.3 days	N/A	MKH 7017 is slightly persistent. Data from the studies of Ripperger *et al*., 1999 were used to estimate the degradation rate of M10.	2375482

Biotrans-formation in anaerobic soil	Propoxycarbazone-sodium [phenyl and triazolinone-^{14}C-labelled] Soil: Höfchen am Hohenseh silt (Germany) 2.5% OC; pH 6.9; 20°C; 150 d	DT_{50} = 185 days DT_{90} = 613 days (SFO – phenyl label) DT_{50} = 99.9 days DT_{90} = 332 days (SFO – troiazolinone label)	Major: MKH 7284 (M07), KTS 9357 (M08), MKH 7017 (M10), 4-methoxy saccharin (transformation product unique to this study), CO_2 Minor: None	Propoxycarbazone-sodium is persistent. The PMRA reviewer did not agree with the study author on when anaerobic conditions were met; therefore, half-lives calculated by the reviewer differ from those presented by the study author.	2375484
Mobility					
Adsorption / desorption in soil (Adsorption / desorption values were obtained in 5 soils: 2 USA soils and 3 German soils. Soils were used in other laboratory fate studies.)	Propoxycarbazone-sodium	BBA 2.2 (loamy sand) K_{FD} = 0.32 K_{FOC} = 12.9 Höfchen (silt) K_{FD} = 0.70 K_{FOC} = 23.9 Laacherhof (silt loam) K_{FD} = 0.25 K_{FOC} = 28.8 Ephrata (loamy sand) K_{FD} = 0.22 K_{FOC} = 59.1 Stilwell (silty clay loam) K_{FD} = 1.71 K_{FOC} = 106.2	N/A	Propoxycarbazone-sodium is classified as having a high to very high potential for mobility in soil.	2375489
	MKH 7018 (M04)	BBA 2.2 (loamy sand) K_{FD} = 0.19	N/A	MKH 7018 is classified as having a very	2375491

		K_{FOC} = 7.5 Höfchen (silt) K_{FD} = 0.24 K_{FOC} = 9.0 Laacherhof (silt loam) K_{FD} = 0.12 K_{FOC} = 13.7 Ephrata (loamy sand) K_{FD} = 0.10 K_{FOC} = 26.2 Stilwell (silty clay loam) K_{FD} = 0.61 K_{FOC} = 37.7		high potential for mobility in soil.	
	STJ 4934 (M05)	Not determined	N/A	STJ 4934 was not stable in aqueous solution; therefore, adsoption / desorption tests could not be performed and a column leaching test was conducted to assess its leaching potential.	2375495
	MKH 7283 (M06)	BBA 2.2 (loamy sand) K_{FD} = 0.003 K_{FOC} = 0.13 Höfchen (silt) K_{FD} = 0.053 K_{FOC} = 2.0 Laacherhof	N/A	MKH 7283 is classified as having a very high potential for mobility in soil.	2375493

		(silt loam) K_{FD} = 0.019 K_{FOC} = 2.16 Ephrata (loamy sand) K_{FD} = 0.003 K_{FOC} = 0.90 Stilwell (silty clay loam) K_{FD} = 0.110 K_{FOC} = 6.84			
	MKH 7284 (M07)	BBA 2.2 (loamy sand) K_{FD} = 0.13 K_{FOC} = 5.2 Höfchen (silt) K_{FD} = 0.12 K_{FOC} = 4.6 Laacherhof (silt loam) K_{FD} = 0.04 K_{FOC} = 5.2 Ephrata (loamy sand) K_{FD} = 0.02 K_{FOC} = 6.7 Stilwell (silty clay loam) K_{FD} = 0.25 K_{FOC} = 15.5	N/A	MKH 7284 is classified as having a very high potential for mobility in soil.	2375498
	KTS 9357 (M08)	BBA 2.2 (loamy sand) K_{FD} = 11.3 K_{FOC} = 456.9 Höfchen (silt) K_{FD} = 18.6 K_{FOC} = 867.5	N/A	KTS 9357 is classified as having a slight to medium potential for mobility in soil.	2375502

		Laacherhof (silt loam) K_{FD} = 20.0 K_{FOC} = 2324.3 Ephrata (loamy sand) K_{FD} = 7.53 K_{FOC} = 2033.8 Stilwell (silty clay loam) K_{FD} = 46.3 K_{FOC} = 2872.7			
	KTS 9304 (M09)	BBA 2.2 (loamy sand) K_{FD} = 0.26 K_{FOC} = 10.4 Höfchen (silt) K_{FD} = 1.35 K_{FOC} = 63.1 Laacherhof (silt loam) K_{FD} = 0.86 K_{FOC} = 99.9 Ephrata (loamy sand) K_{FD} = 2.04 K_{FOC} = 551.5 Stilwell (silty clay loam) K_{FD} = 3.90 K_{FOC} = 242.1	N/A	KTS 9304 is classified as having a low to very high potential for mobility in soil.	2375504
	MKH 7017 (M10)	BBA 2.2 (loamy sand) K_{FD} = 0.22 K_{FOC} = 8.9 Höfchen	N/A	MKH 7017 is classified as having a high to very high potential for mobility in soil.	2375500

		(silt) K_{FD} = 0.38 K_{FOC} = 14.5 Laacherhof (silt loam) K_{FD} = 0.18 K_{FOC} = 20.6 Ephrata (loamy sand) K_{FD} = 0.26 K_{FOC} = 69.6 Stilwell (silty clay loam) K_{FD} = 1.22 K_{FOC} = 75.7			
Soil leaching	Column leaching study STJ 4934 (M05) [phenyl-^{14}C-labelled] Quincy loamy sand (Ephrata, Washington) 0.47% OC; pH 6.4; 20°C; 48 h	K_{OC} = 35	N/A	STJ 4934 is classified as having a very high potential for mobility in soil.	2375506
	Aged column leaching study Propoxycarbazone-sodium [phenyl and triazolinone-^{14}C-labelled] Quincy loamy sand (Ephrata, Washington) 0.47% OC; pH 6.4; 20°C; 28-29 d	Total radioactive residues recovered in the leachates averaged 85.9-89.0% of the applied radioactivity: 76.5% propoxycarbazone-sodium 3.1-3.6% M04 0.8% M06 4.3% M07 0.0% M09	N/A	Propoxycarbazone-sodium and its transformation products, MKH 7018 (M04), MKH 7283 (M06), MKH 7284 (M07) and MKH 7017 (M10) have a high potential to leach. It is noted that the loamy sand used in this	2375507

		7.9% M10 The radioactive residue remaining in the soil column averaged 8-11% of the applied radioactivity.		study has a very low organic carbon content, resulting in a lower degradation rate for poxycarbazone-sodium and its transformation products.	
Field studies					
Field dissipation	Utah Single application of WG 70 formulation to wheat in May (49.5 g a.i./ha)	Half-life = 16.8 days	Major: None Minor: STJ 4934 (M05), MKH 7284 (M07), KTS 9357 (M08), MKH 7017 (M10)	Propoxycarbazone-sodium is slightly persistent.	2376494
	Kansas One application of WG 70 formulation at 32.9 g a.i./ha to bare soil in November and again in April (total of 65.8 g a.i./ha)	Half-life = 22.4 days	Major: None Minor: STJ 4934 (M05), MKH 7284 (M07), MKH 7017 (M10)	Propoxycarbazone-sodium is slightly persistent.	2376492
	Washington Single application of WG 70 formulation to bare soil in the spring (70 g a.i./ha)	Half-life = 44.4 days	Major: None Minor: STJ 4934 (M05), KTS 9357 (M08), KTS 9304 (M09)	Propoxycarbazone-sodium is slightly persistent.	2376489
	France, Germany, Great Britain Single application of	Northern France (silt loam soil, cropped) DT_{50} = 4.55 days	Major: STJ 4934 (M05), MKH 7017 (M10) Minor: STJ 4934 (M05), KTS 9357	Propoxycarbazone-sodium is non-persistent to slightly persistent.	2376498

	WG 70 formulation to wheat or bare soil in September (49.5 g a.i./ha)	DT_{90} = 30 days Germany (sandy loam soil, bare) DT_{50} = 9.6 days DT_{90} = 22 days Germany (silt loam soil, bare) DT_{50} = 13 days DT_{90} = 40 days Great Britain (sandy clay soil, cropped) DT_{50} = 26.6 days DT_{90} = 67 days Great Britain (sandy loam soil, cropped) DT_{50} = 9.4 days DT_{90} = 54 days	(M08)		
Field leaching	Lysimeter study Germany WG 70 formulation mixture of [phenyl and triazolinone-^{14}C-labelled] propoxycarbazone-sodium 70 g a.i./ha	Leachate: Total radioactive residues in the annual leachates were <0.1 µg/L. Propoxycarbazone-sodium as well as its transformation products	N/A		2376502

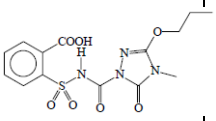
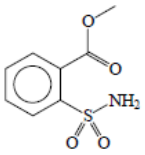
	spring application; single application in year 1 and 2; 2 lysimeters over 3 years Soil: Sandy loam (depth 0-0.7m); pH 6.1-6.4; 0.34-1.41% OC and loamy sand (depth 0.7-1.15 m); pH 6.3-6.6; 0.17-0.19% OC	were detected significantly below 0.1 µg/L for all test years. Soil core: Radioactivity in soil after three test years was 37% of the applied, 34% of which was located in the upper 0-30 cm soil layers. The main portion of total radioactive residues in the soil was comprised of bound residues (80%). No parent compound was present in the soil after study termination. The only transformation product identified, MKH 7017 (M10), was detected at 1.0 and 0.8 µg/kg in the 0-10 and 10-20 cm soil layers, respectively.			

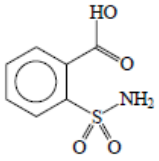
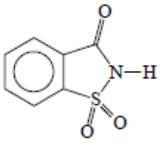
Table 8 Fate and Behaviour of Propoxycarbazone-sodium in the Aquatic Environment

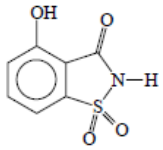
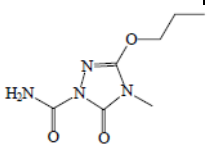
Study type	Test material/test system	Value	Transformation products	Comments	Reference (PMRA#)
Abiotic transformation					
Hydrolysis	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] pH 4, 7 and 9; 25ºC	Stable to hydrolysis	Major: STJ 4934 (M05) Minor: MKH 7284 (M07)	Hydrolysis is not an important route of dissipation for propoxycarbazone-sodium.	2375463
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] pH 4, 7 and 9; 25ºC	Stable to hydrolysis	Major: MKH 7017 (M10) Minor: None	Hydrolysis is not an important route of dissipation for propoxycarbazone-sodium.	2375464
Phototrans-formation in water	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] pH 7; 25 ºC	Half-life (continuous irradiation) = 16 days Half-life (environmental at 40ºN latitude) = 37 days	Major: MKH 7284 (M07) Minor: STJ 4934 (M05), CO_2	Phototransfor-mation is not an important route of dissipation for propoxycarbazone-sodium.	2375469
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] pH 7; 25 ºC	Half-life (continuous irradiation) = 42 days Half-life (environmental at 40ºN latitude) = 94 days	Major: MKH 7017 (M10) Minor: CO_2	Phototransfor-mation is not an important route of dissipation for propoxycarbazone-sodium.	2375470
	MKH 7284 (M07) [phenyl-^{14}C-labelled] pH 7; 25 ºC	Half-life (continuous irradiation) = 49 days Half-life (environmental at 40ºN latitude) = 117 days	Major: None Minor: CO_2	Phototransfor-mation is not an important route of dissipation for MKH 7284 (M07).	2375471

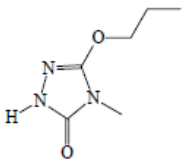
Biotransformation					
Biotrans-formation in aerobic water systems	Propoxycarbazone-sodium [phenyl and triazolinone-^{14}C-labelled] Test system: Hönniger Pond (Germany) 3.4% OC; pH 5.6; 20°C; 100 d Von Diergardt Lake (Germany) 0.4% OC; pH 6.7; 20°C; 100 d	Hönniger (total system) DT_{50} = 11.6 days (SFO – phenyl label) DT_{50} = 12.4 days (SFO – troiazolinone label) Von Diergardt (total system) DT_{50} = 189 days (SFO – phenyl label) DT_{50} = 207 days (SFO – troiazolinone label)	Major: MKH 7018 (M04), STJ 4934 (M05), MKH 7283 (M06), MKH 7017 (M10), CO_2 Minor: None	Propoxycarbazone-sodium is non-persistent to persistent.	2375486
Biotrans-formation in anaerobic water systems	Propoxycarbazone-sodium [phenyl-^{14}C-labelled] Test system: Ephrata, Washington 0.45% OC; pH 6.7; 20°C; 365 d	DT_{50} = 26.1 days (SFO – total system)	Major: MKH 7018 (M04), MKH 7283 (M06) Minor: CO_2	Propoxycarbazone-sodium is slightly persistent.	2375487
	Propoxycarbazone-sodium [triazolinone-^{14}C-labelled] Test system: Ephrata, Washington 0.45% OC; pH 6.7; 20°C; 365 d	DT_{50} = 28.4 days (SFO – total system)	Major: MKH 7018 (M04), MKH 7017 (M10) Minor: CO_2	Propoxycarbazone-sodium is slightly persistent.	2375488

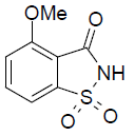
Table 9 Transformation Products of Propoxycarbazone-sodium Formed in the Environment

Code name and synonyms	Chemical name	Chemical structure	Study[1]			Max %AR (day)	%AR at study end (study length)[2]
M04 MKH 6561 carboxylic acid MKH 7018 MKH 8394	Benzoic acid, 2-(((4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl) amino)sulfonyl		Aerobic soil	Quincy loamy sand	Phenyl	1.2 (88)	0.5 (361)
					Triazolinone	nd	
				Höfchen am Hohenseh	Phenyl	0.3 (6)	nd (184)
					Triazolinone	0.4 (2)	nd (182)
				Laacherhof Axxa	Phenyl	2.1 (67)	nd (183)
					Triazolinone	0.3 (8)	nd (182)
				BBA 2.2	Phenyl	3.7 (184)	3.7 (184)
					Triazolinone	2.4 (43)	1.3 (182)
			Anaerobic soil	Höfchen am Hohenseh	na		
			Soil photolysis		nd		
			Aqueous photolysis		nd		
			Hydrolysis		nd		
			Aerobic aquatic	Hönniger	Phenyl	**71.6 (62)**	**47.4 (100)**
					Triazolinone	**67.8 (30)**	**48.3 (100)**
				Von Diergardt	Phenyl	0.21 (30)	0.16 (100)
					Triazolinone	0.1 (100)	0.1 (100)
			Anaerobic aquatic	Ephrata	Phenyl	**84.9 (120)**	**68.8 (365)**
					Triazolinone	**87.8 (90)**	**76.1 (365)**
M05 Sulfonamide methyl ester STJ 4934	Benzoic acid, 2-(aminosulfonyl)-, methyl ester CAS No.: 57683-71-3		Aerobic soil	Quincy loamy sand	Phenyl	4.1 (13)	0.2 (361)
					Triazolinone	nd	
				Höfchen am Hohenseh	Phenyl	**20.9 (6)**	0.6 (184)
					Triazolinone	nd	
				Laacherhof Axxa	Phenyl	**10.0 (67)**	4.0 (183)
					Triazolinone	nd	
				BBA 2.2	Phenyl	4.6 (184)	4.6 (184)
					Triazolinone	nd	
			Anaerobic soil	Höfchen am Hohenseh	na		
			Soil photolysis	Phenyl	pH 7 – irradiated	9.7 (11)	8.7 (18)
					pH 7 – dark	1.2 (7)	0.8 (18)
				Triazolinone	nd		
			Aqueous photolysis	Phenyl	pH 7 – irradiated	5.80 (7)	4.16 (19)
					pH 7 – dark	0.99 (19)	0.99 (19)
				Triazolinone	nd		
			Hydrolysi	Phenyl	pH 4	**16.6 (30)**	**16.6 (30)**

Code name and synonyms	Chemical name	Chemical structure	Study[1]			Max %AR (day)	%AR at study end (study length)[2]
			s		pH 7	nd	
					pH 9	nd	
				Triazolinone	nd		
			Aerobic aquatic	Hönniger	Phenyl	2.6 (1)	nd (100)
					Triazolinone	nd	
				Von Diergardt	Phenyl	**11.3 (100)**	**11.3 (100)**
					Triazolinone	nd	
			Anaerobic aquatic	Ephrata	na		
M06 Sulfonamide acid MKH 7283	Benzoic acid, 2-(aminosulfonyl) CAS No.: 632-24-6		Aerobic soil	Quincy loamy sand	Phenyl	nd	
					Triazolinone	nd	
				Höfchen am Hohenseh	Phenyl	5.0 (14)	nd (184)
					Triazolinone	nd	
				Laacherhof Axxa	Phenyl	1.8 (36)	nd (183)
					Triazolinone	nd	
				BBA 2.2	Phenyl	0.1 (15)	nd (184)
					Triazolinone	nd	
			Anaerobic soil	Höfchen am Hohenseh	na		
			Soil photolysis		nd		
			Aqueous photolysis		nd		
			Hydrolysis		nd		
			Aerobic aquatic	Hönniger	Phenyl	**19.4 (100)**	**19.4 (100)**
					Triazolinone	nd	
				Von Diergardt	Phenyl	1.6 (100)	1.6 (100)
					Triazolinone	nd	
			Anaerobic aquatic	Ephrata	Phenyl	**24.6 (365)**	**24.6 (365)**
					Triazolinone	na	
M07 Saccharin MKH 7284	1,2-Benzisothiazol-3(2H)-one, 1,1,dioxide CAS No.: 81-07-2		Aerobic soil	Quincy loamy sand	Phenyl	1.4 (88)	1.4 (361)
					Triazolinone	nd	
				Höfchen am Hohenseh	Phenyl	**26.6 (14)**	ND (184)
					Triazolinone	nd	
				Laacherhof Axxa	Phenyl	**18.3 (120)**	**15.6 (183)**
					Triazolinone	nd	
				BBA 2.2	Phenyl	2.0 (7)	1.4 (184)
					Triazolinone	nd	
			Anaerobic soil	Höfchen am Hohenseh	Phenyl	**35.5 (120)**	**26.4 (150)**
					Triazolinone	nd	
			Soil	Phenyl	pH 7 –	4.7 (18)	4.7 (18)

Code name and synonyms	Chemical name	Chemical structure	Study[1]			Max %AR (day)	%AR at study end (study length)[2]
			photolysis		irradiated		
					pH 7 – dark	nd	
				Triazolinone	nd		
			Aqueous photolysis	Phenyl	pH 7 – irradiated	**22.3 (19)**	**22.3 (19)**
					pH 7 – dark	3.76 (19)	3.76 (19)
				Triazolinone	nd		
			Hydrolysis	Phenyl	pH 4	1.19 (30)	1.19 (30)
					pH 7	3.26 (30)	3.26 (30)
					pH 9	3.78 (30)	3.78 (30)
				Triazolinone	nd		
			Aerobic aquatic	Hönniger	na		
				Von Diergardt	na		
			Anaerobic aquatic	Ephrata	na		
M08 4-hydroxysaccharin KTS 9357	1,2-Benzisothiazol-3(2H)-one, 4-hydroxy-,1,1,dioxide CAS No.: 80563-77-5		Aerobic soil	Quincy loamy sand	Phenyl	**13.8 (361)**	**13.8 (361)**
					Triazolinone	nd	
				Höfchen am Hohenseh	Phenyl	**19.5 (36)**	**17.5 (184)**
					Triazolinone	nd	
				Laacherhof Axxa	Phenyl	**21.9 (183)**	**21.9 (183)**
					Triazolinone	nd	
				BBA 2.2	Phenyl	1.8 (184)	1.8 (184)
					Triazolinone	nd	
			Anaerobic soil	Höfchen am Hohenseh	Phenyl	**15.7 (0)**	**15.2 (150)**
					Triazolinone	nd	
			Soil photolysis		nd		
			Aqueous photolysis		nd		
			Hydrolysis		nd		
			Aerobic aquatic	Hönniger	na		
				Von Diergardt	na		
			Anaerobic aquatic	Ephrata	na		
M09 N-methyl propoxy triazolinone amide	3H-1,2,4-Triazol-3-one-2-carboxamide-2,4-dihydro-4-methyl-5-		Aerobic soil	Quincy loamy sand	Phenyl	nd	
					Triazolinone	**16.1 (313)**	**16.0 (365)**
				Höfchen am Hohenseh	Phenyl	nd	
					Triazolinone	0.8 (28)	nd (182)
				Laacherhof	Phenyl	nd	

Code name and synonyms	Chemical name	Chemical structure	Study[1]			Max %AR (day)	%AR at study end (study length)[2]
KTS 9304	propoxy			Axxa	Triazolinone	0.8 (29)	nd (182)
				BBA 2.2	Phenyl	nd	
					Triazolinone	8.0 (93)	7.1 (182)
			Anaerobic soil	Höfchen am Hohenseh	na		
			Soil photolysis		nd		
			Aqueous photolysis		nd		
			Hydrolysis		nd		
			Aerobic aquatic	Hönniger	na		
				Von Diergardt	na		
			Anaerobic aquatic	Ephrata	na		
M10 N-methyl propoxy triazolinone MKH 7017	3H-1,2,4-Triazol-3-one, 2,4-dihydro-4-methyl-5-propoxy CAS No.: 145027-96-9		Aerobic soil	Quincy loamy sand	Phenyl	nd	
					Triazolinone	**28.7 (365)**	**28.7 (365)**
				Höfchen am Hohenseh	Phenyl	nd	
					Triazolinone	**32.0 (28)**	**14.0 (182)**
				Laacherhof Axxa	Phenyl	nd	
					Triazolinone	**43.9 (29)**	**19.9 (182)**
				BBA 2.2	Phenyl	nd	
					Triazolinone	**55.2 (182)**	**55.2 (182)**
			Anaerobic soil	Höfchen am Hohenseh	Phenyl	nd	
					Triazolinone	**54.1 (120)**	**44.5 (150)**
			Soil photolysis	Triazolinone	Phenyl	nd	
					pH 7 – irradiated	8.57 (18)	8.57 (18)
					pH 7 – dark	2.85 (0)	2.32 (18)
			Aqueous photolysis	Triazolinone	Phenyl	nd	
					pH 7 – irradiated	**13.6 (19)**	**13.6 (19)**
					pH 7 – dark	na	2.87 (19)
			Hydrolysis	Triazolinone	Phenyl	nd	
					pH 4	**13.9 (33)**	**13.9 (33)**
					pH 7	4.15 (33)	4.15 (33)
					pH 9	4.72 (33)	4.72 (33)
			Aerobic aquatic	Hönniger	Phenyl	nd	
					Triazolinone	**34.4 (100)**	**34.4 (100)**
				Von Diergardt	Phenyl	nd	
					Triazolinone	6.9 (100)	6.9 (100)
			Anaerobic aquatic	Ephrata	Phenyl	na	
					Triazolinone	**20.5 (196)**	**15.1 (365)**

Code name and synonyms	Chemical name	Chemical structure	Study[1]			Max %AR (day)	%AR at study end (study length)[2]
4-Methoxy saccharin	4-methoxy saccharin		Aerobic soil		na		
			Anaerobic soil	Höfchen am Hohenseh	Phenyl	**17.1 (14)**	0.0 (150)
					Triazolinone	nd	
			Soil photolysis		na		
			Aqueous photolysis		na		
			Hydrolysis		na		
			Aerobic aquatic		na		
			Anaerobic aquatic		na		
Carbon dioxide	Carbon dioxide CAS No.: 124-38-9	O=C=O	Aerobic soil	Quincy loamy sand	Phenyl	**49.0 (361)**	**49.0 (361)**
					Triazolinone	**13.0 (313)**	8.6 (365)
				Höfchen am Hohenseh	Phenyl	**44.2 (184)**	**44.2 (184)**
					Triazolinone	**12.6 (182)**	**12.6 (182)**
				Laacherhof Axxa	Phenyl	**26.3 (183)**	**26.3 (183)**
					Triazolinone	9.0 (182)	9.0 (182)
				BBA 2.2	Phenyl	**21.7 (184)**	**21.7 (184)**
					Triazolinone	2.6 (182)	2.6 (182)
			Anaerobic soil	Höfchen am Hohenseh	Phenyl	**13.5 (total at day 150)**	
					Triazolinone	7.6 (total at day 150)	
			Soil photolysis	Phenyl	pH 7 – irradiated	4.8 (11)	4.6 (18)
					pH 7 – dark	0.1 (18)	0.1 (18)
				Triazolinone	pH 7 – irradiated	9.01 (18)	9.01 (18)
					pH 7 – dark	0.16 (18)	0.16 (18)
			Aqueous photolysis	Phenyl	pH 7 – irradiated	6.08 (19)	6.08 (19)
					pH 7 – dark	na	0.03 (19)
				Triazolinone	pH 7 – irradiated	6.7 (19)	6.7 (19)
					pH 7 – dark	na	0.01 (19)
			Hydrolysis		na		
			Aerobic aquatic	Hönniger	Phenyl	**16.4 (100)**	**16.4 (100)**
					Triazolinone	1.6 (100)	1.6 (100)
				Von Diergardt	Phenyl	1.1 (100)	1.1 (100)
					Triazolinone	1.9 (100)	1.9 (100)
			Anaerobic aquatic	Ephrata	Phenyl	0.55 (272)	0.49 (365)
					Triazolinone	1.6 (273)	0.90 (365)

Code name and synonyms	Chemical name	Chemical structure	Study[1]	Max %AR (day)	%AR at study end (study length)[2]

[1] Refer to Tables 1 and 2 for study references
[2] In DAT (days after treatment)
AR = applied radioactivity
na = not analysed (either no reference standard used or minor non-volatile compounds which were not identified)
nd = not detected
Bolded when appearing at >10% (major transformation product)

Table 10 Toxicity of Propoxycarbazone-sodium and Major Transformation Products to Non-Target Terrestrial Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
Invertebrates					
Earthworm, *Eisenia foetida*	14d-Acute	Propoxycarbazone-sodium	LC_{50} >1000 mg a.i./kg dw soil	Not applicable	2375511
	56d-Chronic	EP – MKH 6561 70WG (70.7% a.i.)	NOEC ≥350 g a.i./ha or ≥1.39 mg a.i./kg dw soil (calculated assuming surface applied amount is in the volume of the test box)	Not applicable	2376506
	14d-Acute	STJ 4934 (M05)	LC_{50} >1000 mg/kg dw soil	Not applicable	2375514
	14d-Acute	MKH 7284 (M07)	LC_{50} >1000 mg/kg dw soil	Not applicable	2375513
	14d-Acute	MKH 7017 (M10)	LC_{50} >1000 mg/kg dw soil	Not applicable	2528378
	56d-Chronic	KTS 9304 (M09)	NOEC = 316 mg/kg dw soil	Not applicable	2528387
Bee, *Apis mellifera*	48h-Acute Oral	Propoxycarbazone-sodium	LC_{50} >319 µg a.i./bee	Relatively non-toxic	2375515
	48h-Acute Contact	Propoxycarbazone-sodium	LD_{50} >200 µg a.i./bee	Relatively non-toxic	
	48h-Acute Oral	EP – MKH 6561 70WG (70% a.i.)	LC_{50} >402 µg EP/bee LC_{50} >284 µg a.i./bee	Relatively non-toxic	2376508

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
	48h-Acute Contact	EP – MKH 6561 70WG (70% a.i.)	LD_{50} >200 µg EP/bee LC_{50} >141 µg a.i./bee	Relatively non-toxic	
Ground dwelling predator, P*ardosa spp.*	14d-Overspray	EP – MKH 6561 70WG (70% a.i.)	LR_{50} >70 g a.i./ha	Not applicable	2528380
Foliage dwelling predator, *Coccinella septempunctata*	5d-Contact, Glass plates	EP – MKH 6561 70WG (70% a.i.)	LR_{50} >70 g a.i./ha	Not applicable	2528379
Predatory arthropod, *Typhlodromus pyri*	7d-Contact, Glass plates	EP – MKH 6561 70WG (70% a.i.)	LR_{50} >70 g a.i./ha	Not applicable	2528381
Parasitic arthropod, *Aphidius rhopalosiphi*	48h-Contact, Glass plates	EP – MKH 6561 70WG (70% a.i.)	LR_{50} >70 g a.i./ha	Not applicable	2528382
Birds					
Bobwhite quail, *Colinus virginianus*	14d-Acute Oral	Propoxycarbazone-sodium	LD_{50} >2000 mg a.i./kg bw	Practically non-toxic	2375539
	5d-Dietary	Propoxycarbazone-sodium	LC_{50} >10566 mg a.i./kg diet LD_{50} >2120 mg a.i./kg bw/day	Practically non-toxic	2375543
	25w-Reproduction	Propoxycarbazone-sodium	NOEL = 324 mg a.i./kg diet (mean measured) or 45 mg a.i./kg bw/day Significant reductions were detected in the number of eggs laid per hen, number of hatchlings per hen and	Not applicable	2375551

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
			number of survived hatchlings per hen at the highest treatment level (1000 ppm).		
Mallard duck, *Anas platyrhynchos*	5d-Dietary	Propoxycarbazone-sodium	LC_{50} >10339 mg a.i./kg diet LD_{50} >2277 mg a.i./kg bw/day	Practically non-toxic	2375546
	20w-Reproduction	Propoxycarbazone-sodium	NOEC = 268 mg a.i./kg diet NOEL = 36 mg a.i./kg bw/day Significant reductions were detected in the ratios of viable embryos to eggs set, number of hatchlings to eggs laid, number of hatchlings to eggs set, number of survivors to eggs set, and eggshell thickness at the highest treatment level (1250 ppm).	Not applicable	2375553
Mammals					
Rat	Acute oral	Propoxycarbazone-sodium	LD_{50} >5000 mg/kg bw	Practically non-toxic	1654546
	Acute oral	EP – MKH 6561 70WG (70.7% a.i.)	LD_{50} >2500 mg/kg bw	Practically non-toxic	2376426
	Reproduction (2	Propoxycarbazone-sodium	NOAEL ≥16000 ppm	Not applicable	1654755

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
	generation)		(1605 mg/kg bw/d)		
Vascular plants					
Vascular plant, 10 crop species	21d-Seedling emergence	EP – MKH 6561 70WG (71.3% a.i.)	HC_5 of SSD = 2 g a.i./ha	Not applicable	2376513
Most sensitive test species from 10 tested: canola	21d-Vegetative vigour	EP – MKH 6561 70WG (71.3% a.i.)	HC_5 of SSD = 1.34 g a.i./ha	Not applicable	
[1] Atkins *et al*. (1981) for bees and USEPA classification for others, where applicable					

Table 11 Screening Level Risk Assessment of Propoxycarbazone-sodium and Major Transformation Products for Non-Target Terrestrial Species, Other Than Birds and Mammals

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Invertebrates					
Earthworm	Acute Propoxycarbazone-sodium	LC_{50}/2 >500 mg/kg dw soil	0.2 mg/kg soil	<0.0004	Not exceeded
	Acute STJ 4934 (M05)	LC_{50}/2 >500 mg/kg dw soil	0.01 mg/kg soil	<0.00002	Not exceeded
	Acute MKH 7284 (M07)	LC_{50}/2 >500 mg/kg dw soil	0.009 mg/kg soil	<0.00002	Not exceeded
	Acute MKH 7017 (M10)	LC_{50}/2 >500 mg/kg dw soil	0.007 mg/kg soil	<0.00001	Not exceeded
	Chronic Propoxycarbazone-sodium	NOEC ≥1.39 mg/kg dw soil	0.2 mg/kg soil	≤0.14	Not exceeded
	Chronic KTS 9304 (M09)	NOEC = 316 mg/kg dw soil	0.01 mg/kg soil	0.00003	Not exceeded
Bee	Oral	LD_{50} >284 µg/bee	1.305 µg/bee [2]	<0.004	Not exceeded
	Contact	LD_{50} >141 µg/bee	0.108 µg/bee [3]	<0.0008	Not exceeded
Beneficial Insects	Contact	LR_{50} >70 g/ha	45 g/ha	<0.64	Not exceeded
Vascular plants					

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Vascular plant	Seedling emergence	HC_5 = 2 g/ha	On-field: 45 g/ha	22.5	Exceeded
	Vegetative vigour	HC_5 = 1.34 g/ha	On-field: 45 g/ha	33.6	Exceeded

[1] Risk was assessed based on expected environmental concentrations (EECs) for the highest maximum seasonal application rate of 45 g a.i./ha.
[2] The oral exposure estimate for adult bees is calculated by multiplying the direct single rate by 29 µg a.i./bee per kg/ha. This conversion is based on consumption rates primarily derived from Rortais *et al.* (2005) and Crailsheim *et al.* (1992 and 1993). Consequently, the acute contact EEC is 0.045 kg/ha × 29 µg/bee per kg/ha = 1.305 µg/bee
[3] The single application rate of the end-use products is used as the contact exposure estimate from foliar applications. The proposed upper-bound residue value for estimating exposure to bees is based on the maximum residue value reported by Koch and Weißer (1997). Consequently, the acute contact EEC is 0.045 kg/ha × 2.4 µg/bee per kg/ha = 0.108 µg/bee.

Table 12 Screening Level Risk Assessment of Propoxycarbazone-sodium for Birds and Mammals

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	EDE (mg ai/kg bw) [a]	RQ	Level of Concern
Small Bird (0.02 kg)					
Acute	>200	Insectivore (small insects)	3.66	<0.02	Not exceeded
Reproduction	36	Insectivore (small insects)	3.66	0.10	Not exceeded
Medium Sized Bird (0.1 kg)					
Acute	>200	Insectivore (small insects)	2.86	<0.01	Not exceeded
Reproduction	36	Insectivore (small insects)	2.86	0.08	Not exceeded
Large Sized Bird (1 kg)					
Acute	>200	Herbivore (short grass)	1.85	<0.01	Not exceeded
Reproduction	36	Herbivore (short grass)	1.85	0.05	Not exceeded
Small Mammal (0.015 kg)					
Acute	>500	Insectivore (small insects)	2.11	<0.00	Not exceeded
Reproduction	≥1605	Insectivore (small insects)	2.11	≤0.00	Not exceeded
Medium Sized Mammal (0.035 kg)					
Acute	>500	Herbivore (short grass)	4.09	<0.01	Not exceeded

	Toxicity (mg ai/kg bw/d)	Feeding Guild (food item)	EDE (mg ai/kg bw) [a]	RQ	Level of Concern
Reproduction	≥1605	Herbivore (short grass)	4.09	≤0.00	Not exceeded
Large Sized Mammal (1 kg)					
Acute	>500	Herbivore (short grass)	2.18	<0.00	Not exceeded
Reproduction	≥1605	Herbivore (short grass)	2.18	≤0.00	Not exceeded

[a] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where:
FIR: Food Ingestion Rate (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = 0.398(BW in g) $^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = 0.648(BW in g) 0.651.
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = 0.235(BW in g) 0.822
BW: Generic Body Weight
EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher *et al*. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

Table 13 Toxicity of Propoxycarbazone-sodium and Major Transformation Products to Non-Target Aquatic Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
Freshwater species					
Daphnia magna	48h-Acute	Propoxycarbazone-sodium	EC_{50} >107 mg a.i./L	Practically non-toxic	2375517
	21d-Chronic	Propoxycarbazone-sodium	NOEC ≥106 mg a.i./L	No classification	2375520
	48h-Acute	MKH 7017 (M10)	EC_{50} >100 mg/L (nominal)	Practically non-toxic	2375518
	48h-Acute	MKH 7018 (M04)	EC_{50} >100 mg/L (nominal)	Practically non-toxic	2375516
	48h-Acute	STJ 4934 (M05)	EC_{50} >62 mg/L	Slightly toxic	2528385
Rainbow trout, *Oncorhynchus mykiss*	96h-Acute	Propoxycarbazone-sodium	LC_{50} >77.2 mg a.i./L	Slightly toxic	2375526
Bluegill sunfish, *Lepomis*	96h-Acute	Propoxycarbazone-sodium	LC_{50} >94.2 mg a.i./L	Slightly toxic	2375529
	96h-Acute	MKH 7017 (M10)	LC_{50} >98.7 mg/L	Slightly toxic	2375532

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
macrochirus	96h-Acute	MKH 7018 (M04)	LC_{50} >87.7 mg/L	Slightly toxic	2375528
Fathead minnow, *Pimephales promelas*	35d-Chronic (ELS)	Propoxycarbazone-sodium	NOEC ≥105 mg a.i./L (embryo and larval/fry survival)	No classification	2375537
Zebra fish *Brachydanio rerio*	96h-Acute	STJ 4934 (M05)	LC_{50} >79 mg/L	Slightly toxic	2528383
Diatom, *Navicula pelliculosa*	96h-Acute	Propoxycarbazone-sodium	EC_{50} >111 mg a.i./L	No classification	2375559
Green algae, *Selenastrum capricornutum*	96h-Acute	Propoxycarbazone-sodium	EC_{50} = 1.57 mg a.i./L (biomass)	No classification	2375560
	96h-Acute	MKH 7017 (M10)	EC_{50} >100 mg/L (nominal)	No classification	2375561
	96h-Acute	MKH 7018 (M04)	EC_{50} >100 mg/L (nominal)	No classification	2375555
	72h-Acute	EP – MKH 6561 70WG (70.7% a.i.)	EC_{50} = 4.8 mg a.i./L (cell density)	No classification	2376510
	72h-Acute	STJ 4934 (M05)	EC_{50} >62 mg/L	No classification	2528384
Blue-green algae, *Anabaena flos-aquae*	96h-Acute	Propoxycarbazone-sodium	EC_{50} = 11.3 mg a.i./L	No classification	2375556
Vascular plant, *Lemna gibba*	14d-Dissolved	Propoxycarbazone-sodium	EC_{50} = 0.0064 mg a.i./L (biomass)	No classification	2375565
	7d-Dissolved	MKH 7017 (M10)	EC_{50} >100 mg/L (nominal)	No classification	2375566
	7d-Dissolved	MKH 7018 (M04)	EC_{50} = 12 mg/L	No classification	2375564
	7d-Dissolved	STJ 4934 (M05)	EC_{50} >89.4 mg/L	No classification	2528386
Marine species					
Crustacean, mysid shrimp, *Mysidopsis bahia*	96h-Acute	Propoxycarbazone-sodium	LC_{50} >146 mg a.i./L	Practically non-toxic	2375521
	27d-Chronic	Propoxycarbazone-sodium	NOEC ≥123 mg a.i./L (all endpoints)	No classification	2375524
Mollusk,	96h-Acute	Propoxycarbazo	EC_{50} >130 mg	Practically	2375523

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference (PMRA#)
Eastern oyster, *Crassostrea virginica*		ne-sodium	a.i./L	non-toxic	
Sheepshead minnow, *Cyprinodon variegatus*	96h-Acute	Propoxycarbazone-sodium	LC_{50} >108.3 mg a.i./L	Practically non-toxic	2375534
Marine diatom, *Skeletonema costatum*	96h-Acute	Propoxycarbazone-sodium	EC_{50} >134.0 mg a.i./L	No classification	2375562
[1] USEPA classification, where applicable					

Table 14 Screening Level Risk Assessment of Propoxycarbazone-sodium and Major Transformation Products for Aquatic Organisms

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Freshwater species					
Invertebrates	Acute Propoxycarbazone-sodium	LC_{50}/2 >53500 µg/L	5.6 µg/L	<0.0001	Not exceeded
	Acute MKH 7018 (M04)	LC_{50}/2 >50000 µg/L	5.1 µg/L	<0.0001	Not exceeded
	Acute STJ 4934 (M05)	LC_{50}/2 >31000 µg/L	2.9 µg/L	<0.0001	Not exceeded
	Acute MKH 7017 (M10)	LC_{50}/2 >50000 µg/L	2.1 µg/L	<0.00004	Not exceeded
	Chronic Propoxycarbazone-sodium	NOEC ≥106000 µg/L	5.6 µg/L	≤0.00005	Not exceeded
Fish	Acute Propoxycarbazone-sodium	LC_{50}/10 >7720 µg/L	5.6 µg/L	<0.0007	Not exceeded
	Acute MKH 7018 (M04)	LC_{50}/10 >8770 µg/L	5.1 µg/L	<0.0006	Not exceeded
	Acute STJ 4934 (M05)	LC_{50}/10 >7900 µg/L	2.9 µg/L	<0.0004	Not exceeded
	Acute MKH 7017 (M10)	LC_{50}/10 >9870 µg/L	2.1 µg/L	<0.0002	Not exceeded
	Chronic Propoxycarbazone-sodium	NOEC ≥105000 µg/L	5.6 µg/L	≤0.00005	Not exceeded

Organism	Exposure	Endpoint Value	EEC[1]	RQ	Level of Concern
Amphibians[2]	Acute Propoxycarbazone-sodium	LC_{50}/10 >7720 µg/L	30 µg/L	<0.004	Not exceeded
	Chronic Propoxycarbazone-sodium	NOEC ≥105000 µg/L	30 µg/L	≤0.0003	Not exceeded
Algae	Acute Propoxycarbazone-sodium	EC_{50}/2 = 785 µg/L	5.6 µg/L	0.007	Not exceeded
	Acute MKH 7018 (M04)	EC_{50}/2 >50000 µg/L	5.1 µg/L	<0.0001	Not exceeded
	Acute STJ 4934 (M05)	EC_{50}/2 >31000µg/L	2.9 µg/L	<0.00009	Not exceeded
	Acute MKH 7017 (M10)	EC_{50}/2 >50000 µg/L	2.1 µg/L	<0.00004	Not exceeded
Vascular plant	Dissolved Propoxycarbazone-sodium	EC_{50}/2 = 3.2 µg/L	Direct overspray: 5.6 µg/L	1.75	Exceeded
	Dissolved MKH 7018 (M04)	EC_{50}/2 = 6000 µg/L	5.1 µg/L	0.0008	Not exceeded
	Dissolved STJ 4934 (M05)	EC_{50}/2 >44700 µg/L	2.9 µg/L	<0.00006	Not exceeded
	Dissolved MKH 7017 (M10)	EC_{50}/2 >50000 µg/L	2.1 µg/L	<0.00004	Not exceeded
Marine species					
Crustacean	Acute Propoxycarbazone-sodium	LC_{50}/2 >73000 µg/L	5.6 µg/L	<0.00008	Not exceeded
	Chronic Propoxycarbazone-sodium	NOEC ≥123000 µg/L	5.6 µg/L	≤0.00004	Not exceeded
Mollusk	Acute Propoxycarbazone-sodium	EC_{50}/2 >65000 µg/L	5.6 µg/L	<0.00009	Not exceeded
Fish	Acute Propoxycarbazone-sodium	LC_{50}/10 >10830 µg/L	5.6 µg/L	<0.0005	Not exceeded
Algae	Acute Propoxycarbazone-sodium	EC_{50}/2 >67000 µg/L	5.6 µg/L	<0.00008	Not exceeded

[1] Risk was assessed based on expected environmental concentrations (EECs) for the highest maximum seasonal application rate of 45 g a.i./ha.
[2] Fish data used as a surrogate.

Table 15 Assessment of Potential Risk from Drift of Propoxycarbazone-sodium to Aquatic and Terrestrial Organisms

Organism	Exposure	Endpoint value	EEC	RQ	Level of Concern
Terrestrial vascular plant	21d - Seedling emergence	HC_5 = 2 g/ha	On-field: 45 g/ha	22.5	Exceeded
			Off-field (3% drift): 1.35 g/ha	0.67	Not exceeded
	21d - Vegetative vigour	HC_5 = 1.34 g/ha	On-field: 45 g/ha	33.6	Exceeded
			Off-field (3% drift): 1.35 g/ha	1.01	Exceeded
Aquatic vascular plant	14d - Dissolved	$EC_{50}/2$ = 3.2 µg/L	Direct overspray: 5.6 µg/L	1.75	Exceeded
			Off-field (3% drift): 0.17 µg/L	0.05	Not exceeded

Table 16 Risk Quotients for Aquatic Organisms Determined for Runoff of Propoxycarbazone-sodium in Water Bodies 80 cm deep

Organism (exposure)	Endpoint value	EEC (µg a.i./L) – Peak value and region	RQ	Level of Concern
Vascular plant (Chronic, 14-d)	$EC_{50}/2$ = 3.2 µg/L	1.5 µg a.i./L (BC)	0.5	Not exceeded
		5.1 µg a.i./L (Prairies)	1.6	Exceeded
		2.9 µg a.i./L (ON)	0.9	Not exceeded
		3.2 µg a.i./L (QC)	1.0	Exceeded
		6.6 µg a.i./L (PEI)	2.1	Exceeded

Table 17 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	DT_{50} of 8.7 to 223 days in aerobic and anaerobic soil systems.
	Water	Half-life ≥ 182 days	DT_{50} of 11.6-207 days in total system of aerobic and anaerobic water/sediment systems.
	Sediment	Half-life ≥ 365 days	DT_{50} of 11.6-207 days in total system of aerobic and anaerobic water/sediment systems.
	Air	Half-life ≥ 2 days or	Volatilisation is not an important route of dissipation and long-range atmospheric

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
		evidence of long range transport	transport is unlikely to occur based on the vapour pressure (<1 × 10^{-8} Pa) and Henry's Law Constant (9.9 × 10^{-16} atm·m^3/mol).
Bioaccumulation[4]	Log K_{OW} ≥ 5		-1.55
	BCF ≥ 5000		Not available
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e. all other TSMP criteria are met).
[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4] Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Table 18 Registered Alternatives (for Use in Western Canada)*(as of May 7, 2015 when search was conducted)

Wheat Market Class	Brome Species (C=control; S=suppression)	Registered Alternatives			
		Application Timing [a] (F=Fall; S=Spring)	Active Ingredient [b]	Product Name (Reg. No.) [b]	Resistance Group No.
Winter (Norstar)	Downy (C)	Post (F)	metribuzin	Sencor 75 DF Herbicide (17242)	5
Spring, Durum, Winter	Downy (S)	Post (S)	pyroxsulam	Simplicity Herbicide (28887)	2
Winter	Downy (C)	Post (F)			
Spring, Durum	Japanese (C)	Post (S)			
Spring (Clearfield)	Japanese (S)	Post (S)	imazamox	AC 299,263 120 AS Herbicide (26705)	2
Spring, Durum, Winter	Japanese (C or S)	Post (F, S)	thiencarbazone-methyl	Varro Herbicide (29070)	2

Wheat Market Class	Brome Species (C=control; S=suppression)	Registered Alternatives			
		Application Timing [a] (F=Fall; S=Spring)	Active Ingredient [b]	Product Name (Reg. No.) [b]	Resistance Group No.
Spring, Durum, Winter	Downy (C)	Pre (F, S)	glyphosate ± other active ingredients [c]	glyphosate ± other herbicide products [c]	9 ± others [c]

[a] Application timing = relative to the crop; pre = pre-plant or pre-emergence, post = post-emergence.
[b] For some active ingredients, numerous products are registered; only one example is given for each active ingredient in the table above.
[c] A wide range of glyphosate products are registered for the control of downy brome when applied alone or in tank mix with other herbicide products pre-emergent to wheat; specific products are not mentioned in this table.

* Note that Table 10 denotes registered alternatives for Japanese and downy brome control in wheat grown in western Canada (i.e. the two weeds of particular importance for propoxycarbazone-sodium). However, various other herbicides are registered for the control of annual broadleaved weeds in winter wheat, including those containing active ingredients that belong to herbicide resistance group numbers 2, 4, 5, 6, 8 and 9.

Table 19 List of Supported Uses

Summary of the Value Assessment Results

Use Claims That Are Supported for 2013-7109 (MKH 6561 70WG Herbicide):

a) Items	Use claims that are supported
Appl. rate	42 - 63 g/ha (30 - 45 g ai/ha) + 0.25% v/v nonionic surfactant.
No. of Apps.	One per crop cycle, applied either in the fall or spring.
Use range	Prairie Provinces and the Peace River, Okanagan and Creston Flats regions of British Columbia.
Weed claims	Downy brome: Fall – suppression (30 g ai/ha) and control (45 g ai/ha). Spring – suppression (30 and 45 g ai/ha). Japanese brome: Fall – control (30 and 45 g ai/ha). Spring – suppression (30 g ai/ha) and control (45 g ai/ha). Flixweed, stinkweed, tansy mustard, wild mustard and volunteer canola: Fall – control (30 and 45 g ai/ha) Spring – control (30 and 45 g ai/ha). Redroot pigweed: Fall – suppression (45 g ai/ha). Spring – control (30 and 45 g ai/ha). Shepherd's-purse, black mustard, burr buttercup, small seeded falseflax, tumble mustard and wormseed mustard:

	Fall – control (30 and 45 g ai/ha). Spring – control (30 and 45 g ai/ha). Blue mustard: Fall – control (30 and 45 g ai/ha). Spring – suppression (30 g ai/ha) and control (45 g ai/ha). Bushy wallflower: Fall – suppression (30 g ai/ha) and control (45 g ai/ha). Spring – suppression (30 g ai/ha) and control (45 g ai/ha). Henbit: Fall – suppression (30 and 45 g ai/ha). Spring – suppression (45 g ai/ha). Mouseear chickweed: Fall – suppression (30 g ai/ha) and control (45 g ai/ha). Wild buckwheat: Spring – suppression (45 g ai/ha).
Use sites	Winter wheat.
Appl. timing	Relative to crop: Post-emergence (1-lf to just prior to jointing). Relative to weeds: Post-emergence (see label).
Appl. method	Apply in a minimum of 46.8 L of water per hectare by ground equipment only.
Rotational crops (months after application)	Winter wheat (10 months) and spring wheat (10 months).
Rainfastness	4 hours.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Differences Between MRLs in Canada and in Other Jurisdictions

Propoxycarbazone-sodium is a new active ingredient which is being registered in Canada. The MRLs proposed for propoxycarbazone on livestock commodities in Canada are different from certain (livestock) commodities in the United States, in accordance with Table 1, for which differences may be due to different livestock feed items and practices.

Currently, there are no Codex MRLs[9] listed for propoxycarbazone in or on any commodity on the Codex Alimentarius Pesticide Residues in Food website.

Table 1 compares the MRLs proposed for propoxycarbazone-sodium in Canada with corresponding American tolerances. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Table 1 Comparison of Canadian MRLs and American Tolerances (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)
Fat, meat, meat byproducts (except kidney) of cattle, goat, horse and sheep	0.05	--
Meat, of cattle, goat, horse and sheep	--	0.05
Kidney of cattle, goat, horse and sheep	0.07	--
Meat by-products, of cattle, goat, horse and sheep	--	0.3
Milk	0.01	0.03

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. Harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs specified in this document are necessary. The differences in MRLs outlined above are not expected to impact businesses negatively or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

[9] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1654526	Product chemistry of MKH 6561 technical
1654531	Product chemistry of Olympus technical herbicide 3125-LUG
1654520	Product chemistry of MKH 6561 technical
1654523	The composition of technical BAY MKH 6561
2375455	Analytical method for the determination of MKH 6561 and seven degradates in soil
2375456	Independent laboratory validation of the 'analytical method for the determination of MKH 6561 and seven degradates in soil'
2375457	Propoxycarbazone-sodium Technical Herbicide - Information to Address PMRA DACO Element 8.2.2.2
2375460	Enforcement and confirmatory method for determination of MKH 6561 in drinking water and surface water by HPLC
1654533	Product chemistry of BAY MKH 6561 70% water dispersible granular herbicide
2475764	Physical, chemical and technical properties of Propoxycarbazone-sodium water soluble granule 700 g/kg
2475765	Storage Stability of Propoxycarbazone-sodium water soluble granule 700 g/kg (Two Years Shelf Life at Room Temperature) 1. Amendment
2475766	propoxycarbazone-sodium; water soluble granules, 700 g/kg AE 0298618 00 SG70 A102 - Oxidizing Properties
2475768	propoxycarbazone-sodium; water soluble granules, 700 g/kg AE 0298618 00 SG70 A102 - Flammability (Solids)
2475769	propoxycarbazone-sodium; water soluble granules, 700 g/kg AE 0298618 00 SG70 A102 - Explosive Properties
2475770	Corrosion Evaluation of BAY MKH 6561 70% WG

2.0 Human and Animal Health

1654546	1994. MKH 6561 - Study for acute oral toxicity in rats. Report 23480. DACO 4.2.1
1654548	1999. Bissulfonylurea-MKH 6561 (MKH 6561 byproduct) - Study for acute toxicity in rats. Report 28939. DACO 4.2.1
1654550	1999. KTS 9061 (metabolite of MKH 6561) - Study for acute oral toxicity in rats. Report 28598. DACO 4.2.1
1654553	1999. MKH 8394 (metabolite of MKH 6561) - Study for acute oral toxicity in rats. Report 28432. DACO 4.2.1

1654555	1999. 4-OH-Saccharine (synonym: 4-Hydroxy-saccharine) - MKH 6561-metabolite - Study for acute oral toxicity in rats. Report 28879. DACO 4.2.1
1654558	1999. Methylthio analogue free accid - MKH 6561 (byproduct of MKH 6561) - Study for acute oral toxicity in rats. Report 28875. DACO 4.2.1
1654560	1996. MKH 6561 - Subacute Toxicity Study in B6C3F1-Mice (Administration in the Feed over 5 Weeks). Report 25341. DACO 4.3.1
1654563	1996. MKH 6561 - Study for subacute oral toxicity in rats (feeding study). Report 25104. DACO 4.3.1
1654568	2000. MKH 6561 - Study for subchronic oral toxicity in rats (feeding study for 14 weeks with a 4-week recovery period). Report 25597. DACO 4.3.1
1654579	2000. MKH 6561 - Subchronic toxicity study in B6C3F1-mice (Administration in the feed over 14 weeks). Report 25796. DACO 4.3.1
1654589	1999. KTS 9061 - Study for subacute oral toxicity in rats (feeding study over about 4 weeks). Report 29046. DACO 4.3.1
1654595	1997. Technical grade MKH 6561 - A range finding toxicity feeding study in the beagle dog. Report BC8169. DACO 4.3.2
1654604	1998. Technical grade MKH 6561 - A chronic toxicity feeding study in the beagle dog. Report 108189. DACO 4.3.2
1654621	2000. MKH 6561 - Oncogenicity study in B6C3F1 mice. Dietary administration over 2 years. Report 28845. DACO 4.4.3
1654648	2000. Technical grade MKH 6561 - A combined chronic toxicity/ oncogenicity study in the rat. Report 108361. DACO 4.4.4
1654751	1997. MKH 6561 - One-generation study in Wistar rats. Report 26743. DACO 4.5.1
1654755	2000. MKH 6561 (c.n. Propoxycarbazone-Sodium) - Two-generation study in Wistar rats. Report 109096. DACO 4.5.1
1654774	2000. MKH 6561 - Developmental toxicity study in rats after oral administration. Report 26772. DACO 4.5.2
1654787	2000. MKH 6561 - Developmental toxicity study in rabbits after oral administration. Report 27466. DACO 4.5.3
1654801	1994. MKH 6561 - Salmonella/microsome test. Report 22798. DACO 4.5.4
1654804	1999. KTS 9061 - Metabolite of MKH 6561 - Salmonella/microsome test plate incorporation and preincubation method. Report. DACO 4.5.4
1654807	1999. Methylthio analogue free acid - MKH 6561 - Salmonella/microsome test plate incorporation and preincubation method. Report 28914. DACO 4.5.4
1654810	1999. KTS 9304 - Salmonella/Microsome test plate incorporation and preincubation method. Report 28413. DACO 4.5.4
1654813	1999. MKH 8394 - Salmonella/microsome test plate incorporation and preincubation method. Report 28377. DACO 4.5.4
1654815	1999. 4-OH-Saccharine (soil metabolite of MKH 6561) - Salmonella/microsome test plate incorporation and preincubation method. Report 28646. DACO 4.5.4
1654819	1999. Bissulfonylurea-MKH 6561 - Salmonella/microsome test plate incorporation and preincubation method. Report 28896. DACO 4.5.4
1654821	1996. MKH 6561 - In vitro mammalian chromosome aberration test with Chinese hamster V79 cells. Report 24787. DACO 4.5.5
1654824	1996. MKH 6561 - Test on unscheduled DNA synthesis in rat liver primary cell cultures in vitro. Report 25197. DACO 4.5.5
1654826	1996. MKH 6561 - Mutagenicity study for the detection of induced forward mutations in the V79/HPRT assay in vitro. Report. DACO 4.5.5

1654828	1999. KTS 9061 (metabolite of MKH 6561) - In vitro chromosome aberration test with Chinese hamster V79 cells. Report 28555. DACO 4.5.5
1654833	1995. MKH 6561 - Micronucleus Test on the mouse. Report 23922. DACO 4.5.7
1654836	1998. [Phenyl-Ul-14C]MKH 6561 Absorption, distribution, excretion and metabolism in the rat including whole body autoradiography. Report. DACO 4.5.9
1654848	1997. [Triazolinon-3-14C]MK H 6561: Absorption, distribution, excretion and metabolism in the rat. Report 108304. DACO 4.5.9
1654857	1999. [phenyl-14C]MKH 6561: Occurrence of the plant metabolite 2-hydroxy-MKH 6561 in excreta and liver extracts of the rat. Report 109200. DACO 4.5.9
2376426	1998, MKH 6561 70 WG 05780/0031 - Study for acute oral toxicity in rats, DACO: 4.6.1
2376428	1998, MKH 6561 70 WG 05780/0031 - Study for acute dermal toxicity in rats, DACO: 4.6.2
2376431	1998, MKH 6561 70 WG 05780/0031 (c.n.: --) - Study on acute inhalation toxicity in rats according to OECD No. 403, 92/69/EEC and FIFRA 83-3, DACO: 4.6.3
2376433	1998, Acute eye irritation study of MKH 6561 70 WG 05780/0031 by instillation into the conjunctival sac of rabbits, DACO: 4.6.4
2376435	1998, Acute skin irritation test (patch test) of MKH 6561 70 WG 05780/0031 in rabbits, DACO: 4.6.5
2376438	1999, MKH 6561 70 WG 05780/0031 - Study for the skin sensitization effect in guinea pigs (Buehler Patch Test), DACO: 4.6.6
2375413	KTS 9304 (Metabolite of MKH 6561) - Study for acute oral toxicity in rats DACO: 4.2.1
1654546	MKH 6561 - Study for acute oral toxicity in rats. DACO: 4.6.1
2375419	MKH 6561 - Study for acute dermal toxicity in rats. DACO: 4.6.2
2375421	MKH 6561 - Study on acute inhalation toxicity in rats according to OECD no. 403 DACO: 4.6.3
2375424	MKH 6561 - Study for skin and eye irritation / corrosion in rabbits. DACO: 4.6.5/4
2375427	MKH 6561 - Study for the skin sensitization effect in guinea pigs (Maximization Test of Magnusson & Kligman) DACO: 4.6.6
2376438	MKH 6561 Study for Subacute Dermal Toxicity in Rats (four-week treatment period). DACO 4.3.5.
2375447	MKH 6561 MKH Plaque-Forming-Cell Assay in Rats (Feeding Study Over About 4 Weeks). DACO 4.5.15.
2375440	MKH 6562 Acute Oral Neurotoxicity Screening Study in Wistar Rats. DACO 4.5.12.
375442	MKH 6561 Subchronic Neurotoxicity Screening Study in Wistar Rats (Thirteen-Week Administration in the Diet) DACO 4.5.13.
2376440	2013, Canadian Use Description Scenario for MKH 6561 70WG Herbicide, DACO: 5.2
2376442	2013, Assessment of the Non-Dietary Exposure to Propoxycarbazone-Sodium From Use on Winter Wheat in Canada, DACO: 5.3

2376473	1999, The accumulation of [phenyl-UL-14C/triazolinone-3-14C] MKH 6561 residues in confined rotational crops, DACO: 7.4.3
2376475	1999, MKH 6561 70WG - magnitude of the residue in field rotational crops, DACO: 7.4.4
2420678	2006, Freezer Storage Stability of MKH 6561 and Pr-2-OH MKH 6561 in Turnip Tops, Turnip Roots, and Mustard Greens, DACO: 7.3
1654958	2000, MKH 6561 - a 29-day dairy cattle feeding study - addendum I - data for the 10X feeding level, DACO: 7.5.1
2376480	1999, Request for waiver of poultry feeding study and residue analytical method for MKH 6561, DACO: 7.5.1

3.0 Environment

2375463 1999, Hydrolysis of [phenyl-14C]MKH 6561 in sterile buffer solutions, DACO: 8.2.3.2

2375464 1999, Hydrolysis of [triazolinone-3-14C]MKH 6561 in sterile aqueous buffer solutions Part I: Hydrolytic fate and degradation kinetics of the test substance MKH 6561, DACO: 8.2.3.2

2375465 1999, Hydrolysis of [triazolinone-3-14C]MKH 6561 in sterile aqueous buffer solutions Part II: Interpretation of the hydrolytic fate of the main metabolite MKH 7017, DACO: 8.2.3.2

2375466 1999, Calculation of DT-50 values of MKH 6561 metabolite STJ 4934 generated by hydrolysis in sterile aqueous buffer solutions, DACO: 8.2.3.2

2375467 1999, Photolysis of [triazolinone-3-14C]MKH 6561 on soil surfaces, DACO: 8.2.3.3.1

2375468 1999, Photolysis of [phenyl-UL-14C]MKH 6561 on soil surfaces, DACO: 8.2.3.3.1

2375469 1999, Photolysis of [phenyl-UL-14C]MKH 6561 in aqueous solutions, DACO: 8.2.3.3.2

2375470 1999, Photolysis of [triazolinone-3-14C]MKH 6561 in aqueous solutions, DACO: 8.2.3.3.2

2375471 1999, Photolysis of [phenyl-UL-14C]MKH 7284 in aqueous solutions, DACO: 8.2.3.3.2

2375473 1999, Aerobic degradation of N-methyl propoxy triazolinone amide (a metabolite of MKH 6561) in three soils, DACO: 8.2.3.4.2

2375474 1999, Aerobic degradation of n-methyl propoxy triazolinone (a metabolite of MKH 6561) in quincy loamy sand from Ephrata, WA, DACO: 8.2.3.4.2

2375475 1999, Aerobic degradation of Saccharin (a metabolite of MKH 6561) in quincy loamy sand from Ephrata, WA, DACO: 8.2.3.4.2

2375476 1999, Aerobic degradation of 4-hydroxy saccharin (a metabolite of MKH 6561) in three soils, DACO: 8.2.3.4.2

2375477 1999, Aerobic metabolism of [phenyl-U-14C] MKH 6561 in quincy loamy sand from Ephrata, Washington, DACO: 8.2.3.4.2

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2375479 1999, Aerobic metabolism of [phenyl-U-14C] MKH 6561 in three german soils, DACO: 8.2.3.4.2

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2375482 1999, Calculation of DT-50 values of MKH 6561 metabolite MKH 7017 in soil under aerobic conditions, DACO: 8.2.3.4.2
2375483 1999, Calculation of DT-50 values of MKH 6561 Metabolites MKH 7284 and STJ 4934 in soil under aerobic conditions, DACO: 8.2.3.4.2
2375484 2010, [Triazolinone-3-14C]- and [phenyl-UL-14C]propoxycarbazone-sodium: Anaerobic soil metabolism, DACO: 8.2.3.4.4
2375486 1998, Aerobic aquatic degradation and metabolism of MKH 6561 in the water-sediment system, DACO: 8.2.3.5.4
2375487 1999, Anaerobic aquatic metabolism of [phenyl-U-14C] MKH 6561 in a Washington water and sediment test system, DACO: 8.2.3.5.6
2375488 1999, Anaerobic aquatic metabolism of [triazolinone-3-14C] MKH 6561 in a Washington water and sediment test system, DACO: 8.2.3.5.6
2375489 1997, Adsorption / Desorption of MKH 6561 in five soil types, DACO: 8.2.4.2
2375491 1997, Adsorption/desorption of MKH 6561 carboxylic acid (MKH 7018), a degradate of MKH 6561, in five soil types, DACO: 8.2.4.2
2375493 1997, Adsorption/desorption of MKH 6561 sulfonamide acid (MKH 7283), a degradate of MKH 6561, in five soil types, DACO: 8.2.4.2
2375495 1997, Adsorption/desorption of MKH 6561 sulfonamide methyl ester (STJ 4934), a degradate of MKH 6561, in five soil types, DACO: 8.2.4.2
2375498 1997, Adsorption/desorption of saccharin (MKH 7284), a degradate of MKH 6561, in five soil types, DACO: 8.2.4.2
2375500 1997, Adsorption/desorption of N-methyl propoxy triazolinone (MKH 7017), a degradate of MKH 6561, in five soil types, DACO: 8.2.4.2
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2375506 1999, The leaching potential of [phenyl-U-14C] MKH 6561 sulfonamide methyl ester (STJ 4934) in quincy loamy sand, DACO: 8.2.4.3.1
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2376489 1999, Terrestrial field dissipation of MKH 6561in Washington soil, 1996, DACO: 8.3.2.2
2376492 1999, Terrestrial field dissipation of MKH 6561 in Kansas soil, 1996, DACO: 8.3.2.2
2376494 1999, Terrestrial field dissipation of MKH 6561 in Utah soil, 1997, DACO: 8.3.2.2

2376498 1999, Dissipation of MKH 6561 (70 WG) in soil under field conditions (France, Germany, Great Britian), DACO: 8.3.2.3

2376502 1999, Lysimeter study on the degradation and translocation of the herbicide MKH 6561 under field conditions, DACO: 8.3.4

2425139 2003, Tier II, IIA, Point 7: Environmental fate - MKH 6561, DACO: 8.1

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2375514 1999, Acute toxicity of STJ 4934 to earthworms (Eisenia fetida), DACO: 9.2.3.1

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2375516 1998, Acute toxicity of MKH 8394 (free acid of MKH 7018) to water fleas (Daphnia magna), DACO: 9.3.2

2375517 1998, Acute toxicity of MKH 6561 technical to the waterflea (Daphnia magna) under static conditions, DACO: 9.3.2

2375518 1998, Acute toxicity of MKH 7017 to water fleas (Daphnia magna), DACO: 9.3.2

2375519 1998, Chronic toxicity of MKH 6561 technical to the waterflea (Daphnia magna) under static renewal conditions, DACO: 9.3.3

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2376504 2003, Tier II, IIA, 8: Ecotoxicology, DACO: 9.1,9.2.1,9.3.1,9.5.1,9.6.1,9.8.1

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2376508 1998, Laboratory testing for toxicity (acute contact and oral LD50) of MKH 6561 70 WG on honey bees (Apis mellifera L.) (Hymenoptera, Apidae), DACO: 9.2.4.1,9.2.4.2

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2528378 1999, Acute Toxicity of MKH 6561 - Propoxytriazolinone to Earthworms (Eisenia fetida), DACO: 9.2.3.1

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4.0 Value

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B. Additional Information Considered

i) Published Information

1.0 Chemistry

2.0 Human and Animal Health

3.0 Environment

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ii) Unpublished Information

1.0 Chemistry

2.0 Human and Animal Health

3.0 Environment

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