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Proposed Re-evaluation Decision

PRVD2025-10

Iodosulfuron-methyl- sodium and Its associated end-use product

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Proposed re-evaluation decision for iodosulfuron-methyl-sodium and its associated end-use product

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental safety standards and continue to have value. The re-evaluation considers data and information from various sources such as existing reviews, incident reports and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

Iodosulfuron-methyl-sodium is a selective sulfonylurea herbicide. It inhibits the activity of acetolactate synthase (ALS), which is the key enzyme in the biosynthesis of the branch-chain amino acids, isoleucine, leucine and valine. Although the actual sequence of phytotoxic processes is unclear, plant death results from events occurring in response to inhibition of the ALS enzyme. Iodosulfuron-methyl-sodium is used to control a range of post-emergence grassy and broadleaf weeds in field corn. It is applied once a year by field sprayer. Currently, there is one technical active ingredient and one commercial class end-use product registered for use in Canada. Registered products can be found in the Pesticide Product Information Database and in Appendix I.

This document presents the proposed re-evaluation decision for iodosulfuron-methyl-sodium, including any proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based. All products containing iodosulfuron-methyl-sodium that are registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period,¹ during which the public (including the pesticide manufacturers and stakeholders) may submit written comments and additional information to PMRA Publications. The final re-evaluation decision will be published after taking into consideration the comments received during the consultation period that are directly related to this proposed re-evaluation decision.

Health Canada, under the authority of the *Pest Control Products Act*, has conducted all evaluations considered necessary with respect to the health and environmental risks and value of iodosulfuron-methyl-sodium based on available scientific information in accordance with subsection 16(6) of the *Pest Control Products Act*. Health Canada is proposing for public consultation, pursuant to section 28 of the *Pest Control Products Act*, the continued registration of iodosulfuron-methyl-sodium and associated end-use product registered for sale and use in Canada under section 21 of the *Pest Control Products Act*.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Iodosulfuron-methyl-sodium is a substance with both a contact and selective mode of action that has acceptable value in providing a pest management solution. Based on the current use pattern, potential risks to human health (occupational, dietary, residential and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable when products containing iodosulfuron-methyl-sodium are used according to proposed label amendments (Appendix II).

Proposed label amendments

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health, the environment and ensure the product has acceptable value which must be followed by law. The proposed label amendments as a result of the re-evaluation of iodosulfuron-methyl-sodium are summarized below. Refer to Appendix II for details.

Human health

No label amendments are proposed.

Environment

Label amendments to meet current standards: update runoff statement and add leaching and storage statements.

Next steps

Upon publication of this proposed re-evaluation decision, the public, including the registrants and stakeholders are encouraged to submit comments during the 90-day public consultation period.

Health Canada will accept written comments on this proposal up to 90 days from the date of publication of this document (“consultation period”). Comments on the proposed decision can be submitted during the consultation period to the PMRA through PMRA Publications, or the Public Engagement Portal (Public Engagement Forms - Consultation Comment). For more information or if you have questions, contact the PMRA’s Pest Management Information Service.

Before making a re-evaluation decision on iodosulfuron-methyl-sodium under section 21 of the *Pest Control Products Act*, the comments received during the consultation period that are directly related to this proposed decision, such as comments directed to the science evaluation, will be taken into consideration in preparation of the final re-evaluation decision document.

A science-based approach will be applied in making a final decision on iodosulfuron-methyl-sodium. In accordance with subsection 28(5) of the *Pest Control Products Act*, Health Canada will then publish a final re-evaluation decision document, which will include the decision,² the reasons for it, a summary of the comments received directly related to the proposed re-evaluation decision during the consultation period, and Health Canada's response to these comments.

Refer to Appendix I for details on specific products impacted by this proposed decision.

Other information

The relevant confidential test data on which the proposed decision is based are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Additional scientific information

No additional scientific data are being requested at this time.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science evaluation

1.0 Background

Iodosulfuron-methyl-sodium is a selective sulfonylurea herbicide used to control a range of post-emergence grassy and broadleaf weeds in field corn. The one commercial class end-use product, co-formulated with foramsulfuron, is formulated as wettable granules. The product can be applied once a year by growers and custom applicators by ground equipment.

The re-evaluation of iodosulfuron-methyl-sodium considered existing assessments and available information within Health Canada's Incident Reporting Program and information from the USEPA and EFSA.

2.0 Human health

2.1 Toxicology summary

Iodosulfuron-methyl-sodium is of low acute toxicity via the oral, dermal and inhalation routes of exposure; it is moderately irritating to the eyes, minimally irritating to the skin, and is not a potential skin sensitizer. Iodosulfuron-methyl-sodium is not genotoxic, carcinogenic, neurotoxic, or a developmental or reproductive toxicant (Canada, 2004; Canada, 2008). Toxicology reference values for chronic dietary and dermal and inhalation assessment were established for iodosulfuron-methyl-sodium by Health Canada (Canada, 2004; Canada, 2008). Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied. Since no sensitivity of the young was observed in developmental and reproductive toxicity studies, the *Pest Control Products Act* factor was reduced to onefold (Canada, 2008).

Refer to Regulatory Note REG2004-04 (Canada, 2004), Proposed Registration Decision PRD2008-06 (Canada, 2008) and Registration Decision RD2009-01 (Canada, 2009) for further details on the toxicology assessment for iodosulfuron-methyl-sodium.

2.2 Dietary exposure and risk assessment

Iodosulfuron-methyl-sodium is registered in Canada for use on field corn at a maximum application rate of 2 g a.i./ha (active ingredient/hectare). The residue definition for risk assessment in plant and animal commodities and drinking water assessment was determined by Health Canada to be iodosulfuron-methyl-sodium (Canada, 2004, Canada 2012). An acute reference dose (ARfD) has not been established by Health Canada and therefore an acute dietary risk assessment was not required (Canada, 2004). The Acceptable Daily Intake (ADI) was 0.073 mg/kg bw/day (Canada, 2008). Level 1 estimated environmental concentration (EEC) in drinking water was 0.172 µg a.i./L (REG2004-04). Dietary risk from iodosulfuron-methyl-sodium food uses and drinking water was shown to be acceptable for all representative population subgroups (less than 0.3% of the ADI of 0.073 mg/kg bw/day). A search of publicly available Canadian water monitoring data was completed for the re-evaluation. The search did not indicate a concern from drinking water exposure at this time.

As part of the human health assessment, Health Canada also considered the USEPA Interim Registration Review Decision (USEPA, 2017) in relation to the acute dietary assessment. Iodosulfuron-methyl-sodium is registered by the USEPA on a variety of field crops (including wheat and corn) and turf, with a maximum application rate of 0.0089 lb/A (pounds/acre) (9.98 g a.i./ha). The residue of concern for food and animal commodities was iodosulfuron-methyl-sodium, and the residues of concern for drinking water risk assessment included iodosulfuron-methyl-sodium and the metabolite metsulfuron-methyl (USEPA, 2015). Risk assessments assumed 100% crop treated and modelled estimated drinking water concentrations of 751 µg a.i./L (acute) and 492 µg a.i./L (chronic). The acute and chronic dietary risks (food + drinking water) were below the USEPA level of concern (<100% of the population-adjusted dose (PAD)). Acute dietary risk via food and drinking water exposure pathways comprised 13% of the acute population-adjusted dose (aPAD) of 1.0 mg/kg bw/day for the most highly exposed population, infants <1 year old. Chronic dietary risk comprised 37% of the chronic population-adjusted dose (cPAD) of 0.073 mg/kg bw/day for the most highly exposed population, infants <1 year old (USEPA, 2015; USEPA, 2017). Since the Canadian use pattern is covered by the uses considered in the USEPA dietary review and the acute risk identified was 13% of cPAD, Health Canada considers the acute dietary risk to be acceptable for the Canadian uses.

Metsulfuron-methyl is a metabolite of iodosulfuron-methyl-sodium and is included in the USEPA and EFSA residue definition in water (USEPA, 2017; EFSA, 2016). While Health Canada, in its existing assessment of iodosulfuron-methyl-sodium did not include metsulfuron-methyl in its residue definition for water, it is registered as a pesticide active ingredient in Canada. Health Canada conducted a chronic dietary risk assessment and the chronic dietary risk (food and drinking water) was < 3.9% of the ADI (Canada, 2024b). An ARfD was not established and an acute dietary risk assessment was not required.

Based on the above considerations, dietary risk (food and water) is considered acceptable under the current conditions of use for iodosulfuron-methyl-sodium, and no further mitigation measures are proposed.

2.3 Occupational and non-occupational exposure and risk assessment

There is potential for occupational exposure to iodosulfuron-methyl-sodium during mixing, loading and applying the pesticide, and when entering a treated site to conduct postapplication activities such as scouting or hand set irrigation.

2.3.1 Occupational exposure and risk assessment

2.3.1.1 Mixer, loader, and applicator exposure and risk assessment

Based on the registered use pattern, mixer/loader/applicator exposure is expected to be short-term and to occur via the dermal and inhalation routes. The calculated margin of exposure (MOE) for the combined short term dermal and inhalation exposure was >40 000 (Canada, 2004), and risks were shown to be acceptable for workers mixing/loading wettable granules and applying iodosulfuron-methyl-sodium using groundboom equipment. No further mitigation measures are proposed.

2.3.1.2 Postapplication worker exposure and risk assessment

Based on the registered use pattern, there is potential for short-term dermal exposure to post application workers entering field treated with iodosulfuron-methyl-sodium. The MOE was >75 000 on the day of application (day zero), and therefore risk was shown to be acceptable for all postapplication activities (Canada, 2004). No further mitigation measures are proposed.

2.3.2 Residential (non-occupational) and bystander exposure and risk assessment

Based on the registered use pattern, residential exposure is not expected. There is a potential for exposure to bystanders during outdoor agricultural applications. To minimize the potential for bystander exposure, a standard spray drift statement is currently included in the label.

2.4 Aggregate exposure and risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

Iodosulfuron-methyl-sodium is not registered for use in residential areas and exposure is expected to be minimal in residential settings, and dietary risk (food and water) is considered acceptable (see Section 2.2).

2.5 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, an assessment of potential mechanisms of toxicity with other pesticides was undertaken. Iodosulfuron-methyl-sodium belongs to the sulfonylurea class of herbicides. This class of herbicides includes the following which are not registered in Canada: bensulfuron-methyl, imazosulfuron, primisulfuron-methyl, sulfometuronmethyl, sulfosulfuron, triasulfuron, and trifloxysulfuron-sodium. This class also includes the following which are registered in Canada: chlorsulfuron, chlorimuron-ethyl, ethametsulfuronmethyl, flazasulfuron, halosulfuron-methyl, foramsulfuron, mesosulfuron-methyl, metsulfuron-methyl, nicosulfuron, prosulfuron, rimsulfuron, thifensulfuron-methyl, triflusulfuron-methyl, and tribenuron-methyl. Sulfonylurea herbicides share a common structural element, the sulfonyl group bound to a nitrogen atom of a ureylene group. This structural element defines the sulfonylurea class and is responsible in part for their herbicidal mechanism of action which involves inhibition of acetolactate synthase (ALS). An analogous mammalian ALS enzyme exists in humans which may be inhibited by sulfonylurea herbicides. However, while deleterious effects in humans associated with ALS inhibition have not yet been investigated, the available information on this class of herbicides indicates both low mammalian toxicity and health risk. Other herbicide classes which inhibit ALS include imidazolinones, triazolopyrimidines, pyrimidinyl oxybenzoates, and sulfonylamino carbonyl triazolinones. Sulfonylurea herbicides do not appear to share a common toxic effect across the class. While some members of the sulfonylurea class affect the liver, kidneys, or eyes, these effects are not conserved across the class. In general, the toxic effects of sulfonylurea herbicides appear to be non-specific in nature including liver, bodyweight effects, and blood effects.

The USEPA has published an interim registration review decision for 22 sulfonylurea herbicides including iodosulfuron-methyl-sodium. The USEPA concluded that although the sulfonylureas share some chemical and toxicological characteristics, the toxicological database did not support a testable hypothesis for a common mechanism of action, and no further cumulative evaluation was necessary (USEPA, 2017).

For the current re-evaluation, Health Canada did not identify information indicating iodosulfuron-methyl-sodium shares a known common mechanism of toxicity with other pest control products in this class. A cumulative risk assessment is not being conducted at this time.

Health Canada will continue to monitor the available information on this class of pesticides. If new information becomes available that indicates the need for a cumulative risk assessment, this will be conducted according to the process described in the Health Canada framework on cumulative health risk assessment ([SPN2018-02](#)).

3.0 Environment

3.1 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium is non-volatile thus is not expected to volatilize from water and moist soils. It is not bioaccumulative in the environment. The *n*-octanol–water partition coefficient of the iodosulfuron-methyl-sodium major transformation products indicates that these compounds have limited potential for bioaccumulation in biological organisms (Canada, 2008).

Biotransformation is a principal route of transformation for iodosulfuron-methyl-sodium, and there is low potential for phototransformation on soil and in surface water (Canada, 2004). Iodosulfuron-methyl-sodium is slightly non-persistent to persistent in water, while the major breakdown products range from non-persistent to persistent (Canada, 2008). Hydrolysis is not an important transformation route under neutral and basic conditions; however, it is an important route under acidic conditions. It is also non-persistent to slightly persistent in soil and in aerobic and anaerobic water/sediment systems (Canada, 2004; Canada, 2009). The major transformation products in soil are metsulfuron-methyl (slightly to moderately persistent), AE F059411 (moderately persistent to persistent), and AE F161778 (non-persistent to slightly persistent). Iodosulfuron-methyl-sodium and the transformation products, metsulfuron-methyl and AE F059411, do not readily bind to soil or sediment, and under certain environmental conditions (heavy rainfall) are expected to be very mobile in soils, with the potential to leach or be transported to surface water by run-off and to predominantly partition into the water column (Canada, 2004). Since iodosulfuron-methyl-sodium is non-persistent in soil under field conditions, residues are not expected to carry over to the next growing season. Iodosulfuron-methyl-sodium did not leach under field conditions. The transformation product, metsulfuron-methyl, is moderately persistent in the field and has the potential to leach, depending on the amount of rainfall and soil type. Metsulfuron-methyl is persistent under anaerobic aquatic conditions (Canada, 2004). Label updates for run-off, leaching and storage statements are proposed to meet the current standards (Appendix II).

Iodosulfuron-methyl-sodium does not meet Track 1 criteria, and will not form any transformation products that meet the Track 1 criteria as per the Toxic Substances Management Policy (Canada, 2004; Canada, 2008).

3.2 Environmental risk characterization

Environmental risk characterization for iodosulfuron-methyl-sodium was previously established by Health Canada (Canada, 2004; Canada, 2009). Iodosulfuron-methyl-sodium and its major transformation products present negligible risk to wild mammals, birds, earthworms, bees and most other arthropods (Canada, 2009). It is also of low toxicity to aquatic invertebrates, fish and algae following short-term or long-term exposure.

A risk to terrestrial and aquatic vascular plants was identified and a buffer zone of one metre is currently required for the protection of both non-target terrestrial plants and aquatic habitats from spray drift (Canada, 2009; Canada, 2024a).

Refer to Regulatory Note REG2004-04 (Canada, 2004), Proposed Registration Decision PRD2008-06 (Canada, 2008) and Registration Decision RD2009-01 (Canada, 2009) for further details on the environmental risk assessments for iodosulfuron-methyl-sodium.

Health Canada also considered the USEPA Interim Registration Review Decision (USEPA, 2017) and European Union review (EFSA, 2016) as part of the environmental assessment. The EFSA pollinator assessment concluded a low acute (contact and oral) and chronic risk to honeybees (EFSA, 2016). Risks to aquatic and terrestrial plants were determined by both agencies and risk mitigation was considered. No further risks to non-target organisms were identified (EFSA, 2016; USEPA, 2017).

4.0 Human incident reports

As of 12 September 2025, one domestic animal incident involving iodosulfuron-methyl-sodium was submitted to the PMRA database. The incident occurred in the US and involved a product containing iodosulfuron-methyl-sodium, dicamba and thiencazone-methyl. In the report, a dog was reported to have been exposed to the product as a result of postapplication contact with a treated area. The symptom as reported in the animal (in other words, death) was considered as unlikely to be related to the product based on the reported circumstances of the exposure and toxicological profile for the active ingredients. Overall, given the limited number of incidents involving iodosulfuron-methyl-sodium, no health concerns could be identified following this incident review.

4.1 Environmental incident reports

As of 12 September 2025, no environment incidents involving iodosulfuron-methyl-sodium have been reported to Health Canada.

5.0 Value

Iodosulfuron-methyl-sodium is a contact and a systemic herbicide. It has acceptable value as a selective herbicide to control a range of grassy and broadleaf weeds (Canada, 2004; Canada, 2008). The visible symptoms of herbicidal action are almost immediate with arresting of growth, followed by leaf yellowing, inhibition of anthocyanin production, and, finally, progressive shoot necrosis (Canada, 2004).

Appendix I Registered products containing iodosulfuron-methyl-sodium

Table 1 Products containing iodosulfuron-methyl-sodium that are registered in Canada as of 25 July 2025

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
27421	Technical	Bayer CropScience Inc.	Iodosulfuron-Methyl-Sodium Technical Herbicide	Dust or Powder	IDO-92%
27422	Commercial	Bayer CropScience Inc.	Tribute Solo 32 DF Herbicide	Wettable Granules	IDO-2.0%; FMS-30.0%

FMS = foramsulfuron

IDO = iodosulfuron-methyl-sodium

Appendix II Label updates for products containing iodosulfuron-methyl-sodium

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below. For products co-formulated with other active ingredients, the retain the most stringent label statements.

For technical active ingredient:

1. Replace the term “guarantee” with “active ingredient”.
2. Replace “Precautions” with “Environmental Precautions”
3. Add “Toxic to aquatic organisms.” under Environmental Precautions
4. Under Directions of Use add:

“DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.”

For commercial end-use product:

Directions for use:

1. Add:

“DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

2. Update the field sprayer application statement with:

“Field sprayer application: DO NOT apply when wind speed is less than 1 km/h. Avoid application of this product when winds are gusty. DO NOT apply with sprays finer than the American Society of Agricultural and Biological Engineers (ASABE) S572 (572.1 to 572.3) Medium classification. Boom height must be 60 cm or less above the crop or ground.”

Environmental precautions and information:

1. Update the environmental runoff statement with:

“To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay. Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body. Additional guidance can be found on the Runoff Mitigation portion of the Canada.ca website.”

2. Add:

“This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”

Storage:

1. Add:

“Store this product away from food or feed.”

References

PMRA No.	Reference
73008	Canada, 2004. Regulatory Note, REG2004-04, Iodosulfuron-Methyl-Sodium Technical Herbicide
1528661	Canada, 2008. Proposed Registration Decision, PRD2008-06, Iodosulfuron-Methyl-Sodium Technical Herbicide
1862474	Canada, 2009. Registration Decision, RD2009-01, Iodosulfuron-Methyl-Sodium Technical Herbicide
2138026	Canada, 2012. Evaluation Report for Category B, Subcategory 5.0 – New MRL for Previously Assessed TGAI, Iodosulfuron-Methyl-Sodium Technical Herbicide
3571124	Canada, 2024a. Proposed Re-evaluation Decision, PRVD2024-04, Foramsulfuron and Its Associated End-use Products
3550395	Canada, 2024b. Evaluation Report for Category B, Subcategory 3.12, 3.5 – Changes to Product Labels-New Site or Host and Rotational Crops/Plantback Interval - Metsulfuron-methyl and saflufenacil
3709263	USEPA, 2015. Iodosulfuron-Methyl-Sodium. Draft Human Health Risk Assessment in Support of Registration Review
3709268	USEPA, 2017, Interim Registration Review Decision for 22 Sulfonylurea (SU) Herbicides
3709271	EFSA 2016, Peer review of the pesticide risk assessment of the active substance iodosulfuron-methyl-sodium (approved as iodosulfuron)