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Proposed Registration Decision

Bispyribac-sodium

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Overview

Proposed Registration Decision for Bispyribac-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 Bispyribac-sodium Technical and Velocity SP Herbicide for use on sod farms and golf courses for the reduction of annual bluegrass in turf.

An evaluation of available scientific information found that, under the approved conditions of use, Velocity SP Herbicide 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 Section provides detailed technical information on the human health, environmental and value assessments of bispyribac-sodium and Velocity SP 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 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 of humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

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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* is "...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 bispyribac-sodium, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision document[4] on bispyribac-sodium, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation Section of this consultation document.

What Is Bispyribac-sodium?

Bispyribac-sodium is a postemergence herbicide, i.e. a herbicide applied to emerged plants. It is applied to turf using ground application equipment to reduce the presence of annual bluegrass, a common invasive turf weed. Bispyribac-sodium inhibits the synthesis of key amino acids causing susceptible plants to stop growing and die within about two to three weeks.

Health Considerations

Can Approved Uses of Bispyribac-sodium Affect Human Health?

Bispyribac-sodium is unlikely to affect your health when used according to label directions.

Exposure to bispyribac-sodium may occur when handling and applying the product. When assessing health risks, two key factors are considered: the level 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 (e.g. 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 animals occur at doses more than 100 times higher (and often much higher) than levels to which humans are normally exposed when using bispyribac-sodium products according to label directions.

Health effects in animals given daily doses of bispyribac-sodium over long periods of time included effects on the liver, bile duct, gall bladder and urinary bladder. When bispyribac-sodium was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is no more sensitive to bispyribac-sodium than the adult animal. Bispyribac-sodium was not genotoxic and did not cause cancer, damage the nervous system or have reproductive

[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*.

effects. The risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of Velocity SP Herbicide is limited to non-food/feed situations. It is not anticipated that the use of Velocity SP Herbicide will result in dietary risk from food and/or water.

Occupational risks are not of concern when Velocity SP Herbicide is used according to the proposed label directions, which include protective measures.

Pesticide applicators mixing, loading or applying Velocity SP Herbicide, as well as field workers re-entering freshly treated areas, can come in direct contact with bispyribac-sodium on the skin or through inhalation of spray mists. Therefore, the label will specify that anyone mixing, loading or applying Velocity SP Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. The label also specifies that all unprotected persons must be kept out of operation areas or areas where there may be drift. Taking into consideration these label requirements and that occupational exposure is expected to be brief, risk to applicators or workers is not a concern.

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

Environmental Considerations

What Happens When Bispyribac-sodium Is Introduced Into the Environment?

Bispyribac-sodium is toxic to aquatic and terrestrial plants; therefore, buffer zones are required during application.

Bispyribac-sodium enters the environment when used as a herbicide on turf. Bispyribac-sodium is slightly persistent in soil and moderately persistent in water and sediment systems. Based on its low volatility, residues of bispyribac-sodium are not expected in the air. Based on physical and chemical factors of bispyribac-sodium, including its moderate persistence and moderate to high mobility in soil, bispyribac-sodium has the potential to move into surface and groundwater through runoff and leaching.

Bispyribac-sodium presents a low risk to wild mammals, birds, earthworms, bees, aquatic invertebrates and fish. Given that bispyribac-sodium is a herbicide, it is expected to adversely affect terrestrial plants in areas adjacent to where it is being used, as well as aquatic plants and some species of algae. Therefore, a buffer zone of five metres is required to protect nearby terrestrial plants from the effects of spray drift. Similarly, a buffer zone of one metre is required to protect aquatic plants and algae from the potential effects of spray drift.

Value Considerations

What is the Value of Bispyribac-sodium?

Bispyribac-sodium, a postemergence herbicide, reduces the presence of annual bluegrass in turf.

Multiple applications of bispyribac-sodium, formulated as Velocity SP Herbicide, reduces the presence of annual bluegrass in turf. As bispyribac-sodium is only applied to turf infested with annual bluegrass, golf course superintendents and sod farmers can readily determine whether application of this herbicide is necessary.

Bispyribac-sodium is the only herbicide available in Canada to combat annual bluegrass in turf.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the label of Velocity SP 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 bispyribac-sodium on the skin, anyone handling Velocity SP Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks.

Environment

- Velocity SP Herbicide cannot be sprayed within five metres of susceptible non-target terrestrial plant species, nor within one metre of susceptible aquatic plant species. The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of Application	Buffer Zones (metres) Required for the Protection of:		
	Freshwater habitat of depths:		Terrestrial habitat
	Less than 1 m	Greater than 1 m	
Field sprayer*	1	1	5

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

Next Steps

Before making a final registration decision on bispyribac-sodium, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision document, 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

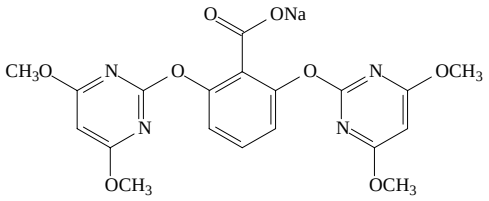
At the time the PMRA makes its registration decision, it will publish a Registration Decision document on bispyribac-sodium (based on the Science Evaluation Section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection,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

Science Evaluation

Bispyribac-sodium

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance		Bispyribac present as sodium salt
Function		Herbicide
Chemical name		
1.	**International Union of Pure and Applied Chemistry (IUPAC)**	Sodium 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy]benzoate
2.	**Chemical Abstracts Service (CAS)**	Benzoic acid, 2,6-bis((4,6-dimethoxy-2-pyrimidinyl)oxy)-, sodium salt
CAS number		125401-92-5
Molecular formula		$C_{19}H_{17}N_4NaO_8$
Molecular weight		452.36
Structural formula		
Purity of the active ingredient		93.2%

1.2 Physical and Chemical Properties of the Active Substances and End-use Product

Technical Product—Bispyribac-sodium Technical

Property	Result
Colour and physical state	white granular powder
Odour	odourless
Melting range	223–224°C
Boiling point or range	N/A
Density at 20°C	1.29 g/mL
Vapour pressure at 2°C	1×10^{-7} mm Hg
Ultraviolet (UV)-visible spectrum	λ_{max} (nm) / pH 246.5 / 1.22 246.5 / 1.99 246.5 / 7.19 246.5 / 12.79
Solubility in water at 25°C	6.75 g/100mL
Solubility in organic solvents at 25°C (g/100 mL)	**Solvent** / **Solubility (g/100 mL)** Methanol / 2.5 Acetone / 1.4×10^{-4} Methylene Chloride / 1.3×10^{-4} Ethyl Acetate / 6.1×10^{-6} *n*-Hexane / 8.34×10^{-7} Toluene / $<1 \times 10^{-5}$ *n*-Octanol / 2.1×10^{-3}
n-Octanol–water partition coefficient (K_{ow})	**pH** / **log K_{ow}** 1.85 / 2.64 ± 0.09
Dissociation constant (pKa)	3.55 ± 0.09
Stability (temperature, metal)	The product is stable.

End-use Product—Velocity SP Herbicide

Property	Result
Colour	Beige
Odour	Odourless
Physical state	Powder
Formulation type	Water-soluble powder
Guarantee	Bispyribac (present as sodium salt) at 76.1% nominal (limits: 73.8–78.3%)
Container material and description	Plastic bag (56.7 g × 4)
Density	0.25 g/mL
pH of 1% dispersion in water	8.8
Oxidizing or reducing action	No oxidizing or reducing reaction (negative to water, elemental Zn and $KMnO_4$ contact tests).
Storage stability	The product is stable for 1 year without loss of assay or change in appearance.
Explodability	The product is not explosive.

1.3 Directions for Use

Velocity SP Herbicide is a selective herbicide for use as a postemergence treatment for the reduction of annual bluegrass, including annual bluegrass seedheads, on established turf of creeping bentgrass, perennial ryegrass, Kentucky bluegrass and tall fescue. The product is designed for application to turf comprised of one or more of these species on sod farms and golf courses only. Velocity SP Herbicide can be applied multiple times at two rates in accordance with three separate programs (Table 1.3.1). Velocity SP Herbicide can also be applied to turf that has been overseeded, reseeded, sprigged or sodded. The product is applied in not less than 234 L water/ha as a broadcast treatment, with groundboom equipment only.

Table 1.3.1 Use Pattern for Velocity SP Herbicide

Turf Species and Use (Program)	Herbicide Rate	Application Interval	Maximum Number of Applications per[1]		Weed Claims and Conditions
			28-day Period	Year	
Program 1 Creeping bentgrass (0.9–1.9 cm height) and perennial ryegrass (1.3–1.9 cm height)	24.7 g a.i./ha (31 g product/ha)	7 days	4	12	Reduction of annual bluegrass and suppression of annual bluegrass seedheads in established turf (for use where complete removal of annual bluegrass during a single season is undesirable)
Program 2 Creeping bentgrass (0.9–1.9 cm height) and perennial ryegrass (1.3–1.9 cm height)	74.1 g a.i./ha (93 g product/ha)	14 days	2	4	Reduction of annual bluegrass and suppression of annual bluegrass seedheads in established turf (for use where complete removal of annual bluegrass would not result in an unacceptable stand of turf)
Kentucky Bluegrass and Tall Fescue Program	24.7 g a.i./ha (31 g product/ha)	7–14 days	4	12	Reduction of annual bluegrass and suppression of annual bluegrass seedheads in established turf
Overseeding used in conjunction with one of the above programs	24.7 or 74.1 g a.i./ha (31 or 93 g product/ha)	As above except no application between 10 days before and 60 days after overseeding (except 30 days after overseeding with creeping bentgrass)	See footnote 1	See footnote 1	Reduction of annual bluegrass in turf with greater than 10% annual bluegrass. A maximum of 1 application of 74.1 g a.i./ha or 2 applications of 24.7 g a.i./ha (made at least one week apart) may be made between 30 and 60 days after overseeding with creeping bentgrass.

Turf Species and Use (Program)	Herbicide Rate	Application Interval	Maximum Number of Applications per[1]		Weed Claims and Conditions
			28-day Period	Year	
Reseeding, sprigging or sodding of any of the above turf species	24.7 or 74.1 g a.i./ha (31 or 93 g product/ha)	As above except no application within 10 days of reseeding or sprigging	See footnote 1	See footnote 1	Reduction of annual bluegrass. Sodded, sprigged or reseeded turf must have a uniform stand and be mowed at least twice before being treated with Velocity SP Herbicide.

[1] Not to exceed 148 g a.i./ha (185 g product/ha) per 28-day period or 296.6 g a.i./ha (370.8 g product/ha) per year.

Velocity SP Herbicide is not to be tank-mixed.

1.4 Mode of Action

Bispyribac-sodium is classified as a Group 2 herbicide. The primary mode of action of bispyribac-sodium is as an inhibitor of acetolactate synthase (ALS) in the biosynthesis of branched-chain amino acids. Within a few days after application, annual bluegrass becomes chlorotic and stops growing. This is followed by necrosis and death of plant tissues. Selectivity is largely based on differential rates of metabolism among species. The tolerance of some turf species to bispyribac-sodium is due to their ability to rapidly metabolize and thereby detoxify this herbicide.

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 the impurities in Bispyribac-sodium Technical have been validated and assessed as 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 and gas chromatography methods with tandem mass spectrometry (HPLC-MS/GC-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 (77–107%) were obtained in plant and animal matrices and environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

The PMRA conducted a detailed review of the toxicological database for bispyribac-sodium. The database consists of an array of laboratory animal (in vivo) and cell culture (in vitro) toxicity studies currently required for health 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 this pest control product.

Technical bispyribac-sodium is of low acute toxicity via oral, dermal and inhalation routes in rats. It was not irritating when applied to the skin of the rabbit but was minimally irritating to the rabbit eye. The skin sensitization testing in guinea pigs, using the Buehler method, was conducted using low doses, in spite of the fact that higher doses did not irritate the skin in other studies. A rationale for the doses selected was not provided. In the absence of adequate explanation, technical bispyribac-sodium will be considered a potential dermal sensitizer.

The formulation Velocity SP herbicide, containing 80% of the technical bispyribac-sodium, was similar in acute toxicity via the oral route compared to the active ingredient alone. It was therefore assumed that the toxicity profile for the remaining acute toxicity studies—namely dermal, inhalation, primary eye and skin irritation and skin sensitization—will be similar to that of the active ingredient alone.

The absorption, distribution, metabolism and excretion of bispyribac-sodium was studied in Fischer 344 rats and B6C-3FI mice following a single gavage and IV dose or a single gavage dose following a 14-day pretreatment with unlabelled bispyribac-sodium and in bile-cannulated Fischer 344 rats following single gavage doses. The results indicated that bispyribac-sodium was rapidly absorbed and excreted. Of the administered dose, approximately 80 to 85% in males and 48 to 69% in females was excreted in 24 hours in the feces. Urinary excretion represented more than 28% of the dose in females and about 11% of the dose in males. Excretion in expired air was less than 0.1% and excretion in bile was 24 to 27% of the dose. Residue levels in tissues were low (<2%). Metabolite identification indicated that 82% of the administered dose was excreted unchanged as bispyribac-sodium. Total unidentified metabolites were less than 5%. Based on the metabolite profiles, the major metabolic pathway occurred via O-demethylation of bispyribac -sodium.

A 21-day dermal toxicity study in rats showed no treatment-related effects following daily application of bispyribac-sodium at 1000 mg/kg bw/day.

In short- and long-term studies in mice, rats and dogs bispyribac-sodium induced reduced food consumption and overall food efficiency, lowered body weight and body weight gain. Target organ toxicity involved the liver and the bile duct. In mice, this included slight hepatocellular hypertrophy, granulation, fatty change with erosion, fibrosis, white patch zones and liver nodules in moribund animals, increased incidence of liver giant cells and single cell necrosis. Epithelial hyperplasia occurred in the gall bladder. In the rat, changes in clinical chemistry (alkaline phosphatase, gamma glutamyl transpeptidase and glutamic transaminase) and liver histopathology (necrosis, vacuolic change, fibrosis, cellular infiltration hepatodiaphragmatic nodule, macrophage accumulation and/or granulation) were noted. There were also increased incidences of cystic choleduchus and dilated choleduchus lumen.

Aside from the observations in the main target organs, there were increased incidences of urinary bladder epithelial hyperplasia, lymphocytosis and epithelial cells in the urine, moribundity, wasting and abdominal distension, intestinal metaplasia, decrease in absolute and relative testicular weight and atrophy.

In the dog studies, there was an increase in absolute and relative liver weights, hyperplasia of the intrahepatic bile ducts, granulation of the liver, pale liver and hyperplasia of the epithelium of the choledochus. Increased salivation was also noted. There were no durational effects noted.

Mode of action studies to assess various aspects of the effects of bispyribac-sodium on the liver, bile duct and gall bladder confirmed that these organs were targets, and changes in the relative compositions of bile acids were noted.

No evidence of mutagenic potential of bispyribac-sodium was observed in a battery of in vitro and in vivo genotoxicity assays assessing gene mutation and chromosome aberration. The Rec assay indicated that mutagenesis may be affected.

When tested in the rat, bispyribac-sodium did not affect reproductive performance. Developmental studies in the rats and rabbits did not demonstrate teratogenic potential of bispyribac-sodium and there was no indication of increased susceptibility of the young to the test substance in either of the studies. Based on this information, the 10× PCPA factor can be removed.

3.2 Determination of Acceptable Daily Intake

Velocity SP Herbicide is not proposed for use on food or feed crops. Thus, a value for an acceptable daily intake was not necessary

3.3 Determination of Acute Reference Dose

An acute reference dose (ARfD) is not required due to the low acute toxicity of bispyribac-sodium.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to Velocity SP Herbicide is characterized as short- to intermediate-term in duration and is predominately by the dermal and inhalation routes. For the short- and intermediate-term dermal route, a 21-day rat dermal toxicity study with a NOAEL of 1000 mg/kg bw/day was considered the most appropriate endpoint. A NOAEL of 100 mg/kg bw/day from a rabbit developmental toxicity study was considered appropriate for short-term inhalation exposure, and a NOAEL of 100 mg/kg bw/day was appropriate for intermediate-term inhalation exposure based on a 90-day dog study. In all cases a target MOE of 100 was deemed appropriate. The standard uncertainty factor of 100 has been applied to account for intraspecies extrapolation and interspecies variability.

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Sod farm and golf course pesticide applicators may be exposed to Velocity SP Herbicide when mixing/loading the product or applying it to turf. Velocity SP Herbicide is applied at 24.8 to 74.1 grams of active ingredient per hectare. A sod farmer or custom applicator can typically treat 300 hectares per day using groundboom equipment and a golf course applicator can typically treat 16 hectares per day using smaller groundboom equipment. A sod farmer or golf course applicator may be exposed for as many as 12 days a year, while a custom applicator may be exposed for up to three months over the course of a year.

Exposure estimates for mixers, loaders and applicators are based on data from the Pesticide Handlers Exposure Database (PHED), version 1.1. The PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software that facilitates the generation of exposure scenario estimates.

PHED subsets were generated for mixers/loaders of a water soluble package and for applicators using groundboom equipment. The data provided by the PHED was appropriate for this situation and compare well with the product use scenario. Exposure estimates are presented on the basis of the best-fit measure of central tendency such as mean, median or geometric mean, i.e. summing the measure of central tendency for each body part.

The estimated worker exposure was based on a worker body weight of 70 kg and dermal absorption of 100%, for males and females. The risk assessment was conducted using the assumption that all mixers, loaders and applicators wear protective clothing consisting of a single layer (a long-sleeved shirt and long pants) and no gloves.

For a sod farmer treating 300 hectares of sod at the maximum label rate of 74.1 g a.i./ha, the daily amount of bispyribac-sodium handled could be 22.2 kg a.i./day. A golf course applicator would handle 1.19 kg a.i./day while treating 16 hectares.

For the risk assessment, MOEs were generated based on the NOAEL of 1000 mg a.i./kg bw/day from the dermal rat study and 100 mg a.i./kg bw/day for inhalation. All MOEs are above the target MOE of 100; therefore, they are considered not of concern (Table 3.4.2.1 and Table 3.4.2.2).

Table 3.4.2.1 Mixer/Loader/Applicator Exposure Estimates

Scenario Groundboom[a]	PHED Unit Exposure (µg a.i./kg a.i. handled)		Exposure Pattern	Daily Dose (µg a.i./kg bw/day)[b]	
	Dermal	Inhalation		Dermal	Inhalation
Sod Farm	79.1	1.14	Application to 300 ha at 0.074 kg a.i./ha (22.2 kg a.i./day)	25.1	0.362
Golf Course	79.1	1.14	Application to 16 ha at 0.074 kg a.i./ha (1.190 kg a.i./day)	1.34	0.019

[a] Mixer/loader and applicator: single layer of clothing, no gloves; closed mix/loading, open cab groundboom

[b] Calculated as µg a.i./kg a.i. handled × application rate × area treated ÷ 70 kg body weight

Table 3.4.2.2 Margins of Exposure for Mixer/Loader/Applicator to Turf

Scenario	Exposure (µg a.i./kg bw/day)[a]		Margin of Exposure[b]	
	Dermal	Inhalation	Dermal	Inhalation
Sod Farm (300 hectares)	25.1	0.362	3.98×10^4	2.76×10^5
Golf Course (16 hectares)	1.34	0.019	7.46×10^5	5.26×10^6

[a] Calculated as µg a.i./kg a.i. handled × application rate (kg a.i./ha) × area treated (hectare) ÷ 70 kg body weight

[b] Dermal NOAEL of 1000 mg a.i./kg bw/day; inhalation NOAEL of 100 mg a.i./kg bw/day; target margin of exposure of 100.

3.4.2.2 Postapplication Worker Exposure and Risk

There is potential for exposure to workers and golfers entering treated areas to perform a variety of turf-related activities, including IPM scouting, mowing, verticutting, aerating, spraying conventional pesticides, fertilizing, topdressing, cup cutting, repairing wear from play (i.e. ball marks and divots), walking over treated areas, irrigating, transplanting sod and activities associated with recreational use of the course (golfing). Individuals involved include males and females aged 12 and older. An eight-hour work day is usually assumed for workers, whereas a four-hour day is assumed for golfers.

The duration of exposure is considered to be intermediate-term, and the primary route of exposure for workers and golfers that enter treated areas would be dermal through contact with residues on the turf. Inhalation exposure is expected to be negligible because the vapour pressure of bispyribac-sodium is 1×10^{-7} mm Hg at 25°C, making it effectively non-volatile.

Dermal exposure to workers entering treated areas is estimated by coupling turf transferable residue (TTR) values with activity-specific transfer coefficients (TC). Chemical-specific TTR data were not submitted. As such, a default turf transferable residue value of 5% of the application rate was used in the exposure assessment. The peak TTR value was determined for each of the application rates and intervals described on the label assuming a 10% dissipation rate per day between applications. The highest transfer coefficient for the above listed postapplication activities is 6800 cm^2/h for mowing, harvesting, transplanting and hand weeding turf. A transfer coefficient of 500 cm^2/h is assumed for golfers.

For the risk estimates, exposure was compared with the NOAEL of 1000 mg/kg/day from the dermal toxicity study. A dermal absorption value was not used because no in vivo dermal absorption studies were submitted, and since exposure was compared to a dermal NOAEL, it was not required.

All margins of exposure are significantly higher than the target MOE of 100; therefore, they are considered to be acceptable (Table 3.4.2.3).

Table 3.4.2.3 Postapplication Margins of Exposure

Activity	Exposure (µg a.i./kg bw/day)[a]	Margin of Exposure[b]
Mowing, harvesting, transplanting and hand weeding	37.2	26 900
Adult golfer	1.37	7.30×10^5
Youth golfer	2.5	4.07×10^5

[a] A conservative estimate of worker exposure was calculated as peak TTR × transfer coefficient of 6800 cm^2/hour × 8 hour/day worked ÷ 70 kg body weight
A conservative estimate of youth golfer exposure was calculated as peak TTR × transfer coefficient of 500 cm^2/hour × 4 hour/day worked ÷ 39 kg body weight

[b] NOAEL of 1000 mg a.i./kg bw/day (dermal toxicity study); target MOE of 100.

3.5 Food Residues Exposure Assessment

Velocity SP Herbicide is to be used in non-food and non-feed situations. A food residue exposure assessment is not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Bispyribac-sodium enters the soil in its use as a herbicide on turf. The assessment of transformation in soil under field conditions relevant to Canada was based on the results of laboratory studies. Aerobic biotransformation in soil is an important transformation pathway for bispyribac-sodium, with a bi-phasic transformation pattern where parent transformation is slower after 55 days. The time to 50% dissipation ranged from 18.6 to 19.1 days. Major transformation products produced in soil were 4,6-dimethoxy-2-hydroxypyrimidine (Me_2BA), sodium 2-hydroxy-6-[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate (Bx-180), and 2,6-dihydroxybenzoic acid (2,6-DBA). Bispyribac-sodium was found to be moderately to highly mobile in soil and slightly persistent in aerobic soil. Bispyribac-sodium meets all the leaching potential characteristics identified by Cohen et al. (1984), those being very soluble in water, anion form at environmentally relevant pHs, non-volatile from both dry soils and water or moist soils, unlikely to hydrolyse and phototransform, and mobile and persistent in soil. Furthermore, the USEPA also determined that bispyribac-sodium "is moderately persistent and mobile and will likely move into surface and groundwater through run-off and leaching" (USEPA, 2004).

Bispyribac-sodium can enter aquatic systems through spray drift or surface runoff and leaching. It is very soluble in water at environmentally relevant pH levels and partitions primarily to the water phase, and is thus not expected to accumulate in sediments. Hydrolysis is not a significant route of transformation under environmentally relevant conditions. Bispyribac-sodium will be moderately persistent in aquatic systems with half-lives ranging from 45 to 102 days in aerobic systems and from 81 to133 days in anaerobic systems. In the aerobic aquatic system, sodium 2-(4,6-dimethoxy pyrimidin-2-yl)oxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) benzoate (DesMe-2023) forms as a major transformation product while in anaerobic aquatic systems, DesMe-2023; Me_2BA; 2,6-DBA; 4,6-dihydroxy-6-methoxypyrimidine (MeBA); and 2-hydroxy-6-[(4-hydroxy-6-methoxypyrimidin-2-yl)oxy] benzoate (DesMe-180) form as major transformation products.

The vapour pressure and Henry's law constant of bispyribac-sodium indicate that the compound is considered to be non-volatile in the environment. Therefore, bispyribac-sodium residues are not expected in the air and long-range transport is not expected.

Data on the fate and behaviour of bispyribac-sodium, as well as the identification of its transformation products are summarized in Tables 3.1.1, 3.1.2, and 3.1.3 of Appendix I. The transformation pathways for bispyribac-sodium in aerobic soil and in water/sediment systems are summarized in Figures 3.1.1 and 3.2.2 of Appendix I.

4.2 Effects on Non-Target Species

To estimate risk of potential adverse effects on non-target species, a quotient method is used. The risk quotient is calculated by dividing the exposure estimate by a value representing a sensitive toxic endpoint. Risk quotients are initially calculated for a conservative screening-level assessment in order to identify products that do not pose a concern. Negligible risk is predicted if

the risk quotient is less than the Level of Concern (LOC), which is a value of one. If the LOC is exceeded under the screening level scenario, then a refined assessment is necessary to further evaluate risk under more realistic conditions. A refined assessment takes into consideration more realistic exposure scenarios (e.g. drift to non-target habitats and runoff to water bodies) and may consider different toxicity endpoints.

4.2.1 Effects on Terrestrial Organisms

Risk of bispyribac-sodium to terrestrial organisms was based upon evaluation of toxicity data for the following:

- terrestrial vertebrates (two mammalian species and two bird species);
- terrestrial invertebrates (one bee species and one earthworm species); and
- ten plant species (Table 3.2, Appendix I).

For birds, bispyribac-sodium did not cause mortality or clinical signs of toxicity in short-term studies. For small mammals, bispyribac-sodium and a formulated end-use product were practically non-toxic on an acute basis. However, body weight reduction and changes in food uptake were reported in dietary studies with rats only. In a multigenerational reproduction study with rats, body weight reduction occurred in the offspring. Risk quotients calculated under a screening level scenario indicate that bispyribac-sodium presents a negligible risk to birds and mammals following acute, short-term or long-term exposure; all risk quotients are less than the LOC (Table 3.3, Appendix I).

For terrestrial invertebrates, bispyribac-sodium did not cause mortality or clinical signs of toxicity in acute studies with earthworms or a 48-hour contact study with bees, with LC_{50} values exceeding the highest dose (limit) tested. Risk quotients calculated under screening level scenarios indicate that bispyribac-sodium presents a negligible risk to terrestrial invertebrates; all risk quotients are less than their respective LOCs (Table 3.3, Appendix I).

For terrestrial plants, seedling emergence and vegetative vigour were affected by exposure to formulated bispyribac-sodium. Dry weight was the most sensitive endpoint in the seedling emergence studies. In vegetative vigour studies, for monocots, plant height was the most sensitive endpoint, while for dicots, dry weight was the most sensitive endpoint. The rates at which bispyribac-sodium negatively affected the seedling emergence of 25% of the population was 1.46 g a.i./ha for monocots and 2.13 g a.i./ha for dicots (ER_{25} or effective rate for 25% of the population). Vegetative vigour was negatively affected in 25% of the population at rates of 2.35 g a.i./ha for monocots and 1.12 g a.i./ha for dicots. For the assessment of risk to terrestrial plants in the area of application (i.e. on-field), the screening level risk assessment indicated that the LOC was exceeded based on both the seedling emergence and vegetative vigour tests (Table 3.3, Appendix I).

A refined Tier I risk assessment was conducted to further characterize the potential risk resulting from spray drift to non-target plants located off-field. Under this scenario, exposure to off-field (non-target) plants was characterized using empirical spray drift curves to estimate the amount of drift reaching plants one metre downwind from the edge of the application swath. Using a

standard field sprayer with a boom height of 60 cm above the crop, and an assumed ASAE spray quality of medium droplet size for this herbicide application, only 6% of the on-target rate is expected to drift one metre downwind from the edge of the application site. The revised expected environmental concentrations and resulting Tier I risk quotients from drift (see Table 3.4, Appendix I) still indicate a risk to off-site non-target plants one metre downwind from the edge of the field. Therefore, the end-use product Velocity SP Herbicide will require a buffer zone of five metres to reduce the risk of adverse effects in non-target terrestrial plants.

4.2.2 Effects on Aquatic Organisms

Risk of bispyribac-sodium to aquatic organisms was based upon evaluation of toxicity data for the following:

- seven freshwater species (one invertebrate, two fish, three algae and one vascular plant); and
- four estuarine/marine species (two invertebrates, one fish and one alga) (Table 3.2, Appendix I).

For freshwater aquatic invertebrates and freshwater fish, exposure to bispyribac-sodium did not result in mortality or clinical signs of toxicity in acute tests. Variable growth inhibition was observed in green algae exposed to bispyribac-sodium (EC_{50} = 0.25 mg a.i./L). However, phytotoxic effects were not observed in freshwater diatoms or blue-green algae. The formulated end-use product was not acutely toxic to estuarine and marine invertebrates, fish, and algae because no effects were observed at the highest concentrations tested. In a study of the chronic exposure of the freshwater invertebrate *Daphnia magna*, no treatment-related effects on survival, reproduction or terminal growth (body length or dry weight) were observed. Studies of the effects of chronic exposure or early life stage exposure were not submitted for any other species. Risk quotients calculated under a screening level scenario indicate that bispyribac-sodium presents a negligible risk to fish, invertebrates and algae; risk quotients are less than the LOC (Table 3.3, Appendix I).

The vascular plant *Lemna gibba* was affected by exposure to a formulation of bispyribac-sodium with various effects—such as growth inhibition, small fronds, reduced root formation and chlorotic fronds—when exposed to the treatment concentrations. *Lemna* was the most sensitive aquatic organism tested with EC_{50} values of 0.010 and 0.0102 mg a.i./L for frond density and biomass, respectively (Table 3.2, Appendix I). A screening level risk assessment demonstrated a potential risk to non-target freshwater plants from exposure to bispyribac-sodium through the end-use product Velocity SP herbicide as the risk quotient calculated under the screening scenario exceeded the LOC of one (Table 3.3, Appendix I). Because the LOC was exceeded, the potential risk from exposure was further investigated using the results of the Level 1 aquatic ecoscenario modelling. The refined risk assessment for *Lemna*, which incorporates modelled results of expected concentrations of bispyribac-sodium in runoff, indicates that the LOC is not expected to be exceeded for aquatic vascular plants. Thus under a realistic scenario, aquatic vascular plants are not expected to be adversely affected by exposure to bispyribac-sodium through runoff. However, to protect aquatic vascular plants from spray drift, a buffer zone will be required.

5.0 Value

5.1 Effectiveness Against Pests

Reports of 21 field trials were submitted in which the efficacy of Velocity SP Herbicide for control of annual bluegrass and suppression of annual bluegrass seedheads was evaluated. Trials were conducted over a four-year period at several locations throughout the northern United States (U.S.). These data were supplemented with data from an additional six studies, mainly of trials conducted in the southern U.S., acquired through a search of the Internet.

For each trial, an appropriate experimental design was used, and an appropriate set of treatments was included to address the proposed pest claims. The herbicide treatments were applied to turf infested with annual bluegrass using small plot application equipment.

The efficacy of Velocity SP Herbicide was visually assessed in each trial and was recorded as one or more of the following: percent annual bluegrass control or injury, annual bluegrass canopy cover before and after application, and/or a rating of annual bluegrass plant damage, phytotoxicity, or quality. Canopy cover and ratings data were converted to percent control prior to review. In most trials, data were recorded at various times throughout the growing season.

5.1.1 Acceptable Efficacy Claims

The submitted efficacy data were adequate to establish the lowest effective rate for Velocity SP Herbicide applied alone to turf for reduction of annual bluegrass (Table 5.1.1.1).

Table 5.1.1.1 Efficacy Claims for Velocity SP Herbicide

Herbicide Rate	Application Interval	Maximum Number of Applications[1]		Supported Claims
		Per 28-day Period	Per Year	
24.7 g a.i./ha (31 g product/ha) to established turf	7–14 days	4	12	Reduction of annual bluegrass and suppression of annual bluegrass seedheads. For use where complete removal of annual bluegrass during a single season is undesirable.
74.1 g a.i./ha (93 g product/ha) to established turf	14 days	2	4	Reduction of annual bluegrass and suppression of annual bluegrass seedheads. For use where complete removal of annual bluegrass would not result in an unacceptable stand of turf.

Herbicide Rate	Application Interval	Maximum Number of Applications[1]		Supported Claims
		Per 28-day Period	Per Year	
24.7 or 74.1 g a.i./ha (31 or 93 g product/ha) to overseeded turf	As above; no application within 10 days of overseeding	See footnote 1	See footnote 1	Reduction of annual bluegrass in turf with greater than 10% annual bluegrass. A maximum of 1 application of 74.1 g a.i./ha or 2 applications of 24.7 g a.i./ha (made at least one week apart) may be made between 30 and 60 days after overseeding with creeping bentgrass.
24.7 or 74.1 g a.i./ha (31 or 93 g product/ha) to reseeded, sprigged or sodded turf	As above; no application within 10 days of reseeding or sprigging	See footnote 1	See footnote 1	Reduction of annual bluegrass. Sodded, sprigged or reseeded turf must be of uniform stand and have received at least two mowings before being treated with Velocity SP Herbicide.

[1] Not to exceed 148 g a.i./ha (185 g product/ha) per 28-day period or 296.6 g a.i./ha (370.8 g product/ha) per year.

5.2 Phytotoxicity to Host Plants

Tolerance data from 28 acceptable studies were submitted. Field trials were conducted over a four-year period at several locations throughout the northern United States. These data were supplemented with data from an additional 10 studies, mainly of trials conducted in the southern U.S., acquired through an Internet search. Crop tolerance was visually assessed at least once, and usually several times following one or more applications of Velocity SP Herbicide. Tolerance was visually assessed as percent injury, phyto-chlorosis or phytotoxicity, or as a rating of turf injury, colour (or discolouration) or quality. Ratings data were converted to percent injury prior to review.

5.2.1 Acceptable Claims for Host Plants

Turf injury data for Velocity SP Herbicide support a tolerance claim for the following turf species: creeping bentgrass, perennial ryegrass, tall fescue, and Kentucky bluegrass (Table 5.2.1.1). Available data indicated that the degree of tolerance of Kentucky bluegrass to Velocity SP Herbicide was largely dependent on cultivar. Therefore, the label includes a statement advising the applicator to first apply the product to small areas to determine whether the herbicide can be used in a widespread application without causing unacceptable damage to the turf.

Table 5.2.1.1 Host Plant Claims for Velocity SP Herbicide on Golf Courses and Sod Farms Only

Turf Species or Use	Herbicide Rate	Application Interval	Maximum Number of Applications[1]		Remarks
			Per 28-day Period	Per Year	
Creeping bentgrass and Perennial ryegrass	24.7 g a.i./ha (31 g product/ha)	7 days	4	12	Application to established turf mowed to 0.9 cm to 1.9 cm height (golf course fairways and tees) and 1.3 to 1.9 cm height (sod farms).
	74.1 g a.i./ha (93 g product/ha)	14 days	2	4	
Kentucky bluegrass and tall fescue	24.7 g a.i./ha (31 g product/ha)	7-14 days	4	12	Application to established turf
Overseeding with any of the above turf species - used in conjunction with one of the above programs	24.7 or 74.1 g a.i./ha (31 or 93 g product/ha)	As above; no application within 10 days of overseeding	See footnote 1	See footnote 1	A maximum of 1 application of 74.1 g a.i./ha or 2 applications of 24.7 g a.i./ha (made at least one week apart) may be made between 30 and 60 days after overseeding with creeping bentgrass.
Reseeding, sprigging or sodding of any of the above turf species	24.7 or 74.1 g a.i./ha (31 or 93 g product/ha)	As above; no application within 10 days of reseeding or sprigging	See footnote 1	See footnote 1	Sodded, sprigged or reseeded turf must be of uniform stand and have received at least two mowings before being treated with Velocity SP Herbicide.

[1] Not to exceed 148 g a.i./ha (185 g product/ha) per 28-day period or 296.6 g a.i./ha (370.8 g product/ha) per year.

5.3 Impact on Succeeding Crops

Not applicable.

5.3.1 Acceptable Claims for Rotational Crops

Not applicable.

5.4 Economics

No market analysis was conducted or reviewed for Velocity SP Herbicide.

5.5 Sustainability

5.5.1 Survey of Alternatives

There are no other herbicides registered for use on turf for combatting annual bluegrass.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Velocity SP Herbicide can be used in conjunction with other management practices currently used to manage annual bluegrass in turf. These practices include:

- using clean seed that contains no annual bluegrass seed;
- overseeding desirable turf grasses into areas containing annual bluegrass;
- removing seed produced by annual bluegrass by removing grass clippings during mowing;
- thoroughly cleaning mowers and cultivation equipment;
- using fertilizer, irrigation and mowing practices that are adjusted to favour development of desirable turf species so that they vigorously compete with annual bluegrass (e.g. lower rates of fertilizer, less frequent but deeper irrigation, increased mowing height);
- reducing compaction and removing thatch; and
- mechanically removing small patches of annual bluegrass.

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

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of naturally selecting the biotypes, i.e. a group of plants within a species that has biological traits that are not common to the population as a whole, with less susceptibility to herbicides of the same mode of action. However, there are currently no other Group 2 herbicides registered for use on turf species on sod farms and golf courses.

The Velocity SP Herbicide label includes the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

5.5.4 Contribution to Risk Reduction and Sustainability

Turf that is infested with annual bluegrass requires more intensive management to maintain a healthy stand of turf. Annual bluegrass generally requires higher rates of fertilizer and more frequent irrigation due to its shallow root system. It is also more likely to require more frequent application of fungicides due to its relatively high susceptibility to several turf diseases. Therefore, by decreasing the presence of annual bluegrass in turf, Velocity SP Herbicide may indirectly reduce the requirement for fertilizer as well as reduce the frequency of irrigation and fungicide application.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, bispyribac-sodium was assessed in accordance with PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of bispyribac-sodium were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use product Velocity SP Herbicide. The PMRA has reached the following conclusions:

- Bispyribac-sodium does not meet the Track 1 criteria for persistence in soil, persistence in water, persistence in sediment or bioaccumulation. Its estimated half-life values in soil, ranging from 23.6 to 27.6 days under field conditions, are below the criterion of $\geq$182 days. Its half-life values in water, ranging from 45 to 102 days in outdoor conditions, are below the criterion of $\geq$182 days. Its half-life in sediment was determined by regression analysis to range from 53 to 124 days in outdoor conditions, which is below the criterion of $\geq$365 days. Its log *n*-octanol–water partition coefficients of 2.73 at pH 3 and $-$1.03 at pH 6.18 are below the criterion of $\geq$5. Bispyribac-sodium does not meet Track 1 criteria; therefore, it is not classified as a Track 1 substance.

- The following major transformation products have log *n*-octanol–water partition coefficients that are below the TSMP criterion for bioaccumulation of $\geq$5.0. As these compounds will not meet all Track 1 criteria, they are not classified as Track 1 substances:

    - 4,6-Dihydroxy-6-methoxypyrimidine (MeBA) (log K_{ow} = 0.20)
    - 4,6-Dimethoxy-2-hydroxypyrimidine (Me_2BA) (0.82)
    - Sodium 2-(4,6-dimethoxy pyrimidin-2-yl)oxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) benzoate (DesMe-2023) (1.67)
    - Sodium 2-hydroxy-6-[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate (Bx-180) (1.93)

- The following major and minor transformation products are not expected to meet Track 1 criteria:

    - 2-Hydroxy-6-[(4-hydroxy-6-methoxypyrimidin-2-yl)oxy] benzoate (DesMe-180)
    - 2,6-Dihydroxybenzoic acid (2,6-DBA)
    - Methyl 2,6-dihydroxybenzoate (2,6-MDB)

- Methyl 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate (Bispyribac-methyl ester)

- Technical grade bispyribac-sodium does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

- The end-use product Velocity SP Herbicide does not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

Therefore, the use of bispyribac-sodium is not expected to result in the entry of Track 1 substances into the environment.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted is adequate to define the majority of toxic effects that may result from human exposure to bispyribac-sodium. In short- and long-term toxicity studies on laboratory animals, target organs included the liver, bile duct and gall bladder.

There was no evidence that bispyribac-sodium was genotoxic, carcinogenic or teratogenic. It is not a reproductive toxicant. There was no evidence of increased susceptibility of the offspring in the reproductive or developmental toxicity studies.

Mixers, loaders, applicators and workers and golfers entering treated areas are not expected to be exposed to levels of bispyribac-sodium that will result in unacceptable risk when Velocity SP Herbicide is used according to label directions. The personal protective equipment on the product label is adequate to protect workers, and no additional personal protective equipment is required.

Velocity SP Herbicide is not to be applied to any food or feed; thus, a maximum residue limit was not promulgated.

7.2 Environmental Risk

Laboratory studies with bispyribac-sodium found the compound to be moderately to highly mobile in soil and slightly persistent in aerobic soil. In water, bispyribac-sodium will be moderately persistent in aquatic systems, although it partitions primarily to the water phase and is not expected to accumulate in sediments. Bispyribac-sodium meets all the leaching potential characteristics identified by Cohen et al. (1984), those being very soluble in water, anion form at environmentally relevant pHs, non-volatile from both dry soils and water or moist soils, unlikely to hydrolyse and phototransform, mobile and persistent in soil. Furthermore, the USEPA also

determined that bispyribac-sodium "is moderately persistent and mobile and will likely move into surface and groundwater through run-off and leaching" (USEPA, 2004).

Bispyribac-sodium presents a low risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, algae and aquatic plants. However, given that bispyribac-sodium is a herbicide, it is expected to adversely affect plants in adjacent areas. Therefore, a buffer zone of five metres is required to protect terrestrial plants from the effects of spray drift to adjacent terrestrial habitats and a buffer zone of one metre is required to protect aquatic plants from the effects of spray drift to adjacent aquatic habitats.

7.3 Value

The data submitted to register Velocity SP Herbicide are adequate to describe its efficacy for use in turf in reducing infestations of annual bluegrass. The tolerance of creeping bentgrass, perennial ryegrass, Kentucky bluegrass and tall fescue are also acceptable, although some cultivars, particularly of Kentucky bluegrass, may exhibit considerable sensitivity to Velocity SP Herbicide.

7.4 Unsupported Uses

Certain uses originally proposed by the applicant with this application are not supported by the PMRA either because value has not been adequately demonstrated or because of unacceptable risk. Unsupported uses are outlined in Table 4 of Appendix I.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing full registration for the sale and use of the technical grade active ingredient bispyribac-sodium and the end-use product Velocity SP Herbicide for use on sod farms and golf courses for the reduction of annual bluegrass in turf. An evaluation of current scientific data from the applicant, scientific reports and information from other regulatory agencies has resulted in the determination that, under the proposed conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	microgram
a.i.	active ingredient
ALP	alkaline phosphatase
ALS	acetolactate synthase
ARfD	acute reference dose
bw	body weight
bwg	body weight gain
BWI	body weight per individual
CAS	chemical abstracts service
cm	centimetre
DNA	deoxyribonucleic acid
DT_{50}	dissipation time to 50% (the dose required to observe a 50% decline in the test population)
DT_{90}	dissipation time to 90% (the dose required to observe a 90% decline in the test population)
EC_{05}	effective concentration on 5% of the population
EC_{25}	effective concentration on 25% of the population
EEC	expected environmental concentration
ER_{25}	effective rate for 25% of the population
FC	food consumption
FE	food efficiency
g	gram
GC	gas chromatography
GD	gestation day
GOT	glutamate oxaloacetate transaminase
GPT	glutamate pyruvate transaminase
GTP	guanosine triphosphate
h	hour
ha	hectare
H&E	hematoxylin and eosin
HDT	highest dose tested
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
IV	intravenous
kg	kilogram
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
mg	milligram
mL	millilitre

mm	millimetre
mm Hg	millimetre of mercury
MAS	maximum average score
MIS	maximum irritation score
mo	month
MOE	margin of exposure
MS	mass spectrometry
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OC	organic carbon content
PHED	Pesticide Handlers Exposure Database
pKa	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal day
ppb	parts per billion
ppm	parts per million
RSD	relative standard deviation
$t_{1/2}$	half-life
T_{max}	time required to reach maximum residue concentration, for example, in blood, plasma, serum
TC	transfer coefficients
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
UF	uncertainty factor
U.S.	United States
USEPA	United States Environmental Protection Agency
UV	ultraviolet
WP	wettable powder
wt	weight
wk	week

Appendix I Tables and Figures

Table 1 Residue Analysis

Summary of Validation Data for All Matrices								
Matrix	**Method**	**Fortification Level, ppb**	**Overall Mean % Recovery (%RSD)**				**LOQ ppb**	**Method**
			Parent	**Me_2BA**	**MeBA**	**DesBA**		
Soil	GC	1	88 (7.3)	—	—	—	1	Accepted
		5	84 (6.2)					
	HPLC	5	—	92 (13)	—	—	50	Accepted
		10		81 (10)				
		50		84 (5.6)				
	HPLC	2	—	—	84 (7.6)	107 (6.2)	2	Accepted
		10			82 (5.6)	77 (11)		
Water	GC	1	91 (6.3)	—	—	—	1	Accepted
		5	94 (3.9)					
	HPLC	1	—	80 (4.7)	—	—	1	Accepted
		5		78 (6.4)				
		10		83 (7.3)				
		50		83 (5.3)				
	HPLC	1	—	—	89 (3.0)	97 (6.3)	1	Accepted
		5			87 (4.1)	96 (3.7)		
Rice straw	GC	20	84 (3.8)	—	—	—	20	Accepted
Rice grain	GC	12	97 (5.4)	—	—	—	20	Accepted
Animal	waiver request has been accepted.							

Table 2 Toxicity of Bispyribac-sodium and Its Associated End-use Product (Velocity SP Herbicide)

METABOLISM
In a metabolism study, bis-(pyrimidine-2 ^{14}C) bispyribac-sodium (≥97.7%, radiochemical purity) or benzene-U-^{14}C) bispyribac sodium (≥99.7%, radiochemical purity) was administered to Fischer 344 rats (5/sex/dose) as a single gavage dose at 30 or 600 mg/kg, or as a single gavage dose of 30 mg/kg following a 14-day pretreatment with bispyribac-sodium at 30 mg/kg, or as a single intravenous (IV) dose at 30 mg/kg. In addition [^{14}C-Py]-bispyribac-sodium was administered to bile duct-cannulated Fischer 344 rats (5/sex/dose) as a single gavage dose at 10 or 100 mg/kg. In a mouse study, bis-(pyrimidine-2 ^{14}C) -2-6 bispyribac-sodium (≥98.2%, radiochemical purity) was administered to 12 B6C 3F1 animals/sex/dose in a single high dose of 100 mg/kg/bw by gavage. An additional group of 20 males and 16 females was dosed at the same level for blood collection. **Absorption:** In rats, within 24 hours of oral dosing 37.8–48.3% of radioactivity was excreted in the urine and bile. The T_{max} in blood was 0.29–0.36 hours. In mice, unchanged parent compound was detected in high proportions (>90%) in the bile in both sexes. The compound was rapidly absorbed. Peak blood levels of radioactivity were measured in 15 minutes for both sexes. There were no sex-related differences in biliary metabolism when dosed at 100 mg/kg bw. **Distribution:** In the rat, concentration of radioactivity in plasma was generally ≥10-fold greater than in erythrocytes. Concentration of radioactivity in each tissue or organ was generally 2-fold higher in males than in females and increasing the nominal dose level by 20 times resulted in a 3-fold increase in tissue concentration for both sexes. The highest concentration was found in plasma, liver, small intestines, urinary bladder, duodenum and caecum. The lowest concentrations of radioactivity were measured in the bile duct, bone and brain. In mice, 15 minutes after dosing, the highest levels of radioactivity were detected in the stomach, small intestine and liver. By 24 hours, the highest levels were found in the small intestine and cecum (32.6% in males, 30.2% in females). **Excretion:** Radioactivity was excreted primarily as the parent in feces of both sexes (36.6–69.2%) and in urine of males (5.2–9.7% at 30 mg/kg and 22.5–27.9% at 600 mg/kg) and females (27.0–40.6%) regardless of radio label. At 24 hours, mice excreted 9.1% and 12.1% of the dose in urine for males and females, respectively. In addition, male mice excreted 15.3% of the dose into feces while females excreted 20.6%. **Metabolism:** Limited metabolism was observed with 82% excreted as the parent and five metabolites resulting from O-demethylation represented up to 14.6% of radioactivity. In mice, approximately 96% of the dose retrieved from the bile was [^{14}C-Py]-bispyribac-sodium. The remaining 4% was DesMe 2023 and a glucuronide conjugate of bispyribac-sodium, indicating the test article was excreted to the bile relatively unchanged in the mice. Metabolism is similar in both species.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES - Bispyribac-Sodium TECHNICAL (KIH-2023)			
Oral	(**95.2%**) Mouse: B63F1 5/sex/dose. **Dose levels:** 2276, 2959, 3846, 5000, 6500 mg/kg bw	LD_{50} ♂ = 3524 mg/kg bw ♀ = 3524 mg/kg bw **Low Toxicity**	2959 mg/kg - 1/5 ♂, 1/5 ♀ died 3846 mg/kg - 4/5 ♂, 4/5 ♀ died 5000 mg/kg - 4/5 ♂, 4/5 ♀ died 6500 mg/kg - 5/5 ♂, 5/5 ♀ died Clinical signs: decreased spontaneous activity, prone position, subnormal temperature, ptosis, diarrhea and loose stool. All surviving animals recovered between 3 hours and 3 days.
Oral	(**95.2%**) Rat: Fischer F344 5/sex/dose. **Dose levels:** 2276, 2959, 3846, 5000, 6500 mg/kg bw	LD_{50} ♂ = 4111 mg/kg bw ♀ = 2635 mg/kg bw **Low Toxicity**	2959 mg/kg - 0/5 ♂, 3/5 ♀ died 3846 mg/kg - 2/5 ♂, 4/5 ♀ died 5000 mg/kg - 4/5 ♂, 5/5 ♀ died 6500 mg/kg - 5/5 ♂, 5/5 ♀ died Clinical signs: decreased spontaneous activity, prone position, subnormal temperature, lacrimation, ptosis, diarrhea and loose stool.
Oral	(**99.9%**) Rat: Sprague Dawley (Crl:CD (SD)IGS BR) 5/sex/dose **Dose levels:** 1000, 2000, 4000, or 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw **Low Toxicity**	1000-4000 mg/kg - 0/5 ♂, 0/5 ♀ died 5000 mg/kg - 0/5 ♂, 2/5 ♀ died Clinical signs: Anogenital staining, hypothermia, red staining of the snout and extremities, irregular gait, decreased food consumption and fecal volume (♂, ♀)
Dermal	(**95.2%**) Rat: Fischer F344 5/sex/dose. **Dose level:** 2000 mg/kg bw	LD_{50} ♂ > 2000 mg/kg bw ♀ > 2000 mg/kg bw combined > 2000 mg/kg bw **Low Toxicity**	None
Dermal	(**94.5%**) Rabbit: New Zealand White 5/sex/dose **Dose level**: 2000 mg/kg bw	LD_{50} ♂ > 2000 mg/kg bw ♀ > 2000 mg/kg bw combined > 2000 mg/kg bw **Low Toxicity**	None
Inhalation	(**94.5%**) Rats: Sprague Dawley 5/sex **Dose level**: 4.48 mg/L Whole body exposure	LC_{50} ♂ > 4.48 mg/L ♀ > 4.48 mg/L **Low Toxicity**	None

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Skin Irritation	**(95.2%)** Rabbit: New Zealand White 6 males **Dose level**: 0.5 grams (4 hours)	MAS (24–72 hours) = 0/8	Non-irritant
Eye Irritation	(**95.2%)** Rabbit: New Zealand White. 6 males **Dose level**: 0.5 g into conjunctiva of right eye and left **unwashed**	MAS (24–72 hours) = 5.5/110 MIS (24 hours) = 9.17/110	Minimally irritating
Eye Irritation	**(95.2%)** Rabbit: New Zealand White. 6 males **Dose level**: 0.1 g into conjunctiva of right eye and **washed** 2–3 minutes after with 180 mL of water	MAS (24–72 hours) = 1.78/110 MIS (1 hour) = 3.33/110	Minimally irritating
Skin Sensitization (Buehler)	**(95.2%)** Guinea Pig: Dunkin-Hartley **Dose level**: Induction - 30% Challenge - 5 or 30%	Negative	None
ACUTE STUDIES - (KIH-2023-I-1) **as Impurity** (0.4% TGAI)			
Oral	(**97.6%)** Radiate: Sprague Dawley) 5/sex **Dose levels**: 1201, 2450, 3500 or 5000 mg/kg bw	LD_{50} ♂ = 2050 mg/kg bw ♀ = 1979 mg/kg bw combined = 2010 mg/kg bw **Slight Toxicity**	1201 mg/kg - 1/5 ♂, 0/5 ♀ died 2450 mg/kg - 3/5 ♂, 4/5 ♀ died 3500 mg/kg - 3/5 ♂, 3/5 ♀ died 5000 mg/kg - 5/5 ♂, 5/5 ♀ died Clinical signs: hunched posture, lethargy, ataxia, decreased respiratory rate and laboured respiration. Rats treated at 2450 mg/kg or higher showed red stains around the eyes or ptosis. Surviving animals appeared normal within 2 days. Necropsy: hemorrhagic or abnormally red lungs, dark or patchy pallor of the liver, hemorrhage of the gastric mucosa and sloughing of the non-glandular stomach epithelium.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES - (KIH-2023-I-2) **as Impurity** (0.2% TGAI)			
Oral	(**97.1%)** Rat: Sprague Dawley) 5/sex **Dose level**: 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw **Low Toxicity**	None
ACUTE STUDIES - (KIH-2023-I-4) **Impurity** (0.06% TGAI)			
Oral	(**99.9%)** Rat: Sprague Dawley) 5/sex **Dose level**: 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw combined > 5000 mg/kg bw **Low Toxicity**	Clinical signs: ataxia, hunched posture and lethargy with cases of decreased respiration in 3 females, which resolved after 1 day.
ACUTE STUDIES - (KIH-2023-M-8-Na) **Impurity** (Trace)			
Oral	(**87.9%)** Rat: Sprague Dawley) CD 5/sex **Dose level**: 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw **Low Toxicity**	None
ACUTE STUDIES - (KIH-2023 - M9- Na) **Impurity** (Trace)			
Oral	(**88.1%)** Rat: Sprague Dawley) 5/sex **Dose level**: 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw **Low Toxicity**	None
ACUTE STUDIES - FORMULATION ***[Velocity SP Herbicide]***			
Oral	Rat: Albino Crl:CD®(SD)IGS BR 5/sex **Dose levels**: 1000, 2000 (males only) or 5000 mg/kg bw	LD_{50} ♂ > 5000 mg/kg bw ♀ > 5000 mg/kg bw combined > 5000 mg/kg bw **Low Toxicity**	Clinical signs: ano-genital staining and red staining of the snout were observed in all dose groups. 2000/5000 mg/kg bw: red staining of the extremities, ↓ food consumption and fecal volume ♂,♀

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Dermal			Waived Based on the following considerations Acute Oral bridging studies in CD rats conducted with the TGAI and the formulated product indicate that there is no difference in acute oral toxicity between the two products with acute oral LD_{50} > 5000 mg/kg. Furthermore, Velocity SP Herbicide consists of 80% Bispyribac-sodium Technical and 20% inert ingredient.
Inhalation			
Skin Irritation			
Eye Irritation			
Skin Sensitization (test method)			
SHORT-TERM TOXICITY			
21-day dermal	Rat: Sprague Dawley (Crl:CD BR) 5/sex. **Dose levels:** 0, 10, 100 or 1000 mg/kg/day (21 days)	NOAEL = 1000 mg/kg/day (limit dose) LOAEL not established	No treatment-related effects.
90-day (3-month) dietary	Mouse: B63F1 (C57BL/6XC 3H) 10/sex/group **Dose levels:** 0, 35, 350, 3500 or 7000 ppm in the diet (Equivalent to 0, 6.8, 68.6, 699.1 or 1478.9 mg/kg/day ♂ and 0, 8.0, 79.0, 806.1 or 1590.5 mg/kg/day ♀	NOAEL = 350 ppm (68.6/79.0 mg/kg.♂/♀) LOAEL = 3500 ppm. (699.1 mg/kg ♂ and 806.1 mg/kg ♀ **Control**: Terminal body weights 31.0 ± 1.2 g ♂, 27.9 ± 2.7 g ♀ Terminal food consumption 36.1 ± 3.1g ♂, 38.1 ± 3.3 ♀	<u>3500 ppm</u> Hepatocellular hypertrophy ♂, ♀ Slight liver granulation ♀ <u>7000 ppm</u> ↓ bw (4-8%) ♂, ↓ bwg (19%) ♂, and ↓ overall (0–13 wks) and food efficiency (24%). ↓ liver weight (6%) ♂ Fatty change in the liver ♀, erosion, fibrosis and epithelial hyperplasia ♂, ♀ in the gall bladder

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
90-day Dietary	Rat: Fischer F344 10/sex/dose group **Dose levels:** 0, 100, 1000, 10 000 or 20 000 ppm in the diet. (Equivalent to 0, 7.2, 71.9, 724.0 or 1450.5 mg/kg bw/day ♂ and 0, 8.1, 79.9, 790.8 or 1582.5 mg/kg bw/day ♀) An additional 10 rats/sex/dose were treated at 0 or 20 000 ppm for 13 weeks followed by a 4-week recovery period	NOAEL = 1000 ppm (71.9/79.9 mg/kg ♂/♀) LOAEL = 10 000 ppm (724.0 mg/kg ♂ and 790.8 mg/kg ♀) **Control**: Terminal body weights 303.0 ± 12 g ♂, 171.0 ± 7g ♀ Terminal food consumption 107.0 ± 9 g ♂, 72.0 ± 5.9 ♀	≥10 000 ppm ↓ body weight gain (12% ♂, 11% ♀) ↓ overall food efficiency (6%) ♂ ↑ absolute (16%) and relative to body weight (25%) liver weights ♂ ↑ serum alkaline phosphatase and gamma-GTP levels and ↑ incidence of grossly dilated bile duct lumens in males and microscopic lesions in the liver, biliary system and urinary bladder in both sexes 20 000 ppm ↓ mean body weight (9-14%) ♂ ↓ overall body weight gain (19%) ♂ ↓ food consumption (11%) ♂ and ↓ overall (0-13 wks) food efficiency (9%) ↑ incidence of necrosis, deposit of pigment, fibrosis, moderate condition of proliferative ducts ♂/♀, incidence of dilated choledochus ♂/♀ and ↑ incidence in the urinary bladder epithelial hyperplasia, lymphocytosis and epithelial cells in the urine ♂/♀ After a 4-week recovery period, microscopic lesions in the liver and urinary bladder were still evident.
90-day (13 weeks) capsule	Dog: Beagle 4/sex/dose 0, 30, 100 or 600 mg/kg/day	NOAEL = 100 mg/kg/day LOAEL = 600 mg/kg **Control**: Terminal body weights 9.3 ± 1.1 kg ♂, 9.2 ± 1.0 kg ♀ Terminal food consumption 250 ± 0 g ♂, 237 ± 16 ♀	600 mg/kg bw/day Slight proliferation of the intrahepatic bile ducts.↑ salivation ♂,♀
12-month (52 weeks) capsule	Dog: Beagle 4/sex/dose **Dose levels:** 0, 10, 100 or 750 mg/kg/day	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg	≥100 mg/kg bw/day ↑ hyperplasia of the intrahepatic bile ducts ♂, ♀ and granulation of the liver ♀. 750 mg/kg bw/day ↑ abs (23%) + rel (15%) liver weights pale liver ♂. Hyperplasia of the epithelium of the choledochus (common bile duct) ♂. Salivation ♂,♀.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
CHRONIC TOXICITY AND ONCOGENICITY			
2-year (104 weeks)/ oncogenicity dietary	Mouse: B63F1 50/sex/group **Dose levels**: 0, 10, 100, 2500 or 5000 ppm. (Equivalent to 0, 1.4, 14.1, 353 or 728.9 mg/kg/day ♂, 0, 1.7, 17.4, 447.8 or 902.9 mg/kg/day ♀) 10/sex/dose for blood collection at 26, 52 and 78 weeks.	NOAEL = 100 ppm = 14.1 mg/kg/day ♂, 17.4 mg/kg/day ♀ LOAEL = 2500 ppm = 353 mg/kg/day ♂, 447.8 mg/kg/day ♀ **Not carcinogenic**	≥2500 ppm ↓ body weight gain and food efficiency ↑ macroscopic lesions in the liver and gall bladder ♂ e.g. ↑ incidence (18% at week 104) of white patches/zone on the liver ♂ ↑ incidence of the liver giant cells, hypertrophy (70% at week 78 and 26% at week 104), single cell necrosis (18%) 5000 ppm ↑ incidences of giant cells (27%), single cell necrosis (18%), hypertrophy of the liver cells (9%)

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Combined Chronic/ Oncogenicity (feeding) 97.2% a.i.	**(92.7% a.i.)** Rat, Fischer F344 58/sex/dose Satellite group: 10/sex/dose, sacrificed at weeks 13, 26, 52 and 78 **Dose level:** 0, 20, 200, 3500, 7500 ppm (♂; equal to 0, 1.1, 10.9, 194.5 or 404.5 mg/kg bw/day) 0, 20, 200, 5000, 10 000 ppm (♀; equal to 0, 1.4, 13.8, 352.2 or 714.9 mg/kg bw/day)	<u>Males</u> NOAEL = 200 ppm (10.9 mg/kg bw/day) LOAEL = 3500 ppm (194.5 mg/kg bw/day), based on clinical signs, ↓ bw and bwg, ↓ food efficiency and macroscopic and microscopic changes in the liver and choledochus. <u>Females</u> NOAEL = 5000 ppm (352.2 mg/kg bw/day). LOAEL = 10 000 ppm (714.9 mg/kg bw/day), based on ↓ bw & bwg, ↓ food efficiency, clinical signs and microscopic changes in the liver and choledochus. **Not carcinogenic**	**≥194 mg/kg bw/day M:** Clinical signs (moribundity, wasting, piloerection, subnormal temperature, ↓ spontaneous motor activity) in males (wk 79-104); Liver - yellow liver, slight-moderate bile duct hyperplasia, necrosis, hepatodiaphragmatic nodule, macrophage accumulation and/or granulation (♂) Choledochus - vacuolic change/cellular infiltration (♂; wk 13), dilated choledochus lumen (♂) **404.5/714.9 mg/kg bw/day M/F:** Clinical signs (moribundity, wasting, abdominal distention) (♂; wk 53–104; ♀ wk 79–104); ↓ bw (♂, 3–10%; ♀ 2–8%), ↓ bwg (♂, 6–12%; ♀ 5–11%), ↓ food efficiency (♂, 6–11%; ♀ 6–7%); whole body wasting (♂ wk 78, 104); ↓ term. bw (♂♀); ↑ ALP (♂♀), ↑ γ-GTP (♂♀), ↑ GPT (♀), ↑ GOT (♀); ↑ abs and rel liver wt (♂); ↓ abs and rel testis wt (♂) , testicular atrophy (wk 104; 75 vs 18% control) Liver - enlarged, hard, (♂); black patch zones (wk 52), nodules, enlarged, white patch zones,(♀; wk 104). Choledochus - dilation, muscular hypertrophy, erosion, dilated choledochus lumen (wk 26–104, cystic choleodochus (wk 78–104 and/or intestinal metaplasia (♂♀) Testicular atrophy, seminiferous atrophy, interstitial cell hyperplasia (♂) **Mortality:** ↓ survival in males (starting wk 78; 48.3% by 24 mo

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
REPRODUCTION AND DEVELOPMENTAL TOXICITY			
Multi-generation	Rat: Crl:CDR VAF/PlusR 0, 20, 1000 or 10 000 ppm (Equivalent to 0, 1.5, 75.7 and 759.0 mg/kg/day ♂, 0, 1.72, 86.3 or 874.0 mg/kg/day ♀	NOAEL (parental) = 20 ppm (1.50 mg/kg/day) LOAEL (parental) = 1000 ppm (75.7 mg/kg/day) NOAEL (offspring) = 1000 ppm (75.7 mg/kg/day) LOAEL (offspring) = 10 000 ppm (759.0 mg/kg/day) NOAEL (reproductive performance) = 10 000 ppm (759.0 mg/kg/day) LOAEL (not established)	**Parental** ≥1000 ppm ↑ incidence of trace to mild choledochus hyperplasia noted in the parents (56% treated vs 0% control), ↑ severity with dose **Offspring** 10 000 ppm ↓ bw in the F1 (11-18%), F2 (14–19%) ↓ bwg LD (0–21), F1/F2 (16–17%) ↓ liver wt (24–25%) F2 ♂,♀ ↓ Rel liver weights (8–9%) ♂,♀ ↑ changes in the liver of F2 pups on PND 4, increased incidences of consolidated* and circumscribed** areas of the liver were noted in F2 as well as F1 pups * Focal area of intense staining (H&E) ** More diffuse area of staining (H&E)
Developmental toxicity	Rat: Crl:CDVAF/Plus® 25/dose Dose levels: 0, 100, 300 or 1000 mg/kg/day . GDs 6 through 15	NOAEL (maternal) = 1000 mg/kg/day LOAEL not established NOAEL (developmental) = 1000 mg/kg/day (limit dose)	
Developmental range-finding study **Non guideline**	**Rabbit:** Japanese White (JW-NIBS) 7/dose **Dose levels:** 0, 75, 150, 300 or 500 mg/kg/day		300 mg/kg ↓ body weight gain 500 mg/kg 4 out of 6 animals died. First death occurred on day 15. ↓ food consumption, hemorrhage of the gastric mucosa and atrophy of the spleen

STUDY	SPECIES, STRAIN AND DOSES	NOAEL AND LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Developmental toxicity	**Rabbit:** Japanese White (JW-NIBS) 20/dose **Dose levels:** 0, 30, 100 or 300 mg/kg/day	NOAEL (maternal) = 100 mg/kg/day LOAEL (maternal) = 300 mg/kg/day NOAEL (developmental) = 300 mg/kg/day. LOAEL (developmental) Not observed	300 mg/kg ↓ body weight gain, lethargy and diarrhea
GENOTOXICITY- Bispyribac-Sodium (KIH-2023)			
STUDY	**SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES**		**RESULTS**
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 333, 667, 1000, 3330, 6670 or 10 000 µg/plate; with and without activation		Negative
Unscheduled DNA synthesis (in vitro)	Primary rat hepatocytes (male Fischer 344 rats) 5–500 µg/mL		Negative
Micro nucleus assay (in vivo)	Male and female (ICR) mice 1250, 2500 or 5000 mg/kg (single oral dose; bone marrow harvested 24 hours post-dosing)		Negative
Mutagenicity-Rec-Assay with *Bacillus subtilis*	Spot test (disk diffusion) and differential killing (suspension) assay 50, 150, 500, 1500 or 5000 µg/mL with and without activation		Positive. Spot test showed no zones of growth inhibition. In the differential killing assay, survival index ratios ranged from 0.46–0.74 (<0.75 is considered to be indicative of preferential inhibition of the DNA repair deficient strain (M45) over H17 (DNA repair proficient strain)
In vitro mammalian cell assay	Mouse: L5178Y/TK$^{\pm}$ cells. Dose levels: 0, 250, 600, 600, 750, 1000 or 1500 µg/mL ± S9		Equivocal
GENOTOXICITY- (KIH-2023-I-1) **Impurity** (0.4% TGAI)			
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 8, 40, 200, 312.5, 625, 1000, 1250, 2500 or 5000 µg/plate; with and without activation		Negative

STUDY	SPECIES and STRAIN or CELL TYPE AND CONCENTRATIONS or DOSES	RESULTS
GENOTOXICITY- (KIH-2023-I-2) **Impurity** (0.2% TGAI)		
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 50, 150, 500, 1500 or 5000 µg/plate; with and without activation	Negative
GENOTOXICITY- (KIH-2023-I-4) **Impurity** (0.06% TGAI		
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 50, 150, 500, 1500 or 5000 µg/plate; with and without activation	Negative
GENOTOXICITY- (KIH-2023-M-8-Na) **Impurity** (% not provided)		
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 50, 158, 500, 1580 or 5000 µg/plate; with and without activation	Negative
GENOTOXICITY- (KIH-2023-M-9-Na) **Impurity** (% not provided)		
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537; *E. coli* WP2uvrA 50, 158, 500, 1580 or 5000 µg/plate; with and without activation	Negative

SPECIAL STUDIES

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
14-day Dietary **Non guideline** Determination of bile acids in serum	Mouse: 10 male B6C3F1 **Dose level**: 0 and 7000 ppm (1290 mg/kg/day)		↑ serum concentration of total bile acids (115%) Slight enlargement of the cecum (9/10 treated vs 0/10 control

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
4, 13 and 52 weeks dietary mechanistic study **Non guideline** Determination of bile acids in serum	Rat: Fischer (F344) 5/sex/group **Dose level**: 0, 200, 7000 ppm (Equivalent to 0, 12.3 or 446.8 mg/kg/day ♂ and 0, 200 or 10 000 ppm, 0, 13.8 or 724.2 mg/kg/day ♀ An additional 5 rats /sex/group were similarly treated for 13 weeks followed by a 4- or 13-week recovery		<u>≥200 ppm</u> ↓ food consumption ♂ ↑ total bilirubin, GGT ♂ recovery in all instances ↑ incidences of granulation in the liver, lymphocytic infiltration, muscular hypertrophy of the choleduchus ♀ <u>7,000/10 000 ppm</u> ↓ body weight, ↑ leucine aminopeptidase, γ-glutamyl transpeptidase (GGT) and total bile acids (weeks 4 and 13), total bilirubin (week 13), alkaline phosphatase and 5'-nucleotidase (weeks 13 and 52) , ↑ total bilirubin recovery in all instances. After 52 weeks, there were ↑ incidences of macroscopic lesion, dilated choledochus lumen., macrophages in the liver, fibrosis, proliferative ducts, moderate and severe choledochus dilation, slight fibrosis, epithelial hyperplasia and muscular hypertrophy of the choledochus.
52 weeks Dietary Mechanistic Study **Non guideline** Effects on gall bladder in prolonged dietary administration of bispyribac-sodium	Mouse: B6C3F1 12/sex/group **Dose levels**: 0, 100 and 5000 ppm (Equivalent to 0, 15.3 or 854.1 mg/kg/day ♂, 0, 19.6 or 1025.9 mg/kg/day ♀		<u>5000 ppm</u> Slight anisonucleosis and slight multi-nuclear giant cells were observed in the liver of males at 52 weeks No other treatment-related microscopic findings

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Special Bile Acid Analysis **Non guideline** Effect on urinary bladder and ductus choleduchus in prolonged dietary administration of bispyribac-sodium	Rat: F344/DuCrj 5 males/dose **Dose levels**: 0 and 20 000 ppm (Equivalent to 0 and 1792 mg/kg/day		<u>20 000 ppm</u> ↓ mean body weight, ↓ food consumption, ↑ incidence of cecum enlargement (5/5 treated vs 0/5 control). One treated rat had hematuria. 1/5 treated had dark red spots in the mucosa of the urinary bladder. ↑ in total bile acids (TBA) and components). Altered degree of conjugation of several bile acids.

Compound-Induced Mortality: Long-term (104 weeks dietary) mouse study, 7–14 dead or moribund at 5000 ppm (728.9 mg/kg bw/day ♂) and developmental toxicity (range-finding study in rabbits). 4 out of 6 dead at 500 mg/kg bw/day.

Tox Endpoints for Occupational Risk Assessment: For the short- and intermediate-term dermal route, the 21-day rat dermal study with a NOAEL of 1000 mg/kg bw/day was considered most appropriate. An MOE of 100× to account for intra and interspecies variation was applied.
The NOAEL of 100 mg/kg bw/day from the rabbit developmental toxicity study was considered appropriate for short-term inhalation exposure.
The NOAEL of 100 mg/kg bw/day from 90-day dog study was considered appropriate for intermediate-term inhalation exposure.
An MOE of 100× (10× for each of inter and intraspecies variations) was applied to both.

Table 3.1.1 Fate and Behaviour in the Environment

Property	Test Substance	Value	Comments	PMRA Reference Number
Terrestrial Environment				
Abiotic Transformation				
Hydrolysis	Bispyribac-sodium	Half-life at 25ºC: pH 5: 88 days pH 7: stable pH 9: stable	Not an important route of transformation.	1285577
Phototransformation on soil	Bispyribac-sodium	Half-life: stable	Not a significant route of transformation.	1285579
Phototransformation in air	Not submitted. Non-volatile under field conditions.			1285581

Property	Test Substance	Value	Comments	PMRA Reference Number
Biotransformation				
Biotransformation in aerobic soil	Bispyribac-sodium	California clay loam (pH 6.1): **<u>Two compartment model</u>** **DT_{50}:** 18.6 days (benzene-labelled); 19.1 days (pyrimidine-labelled) **DT_{90}:** 78.3 days (benzene-labelled); 91.6 days (pyrimidine-labelled) **<u>Estimated first order $t_{1/2}$</u>** **⅓ DT_{90}:** 23.6 days (benzene-labelled); 27.6 days (pyrimidine-labelled)	Slightly persistent[a]	1285582
Biotransformation in anaerobic soil	Not submitted			N/A
Mobility				
Adsorption/ desorption in soil	Bispyribac-sodium	Sand (pH 6.5, 0.12% OC): $K_{oc\text{-}ads}$ = 550 Clay loam (pH 7.0, 1.61% OC): $K_{oc\text{-}ads}$ = 146 Sandy loam (pH 5.4, 0.57% OC): $K_{oc\text{-}ads}$ = 186 Silt loam soil (pH 7.0, 0.23% OC): $K_{oc\text{-}ads}$ = 308	Moderately to highly mobile[b]	1285592
Soil leaching	Not submitted			N/A
Volatilization	Not submitted			N/A

Property	Test Substance	Value	Comments	PMRA Reference Number
Field Studies				
Field dissipation	Bispyribac-sodium	**Unacceptable studies**		1286660 1286661 1286662 1286663 1286664 1286665
Field leaching	Not submitted			N/A
Aquatic Environment				
Abiotic Transformation				
Hydrolysis	Bispyribac-sodium	Half-life at 25°C: pH 5: 88 days pH 7: stable pH 9: stable	Not an important route of transformation	1285577
Phototransformation in water	Bispyribac-sodium	Half-life: stable	Not an important route of transformation	1285580
Biotransformation				
Biotransformation in aerobic water systems (water/soil)	Bispyribac-sodium	Half-lives in whole system: **Louisiana silty loam (pH 7.3):** 45 days (benzene-labelled) 47 days (pyrimidine-labelled) **Arkansas sandy loam (pH 6.1):** 102 days (benzene-labelled) 68 days (pyrimidine-labelled) 81–83% of the radiolabelled bispyribac-sodium, compared to the amount found in the whole system, was found in the water phase at day 0, and 75–78% after 30 days (test termination).	Moderately persistent[c]	1285586

Property	Test Substance	Value	Comments	PMRA Reference Number
Biotransformation in anaerobic water systems (water/soil)	Bispyribac-sodium	Half-lives in whole system: **Louisiana silty loam (pH 7.3):** 97.2 days (benzene-labelled) 81.8 days (pyrimidine-labelled) **Arkansas sandy loam (pH 6.1):** 133 days (benzene-labelled) 92.8 days (pyrimidine-labelled) 82–83% of the radiolabelled bispyribac-sodium, compared to the amount found in the whole system, was found in the water phase at day 0, 79–84% at 3 months, and almost 100% at 12 months (test termination)	Moderately persistent[c]	1285587 1285588 1285589
Partitioning				
Adsorption/ desorption in sediment	Bispyribac-sodium	Silt loam sediment (pH 5.9, 0.69% OC): $K_{oc\text{-}ads}$= 308 (results from soil adsorption/desorption study)	Moderate mobility[b]	1285592

[a] Classification of Goring et al. (1975), based on estimated first-order half-life.
[b] Classification of McCall et al. (1981).
[c] Classification of McEwen and Stephenson (1979).
N/A = Not applicable

Table 3.1.2 Identification of Major and Minor Transformation Products

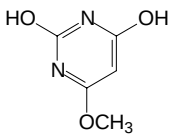
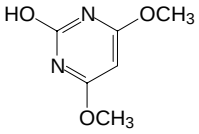
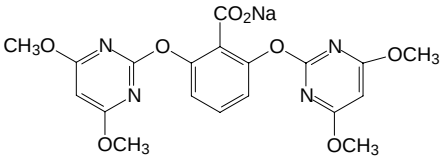
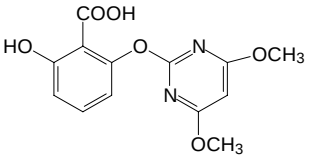
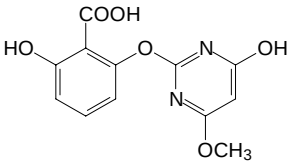
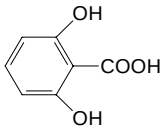
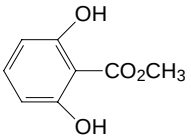
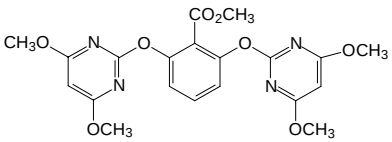
Chemical Name	Code	Chemical Structure
Major Transformation Products		
4,6-Dihydroxy-6-methoxypyrimidine	**MeBA**	
4,6-Dimethoxy-2-hydroxypyrimidine	**Me_2BA**	
Sodium 2-(4,6-dimethoxy pyrimidin-2-yl)oxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl) benzoate	**DesMe-2023**	
Sodium 2-hydroxy-6-[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate	**Bx-180**	
2-Hydroxy-6-[(4-hydroxy-6-methoxypyrimidin-2-yl)oxy] benzoate	**DesMe-180**	
2,6-Dihydroxybenzoic acid	**2,6-DBA**	
Minor Transformation Products		
Methyl 2,6-dihydroxybenzoate	**2,6-MDB**	
Methyl 2,6-bis[(4,6-dimethoxypyrimidin-2-yl)oxy] benzoate	**Bispyribac-methyl ester**	

Table 3.1.3 Production of Transformation Products of Bispyribac-sodium

Fate Process	Test Material	Major Transformation Products	Minor Transformation Products
Terrestrial Fate Processes			
Phototransformation on soil	Bispyribac-sodium (radiolabelled pyrimidine ring)	None	Me_2BA, Bx-180, DesMe-2023, MeBA, DesMe-180, CO_2
Biotransformation in aerobic soil	Bispyribac-sodium Bispyribac-sodium (radiolabelled benzene ring and pyrimidine ring)	CO_2, Me_2BA, 2,6-DBA, Bx-180	2,6-MDB, DesMe-2023, DesMe-180, MeBa, Bispyribac-sodium ester
Aquatic Fate Processes			
Hydrolysis	Bispyribac-sodium (radiolabelled pyrimidine ring)	Me_2BA	Bx-180
Phototransformation in water	Bispyribac-sodium (radiolabelled pyrimidine ring)	None	None
Biotransformation in aerobic water systems	Bispyribac-sodium (radiolabelled benzene ring and pyrimidine ring)	DesMe-2023	Bx-180, MeBA, 2,6-DBA
Biotransformation in anaerobic water systems	Bispyribac-sodium (radiolabelled benzene ring and pyrimidine ring)	MeBA, 2,6-DBA, DesMe-180, DesMe-2023, Me_2BA, CO_2	Bx-180

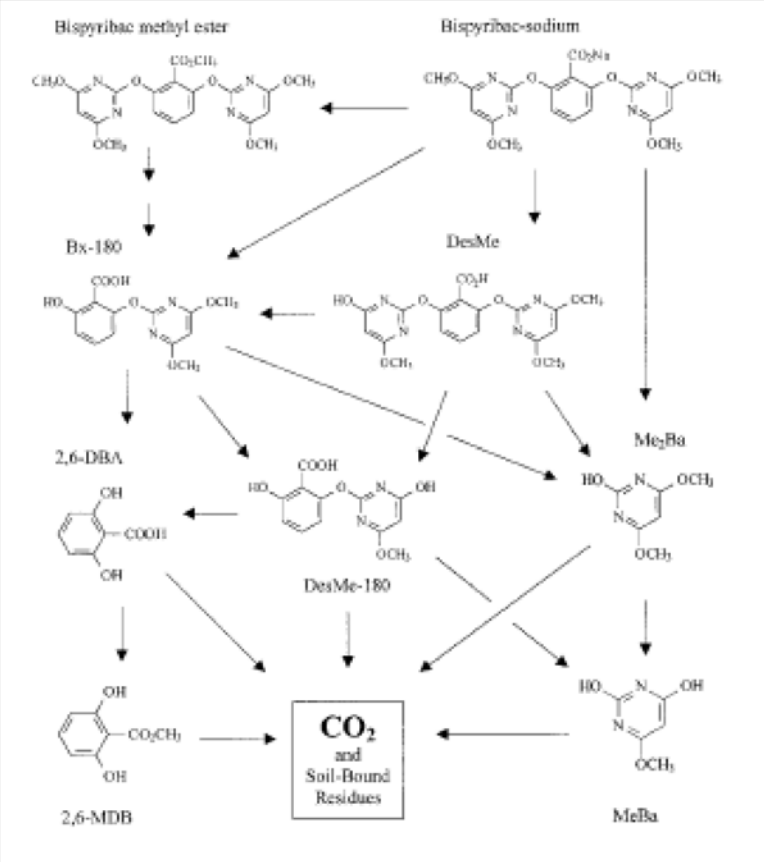


Figure 3.1.1 Transformation pathway for bispyribac-sodium in aerobic soil.

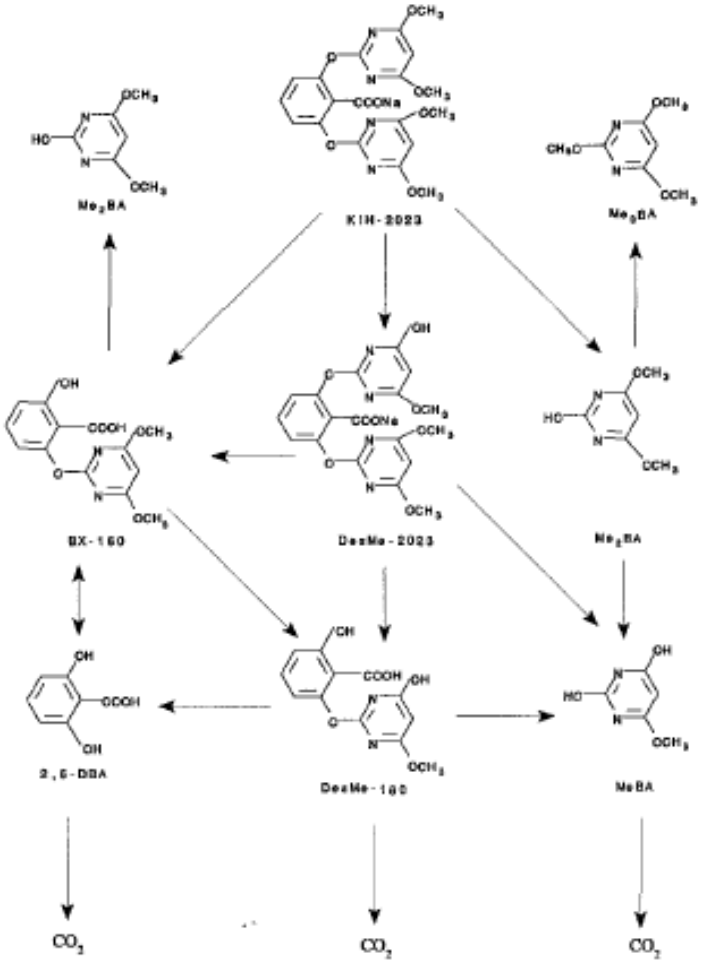


Figure 3.1.2 Transformation pathway for bispyribac-sodium in aerobic and anaerobic water/soil systems

Table 3.2 Toxicity to Non-Target Species

Organism	Exposure	Test Substance	Endpoint Value	Toxicity Classification[a]	PMRA Reference Number
Terrestrial Invertebrates					
Earthworm	14-d Acute	Bispyribac-sodium	LC_{50} > 1000 mg a.i./kg NOEC: 1000 mg a.i./kg	—	1285433 1285601
Bee	Oral	Not submitted			N/A
	48-h Contact	Bispyribac-sodium	LD_{50} > 25 µg a.i./bee NOEC: 25 µg a.i./bee	Relatively non-toxic	1285434 1285602
	Brood/hive	Not submitted			N/A
Predatory arthropod	Contact	Not submitted			N/A
Parasitic arthropod	Contact	Not submitted			N/A
Birds					
Bobwhite quail	Acute	Bispyribac-sodium	LD_{50} > 2250 mg a.i./kg bw NOEL: 2250 mg a.i./kg bw	Practically non-toxic	1285440 1285626
	Dietary	Bispyribac-sodium	LC_{50} > 5620 mg a.i./kg diet NOEC: 5620 mg a.i./kg diet	Practically non-toxic	1285441 1285629
	Reproduction	Bispyribac-sodium	NOEC: 1000 mg a.i./kg diet LOEC > 1000 mg a.i./kg diet	—	1285443 1285632
Mallard duck	Acute	Not submitted			N/A
	Dietary	Bispyribac-sodium	LC_{50} > 5620 mg a.i./kg diet NOEC: 5620 mg a.i./kg diet	Practically non-toxic	1285442 1285630
	Reproduction	Bispyribac-sodium	NOEC: 1000 mg a.i./kg diet LOEC >1000 mg a.i./kg diet	—	1285444 1285633
Mammals					
Rat	Acute	Bispyribac-sodium (95.2% purity)	LD_{50} ♂: 4111 mg a.i./kg bw LD_{50} ♀: 2635 mg a.i./kg bw	Practically non-toxic	1286701
		End-use product (Bispyribac-sodium 80WP)	LD_{50} ♂ >5000 mg EP/kg bw LD_{50} ♀ >5000 mg EP/kg bw	Practically non-toxic	1286701

Organism	Exposure	Test Substance	Endpoint Value	Toxicity Classification[a]	PMRA Reference Number
	90-day dietary	Bispyribac-sodium	NOAEL: 1000 mg a.i./kg diet ♂ = 71.9 mg a.i./kg bw/day ♀ = 79.9 mg a.i./kg bw/day LOAEL: 10 000 mg a.i./kg diet ♂ = 724.0 mg a.i./kg bw/day ♀ = 790.8 mg a.i./kg bw/day Endpoints: body weight reduction, food uptake, hepatic changes	—	1286701
	Reproduction (multi-generation)	Bispyribac-sodium	NOAEL (parental): 20 mg a.i./kg diet ♂ = 1.50 mg a.i./kg bw/day ♀ = 1.72 mg a.i./kg bw/day LOAEL (parental): 1000 mg a.i./kg diet ♂ = 75.7 mg a.i./kg bw/day ♀ = 86.3 mg a.i./kg bw/day Endpoint: mild choledochus hyperplasia (not environmentally relevant) NOAEL (offspring): 1000 mg a.i./kg diet ♂ = 75.7 mg a.i./kg bw/day ♀ = 86.3 mg a.i./kg bw/day LOAEL (offspring): 10 000 mg a.i./kg diet ♂ = 759.0 mg a.i./kg bw/day ♀ = 874.0 mg a.i./kg bw/day Endpoint: body weight reduction NOAEL (reproductive performance): 10 000 mg a.i./kg diet ♂ = 759.0 mg a.i./kg bw/day ♀ = 874.0 mg a.i./kg bw/day LOAEL (reproductive performance): N/A (no effect at highest tested dose)	—	1286701

Organism	Exposure	Test Substance	Endpoint Value	Toxicity Classification[a]	PMRA Reference Number
Mouse	Acute	Bispyribac-sodium (95.2% purity)	LD_{50} ♂: 3524 mg a.i./kg bw LD_{50} ♀: 3524 mg a.i./kg bw	Practically non-toxic	1286701
	90-day Dietary	Bispyribac-sodium	NOAEL: 350 mg a.i./kg diet ♂ = 68.6 mg a.i./kg bw/day ♀ = 79.0 mg a.i./kg bw/day LOAEL: 3500 mg a.i./kg diet ♂ = 699.1 mg a.i./kg bw/day ♀ = 806.1 mg a.i./kg bw/day Endpoints: slight liver swelling and granulation (not environmentally relevant endpoints)	Practically non-toxic	1286701
Terrestrial Vascular Plants					
Vascular plants	Seedling emergence	End-use product (Bispyribac-sodium 80WP)	EC_{25}: 1.46 g a.i./ha NOEC (as EC_{05} value): 0.45 g a.i./ha Most sensitive monocot: Onion Endpoint affected: Plant dry weight EC_{25}: 2.13 g a.i./ha NOEC (as EC_{05} value): 0.45 g a.i./ha Most sensitive dicot: Cabbage Endpoint affected: Plant dry weight	—	1286708
	Vegetative vigour	End-use product (Bispyribac-sodium 80WP)	EC_{25}: 2.35 g a.i./ha NOEC: 0.73 g a.i./ha Most sensitive monocot: Onion Endpoint affected: Plant height EC_{25}: 1.12 g a.i./ha NOEC: 0.73 g a.i./ha Most sensitive dicot: Cabbage Endpoint affected: Plant dry weight	—	1286709

Organism	Exposure	Test Substance	Endpoint Value	Toxicity Classification[a]	PMRA Reference Number
Freshwater Invertebrates					
Daphnia magna	48-h Acute	Bispyribac-sodium	LC_{50} > 99.2 mg a.i./L NOEC: 99.2 mg a.i./L	Practically non-toxic	1285609
	21-d Chronic	Bispyribac-sodium	EC_{50} > 110 mg a.i./L NOEC: 110 mg a.i./L	—	1285610
Freshwater Fish					
Rainbow trout	96-h Acute	Bispyribac-sodium	LC_{50}: >102 mg a.i./L NOEC: 102 mg a.i./L	Practically non-toxic	1285617
	Chronic	Not submitted			N/A
Bluegill sunfish	96-h Acute	Bispyribac-sodium	LC_{50} : >102 mg a.i./L NOEC: 102 mg a.i./L	Practically non-toxic	1285618
	Chronic	Not submitted			N/A
Freshwater Algae and Plants					
Freshwater alga	96-h Acute *P. subcapitata*	Bispyribac-sodium	EC_{50}: 0.25 mg a.i./L $EC_{.05}$: 0.053 mg a.i./L NOEC: 0.031 mg a.i./L	—	1285639
	96-h Acute *A. flos-aquae*	End-use product (Bispyribac-sodium 80S)	EC_{50} > 1.0 mg a.i./L NOEC: 1.0 mg a.i./L	—	1286705
	96-h Acute *N. pelliculosa*	End-use product (Bispyribac-sodium 80S)	EC_{50} > 1.0 mg a.i./L NOEC: 1.0 mg a.i./L Endpoint: Cell density	—	1286706
Vascular plant	14-d Acute *Lemna gibba*	End-use product (Bispyribac-sodium 80S)	EC_{50} = 0.010 mg a.i./L NOEC = 0.0066 mg a.i./L Endpoint: Frond density EC_{50} = 0.0102 mg a.i./L NOEC = 0.0066 mg a.i./L Endpoint: Biomass	—	1286704
Marine Invertebrates					
Crustacean	96-h Acute (Mysid shrimp)	End-use product (Bispyribac-sodium 80S)	LC_{50}: >130 mg a.i./L NOEC: 130 mg a.i./L	Practically non-toxic	1286691
	Chronic	Not submitted			N/A

Organism	Exposure	Test Substance	Endpoint Value	Toxicity Classification[a]	PMRA Reference Number
Mollusk	96-h Acute (shell deposition)	End-use product (Bispyribac-sodium 80S)	EC_{50}: >110 mg a.i./L NOEC: 110 mg a.i./L	Practically non-toxic	1286690
	Chronic	Not submitted			N/A
Marine Fish					
Fish	96-h Acute (Sheepshead minnow)	End-use product (Bispyribac-sodium 80S)	LC_{50}: >120 mg a.i./L NOEC: 120 mg a.i./L	Practically non-toxic	1286694
	Salinity challenge	Not submitted			N/A
Marine Algae					
Marine alga	5-day Acute *Skeletonema costatum*	End-use product (Bispyribac-sodium 80S)	EC_{50} > 1.1 mg a.i./L NOEC: 1.1 mg a.i./L	—	1286707

[a] Atkins et al. (1981) for bees and USEPA classification for others, where applicable.
N/A = Not applicable

Table 3.3 Screening Level Risk Assessment on Non-Target Species

Organism	Exposure	Endpoint Value	EEC	Risk Quotient[a] (EEC/Tox)	Risk Greater Than LOC?
Terrestrial Invertebrates					
Earthworm	Acute	½ LC_{50}: >500 mg a.i./kg dw soil	0.084 mg a.i./kg dw soil[b]	0.0002	No
Bees	Contact	LD_{50}: >25 µg a.i./bee, equivalent to 28 kg a.i./ha[c]	205.92 g a.i./ha[d]	0.0074	No
Birds					
Bobwhite quail	Acute	NOEL: 2250 mg a.i./kg bw	36.05 mg a.i./kg dw diet[e], equivalent to 4.34 mg a.i./kg bw[f]	0.0019	No
	Dietary	NOEC: 5620 mg a.i./kg diet	36.05 mg a.i./kg dw diet[e]	0.0064	No
	Reproduction	NOEC: 1000 mg a.i./kg diet	36.05 mg a.i./kg dw diet	0.0361	No

Organism	Exposure	Endpoint Value	EEC	Risk Quotient[a] (EEC/Tox)	Risk Greater Than LOC?
Mallard duck	Dietary	NOEC: 5620 mg a.i./kg diet	6.96 mg a.i./kg dw diet[g]	0.0012	No
	Reproduction	NOEC: 1000 mg a.i./kg diet	6.96 mg a.i./kg dw diet	0.007	No
Mammals					
Rat	Acute	LD_{50} ♂: 4111 mg a.i./kg bw LD_{50} ♀: 2635 mg a.i./kg bw	103.89 mg a.i./kg dw diet[h,i], equivalent to 4.84 mg a.i./kg bw[j]	0.0018	No
	90-day Dietary	NOAEL: 1000 mg a.i./kg dw diet	103.89 mg a.i./kg dw diet[h,i]	0.104	No
	Reproduction (multi-generation)	NOAEL (off-spring): 1000 mg a.i./kg diet	103.89 mg a.i./kg dw diet	0.104	No
Mouse	Acute	LD_{50} ♂: 3524 mg a.i./kg bw LD_{50} ♀: 3524 mg a.i./kg bw	103.26 mg a.i./kg dw diet[h,k], equivalent to 19.31 mg a.i./kg bw[l]	0.0055	No
	90-day Dietary	NOAEL: 3500 mg a.i./kg dw diet (LOAEL used as $NOAEL_{environment}$ because effects were not considered environmentally relevant)	103.26 mg a.i./kg dw diet	0.03	No
Terrestrial Vascular Plants					
Vascular plants	Seedling emergence	Monocot EC_{25}: 1.46 g a.i./ha	189.5 g a.i./ha[m]	**130**	**Yes**
		Dicot EC_{25}: 2.13 g a.i./ha	189.5 g a.i./ha	**89**	**Yes**
	Vegetative vigour	Monocot EC_{25}: 2.35 g a.i./ha	189.5 g a.i./ha	**81**	**Yes**
		Dicot EC_{25}: 1.12 g a.i./ha	189.5 g a.i./ha	**169**	**Yes**
Freshwater Species					
Daphnia magna	Acute	½ LC_{50} > 49.6 mg a.i./L	0.032 mg a.i./L[n]	0.0006	No
	Chronic	NOEC: 110 mg a.i./L	0.032 mg a.i./L	0.0003	No
Rainbow trout	Acute	1/10 LC_{50} > 10.2 mg a.i./L	0.032 mg a.i./L	0.0031	No
Bluegill sunfish	Acute	1/10 LC_{50} >10.2 mg a.i./L	0.032 mg a.i./L	0.0031	No
Amphibian	Acute	1/10 LC_{50} > 10.2 mg a.i./L[o]	0.173 mg a.i./L[p]	0.017	No

Organism	Exposure	Endpoint Value	EEC	Risk Quotient[a] (EEC/Tox)	Risk Greater Than LOC?
Freshwater alga	96-h Acute *P. subcapitata*	½ EC_{50}: 0.125 mg a.i./L	0.032 mg a.i./L	0.256	No
	120-h Acute *A. flos-aquae*	½ EC_{50} > 0.5 mg a.i./L	0.032 mg a.i./L	0.058	No
	120-h Acute *N. pelliculosa*	½ EC_{50} > 0.5 mg a.i./L	0.032 mg a.i./L	0.058	No
Vascular plant	14-d Acute *Lemna gibba*	½ EC_{50}: 0.005 mg a.i./L	0.032 mg a.i./L	**6.4**	**Yes**
Marine Species					
Crustacean	Acute Mysid shrimp	½ LC_{50} > 65 mg a.i./L	0.032 mg a.i./L	0.0005	No
Mollusk	Acute Eastern oyster	½ EC_{50} > 55 mg a.i./L	0.032 mg a.i./L	0.0006	No
Fish	Acute Sheepshead minnow	1/10 LC_{50} > 12.0 mg a.i./L	0.032 mg a.i./L	0.0027	No
Marine alga	Acute *S. costatum*	½ EC_{50} > 0.55 mg a.i./L	0.032 mg a.i./L	0.058	No

[a] Risk quotient = exposure/toxicity. Bold RQ value indicates that the risk quotient exceeds the PMRA LOC of 1.

[b] EEC (for direct overspray application) is calculated using a half-life of 27.6 days (from aerobic soil study), a maximum cumulative application rate of 189.50 g a.i./ha per year, assuming the product is evenly distributed in the 0–15 cm depth of the soil and a bulk density of 1.5 g/cm^3.

[c] The LD_{50} (µg/bee) is converted to an application rate (kg/ha) by multiplying µg/bee by 1.12.

[d] EEC for bees is the cumulative application rate on vegetation treated four times with 14 days between applications, based on a foliar dissipation half-life of 35 days.

[e] Birds would be exposed to a maximum cumulative rate of 205.92 g a.i./ha based on a foliar dissipation half-life of 35 days. The diet of the bobwhite quail is assumed to be composed of 30% small insects, 15% forage crops and 55% grain.

[f] EEC (mg a.i./kg diet) is converted to EEC (mg a.i./kg bw) using the food consumption (FC) and body weight per individual (BWI) from study data for the control group. FC = 0.0244 kg diet/ind/day; BWI = 0.2026 kg bw/ind. EEC (mg a.i./kg bw) = EEC (mg a.i./kg diet) × FC ÷ BWI

[g] The diet of the mallard is assumed to be composed of 30% large insects and 70% grain.

[h] Mammals would be exposed to a maximum cumulative rate of 205.92 g a.i./ha based on a foliar dissipation half-life of 35 days.

[i] The diet of the rat is assumed to be composed of 70% short grass, 20% grain/seeds and 10% large insects.

[j] EEC (mg a.i./kg diet) is converted to EEC (mg a.i./kg bw) using FC and BWI from study data for the control group. FC = 0.015 kg/ind/d; BWI = 0.322 kg bw/ind. EEC (mg a.i./kg bw) = EEC (mg a.i./kg diet) × FC ÷ BWI

[k] The diet of the mouse is assumed to be composed of 25% short grass, 50% grain/seeds, and 25% leaves and leafy crops.

l EEC (mg a.i./kg diet) is converted to EEC (mg a.i./kg bw) using FC and BWI from study data for the control group. FC = 0.006 kg/ind/d; BWI = 0.032 kg bw/ind. EEC (mg a.i./kg bw) = EEC (mg a.i./kg diet) × FC ÷ BWI

m EEC is calculated using a soil half-life of 27.6 days based on laboratory aerobic soil study.

n EEC for aquatic organisms (except amphibians) is based on four applications, a 14-day application interval, an aerobic water/sediment half-life of 102 days (entire system), and a water depth of 80 cm.

o The endpoint value for the most sensitive fish is used.

p EEC is calculated using a water depth of 15 cm, which is representative of a seasonal water body used by amphibians to reproduce.

Table 3.4 Refined Risk Assessment on Non-Target Species

Organism	Test Substance	Exposure	Endpoint Value	EEC	Risk Quotient [a]	Risk Greater Than LOC?
Terrestrial Plants						
Vascular plant	Bispyribac-sodium 80WP	Seedling emergence	Monocot EC_{25}: 1.46 g a.i./ha	11.37 g a.i./ha[b]	**7.79**	**Yes**
			Dicot EC_{25}: 2.13 g a.i./ha	11.37 g a.i./ha	**5.34**	**Yes**
	Bispyribac-sodium 80WP	Vegetative vigour	Monocot EC_{25}: 2.35 g a.i./ha	11.37 g a.i./ha	**4.84**	**Yes**
			Dicot EC_{25}: 1.12 g a.i./ha	11.37 g a.i./ha	**10.15**	**Yes**
Aquatic Plants						
Vascular plant	Bispyribac-sodium 80WP	14-d Acute *Lemna gibba*	½ EC_{50}: 0.005 mg a.i./L	0.0018 mg a.i./L[c]	0.36	No

a Risk quotient = exposure/toxicity. Bold RQ values indicate that the risk quotients exceed the PMRA LOC of 1.

b Refined EEC is 6% of the cumulative application rate of 189.5 g a.i./ha, which is based on four applications of 74.4 g a.i./ha, at 14-day intervals and a soil half-life of 27.6 days.

c Refined EEC uses the highest 96-h EEC of 1.8 µg a.i./L from the Level 1 aquatic ecoscenario model (modelling data for Winnipeg, Manitoba).

Table 4 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant-proposed Label Claims	Accepted Label Claims	Unsupported Label Claims and Comments
Control of annual bluegrass	Reduction of annual bluegrass	Inconsistent control of annual bluegrass
Control of dandelion, white clover, plantain, suppression of crabgrass	None	Insufficient data
Application to fescue spp.	Application to tall fescue	Insufficient data to support other fescue species
No application of Velocity SP Herbicide until 30 days after overseeding	No application of Velocity SP Herbicide until 60 days after overseeding with perennial ryegrass, Kentucky bluegrass and tall fescue, and 30 days after overseeding with creeping bentgrass	No data to support 30-day overseeding to application interval for perennial ryegrass, Kentucky bluegrass and tall fescue

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B. ADDITIONAL INFORMATION CONSIDERED

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