

Proposed Regulatory Decision Document PRDD2006-01

Sodium Chloride

The technical grade active ingredient sodium chloride and associated end-use product AdiosAmbros, containing sodium chloride as the active ingredient for the control of common ragweed on roadsides, highways, walkways, vacant lots and other non-cropland sites, are proposed for full registration under the Pest Control Products Regulations.

This Proposed Regulatory Decision Document provides a summary of information received and the rationale for the proposed full registration of these products. Health Canada's Pest Management Regulatory Agency (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 at the address below.

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Foreword

The submissions for full registration of sodium chloride technical grade active ingredient and the end-use product AdiosAmbros, developed by HerbaNatur Inc. for control of common ragweed on roadsides, highways, walkways, vacant lots and other non-cropland sites, have been reviewed by Health Canada's Pest Management Regulatory Agency (PMRA).

The PMRA has carried out an assessment of available information in accordance with the Pest Control Products Regulations and has found it sufficient to allow a determination of the safety, merit and value of sodium chloride technical grade active ingredient and the end-use product AdiosAmbros. The Agency has concluded that the use of the technical grade active ingredient sodium chloride and the end-use product AdiosAmbros in accordance with the label has merit and value consistent with the Pest Control Products Regulations and does not entail an unacceptable risk of harm. Therefore, based on the considerations outlined above, the use of sodium chloride technical grade active ingredient and the end-use product AdiosAmbros for control of common ragweed on roadsides, highways, walkways, vacant lots and other non-cropland sites is proposed for full registration pursuant to the Pest Control Products Regulations.

Methods for analyzing sodium and chloride in environmental media are available to research and monitoring agencies upon request to the PMRA.

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1.0 The Active Substance, its Properties and Uses

1.1 Identity of the Active Substance and Impurities

Identification of the Technical Grade Active Ingredient

Active substance		Sodium chloride	
Function	on	Herbicide	
Chemi	cal name		
1.	International Union of Pure and Applied Chemistry	Sodium chloride	
2.	Chemical Abstracts Service	Sodium chloride	
CAS number		7647-14-5	
Molecular formula		NaCl	
Molecular weight		58.44	
Structural formula		Na ⁺ Cl ⁻	
Nominal purity of active		99.86%	
Identity of relevant impurities of toxicological, environmental or other significance		Impurities of human health or environmental concern as identified in Section 2.13.4 of Regulatory Directive <u>DIR98-04</u> and Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Appendix II of Regulatory Directive <u>DIR99-03</u> are not expected to be present in this product.	

1.2 Physical and Chemical Properties of Active Substances and End-use Product(s)

Property	Result	Comment
Colour and physical state	White	
Odour	Odourless	
Melting point or range	800.8°C	

Technical Product—Sodium Chloride

Property	Result	Comment
Boiling point or range	N/A	
Specific gravity	2.165	
Vapour pressure at 865°C	0.1 kPa (1 mm Hg)	Non-volatile
Henry's law constant at 20°C	$K = 1211 \text{ Pa} \\ 1/\text{H} = 4.3 \times 10^5$	Non-volatile from water and moist soil surface
Ultraviolet (UV)– visible spectrum	N/A	Does not phototransform.
Solubility in water at 25°C	357.14 g/L	Highly soluble in water.
Solubility in organic solvents at 20°C	SolventSolubility (g/L)Dimethylsulfoxide (DMSO)< 1	
<i>n</i> -Octanol–water partition coefficient (K_{ow})	N/A	The product is highly soluble in water.
Dissociation constant (pK_a)	N/A	
Stability (temperature, metal)	Stable in presence of metals and high temperature.	

End-use Product—AdiosAmbros Water Soluble Granule

Property	Result
Colour	White
Odour	None
Physical state	White translucent crystals
Formulation type	Soluble granular

Property	Result	
Guarantee (nominal)	99.86% (limits: 99.8–100.0%)	
Formulants	The product does not contain any United States Environmental Protection Agency List 1 or 2 formulants or formulants known to be TSMP Track 1 substances.	
Container material and description	20 and 40 kg polyethylene bags	
Density	1100–1200 kg/m ³	
рН	6.7–7.3	
Oxidizing or reducing action	N/A	
Storage stability	The product is known to have a long storage stability.	
Explodability	N/A	

1.3 Details of Uses and Further Information

Sodium chloride is a postemergent herbicide applied as a directed spray to control common ragweed on roadsides, highways, walkways, vacant lots and other non-cropland sites.

AdiosAmbros consists of a 100% re-pack of the sodium chloride technical, which consists of 99.86% sodium chloride and 0.2% yellow prussiate of soda used as an anti-caking agent. A single application is to be made of a 12% concentration of sodium chloride in 1250 L water/ha (150 kg of AdiosAmbros in 1250 L of water).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Substance as Manufactured

An American Society for Testing and Materials (ASTM) method E 534-98 for the determination of sodium chloride, moisture, water insolubles, calcium and magnesium and sulfate was provided. This is an official as well as published method; consequently, the submission of the validation data has been waived.

2.2 Method for Formulation Analysis

The same ASTM method E 534-98, which is used for the determination of the active ingredient in the technical product, may be also used for the end-use product.

2.3 Method for Residue Analysis

2.3.1 Analytical Methodology (for Na⁺ and Cl⁻)—Soil

Two official analytical methods were provided for the determination of sodium and chloride in soil samples.

The first method, Association of Official Analytical Chemists (AOAC) Method 990.08, is used to determine sodium and other metals in coal fly ash, industrial and electroplating sludges, mine tailings, river sediments as well as in soils. This method measures element-emitted light by optical spectrometry. Digested materials are nebulized into radio-frequency inductively coupled plasma. The recommended wavelength for detection of sodium is 588.995 nm and the estimated instrumental detection limit is 29 μ g/L. An external certified standard is used for quantitation.

The second method involves the quantitative extraction of chloride from soil using 0.1M $Ca(NO_3)_2$. Chloride in the soil extracts is determined spectrophotometrically by complexation with mercury (II) thiocyanate. The method detection limit is 2.0 mg/kg (on a dry soil basis) and is reproducible \pm 7%.

2.3.2 Analytical Methodology (for Na⁺ and Cl⁻)—Sediment

The methods used to analyze soil samples are also applicable for sediment samples.

2.3.3 Analytical Methodology (for Na⁺ and Cl⁻)—Water

Two official analytical methods were provided for the determination of sodium and chloride in water samples.

The first method, AOAC method 973.54, is applicable for determination of sodium at 1-200 mg/L in surface and saline waters and domestic and industrial wastes. Atomic absorption spectrophotometer, equipped with Na hollow cathode lamp, 330.2 nm, boiling burner and oxidizing air C_2H_2 flame is used for the analysis. The quantitation is done by external standard solution. The method is precise as shown by the standard deviation of 3.5%.

The second method, AOAC method 993.30, is applicable for determination of bromide, chloride, fluoride, nitrate, nitrite, orthophosphate and sulfate in drinking water and waste water. Anions in test samples are separated by ion chromatographic system and measured using conductivity detector. The quantitation is done by external standard solutions.

2.3.4 Analytical Methodology (for Na⁺ and Cl⁻)—Biota (plant and animal tissues)

Methods for Plant Matrix

Two official analytical methods were provided for the determination of sodium and chloride in plant samples.

The first method, AOAC method 980.03, for sodium is a direct reading spectrographic method. Dry plant material is ground and sieved followed by the addition of buffer solution. Mixed element standard solutions and known plant tissue standards are used to calibrate spectrograph.

The second method, AOAC method 935.05, for chloride is a titration method. A solution of $0.3M \text{ AgNO}_3$ is added to the test samples followed by HNO₃ and KMnO₄ until the colour disappears. The filtrate is treated with K₂SO₄-CuSO₄ mixture and H₂SO₄, and titrated with KI using a starch indicator.

Method for Animal Matrix

An AOAC method 935.47 was provided for the determination of sodium chloride in meat samples. A solution of AgNO₃ is added to the meat samples to precipitate all Cl as AgCl, and then HNO_3 is added to dissolve the meat. A ferric indicator is added, and the sample is titrated with NH_4SCN solution until the solution becomes permanent light brown.

All methods provided were assessed to be acceptable for use as postregistration monitoring methods.

3.0 Impact on Human and Animal Health

3.1 Integrated Toxicological Summary

Sodium chloride was of low acute oral toxicity ($LD_{50} > 2000 \text{ mg/kg bw}$; recorded value of 3000 mg/kg bw), dermal toxicity (LD_{50} 10 000 mg/kg bw) and a 1-hour inhalation (LC_{50} 42 000 mg/L) toxicity. The active ingredient was non-irritating to slightly irritating to the skin and minimally irritating to the eyes. Sodium chloride is not a skin sensitizer.

The evaluation was limited to acute toxicity and irritative effects because sodium chloride is a List 4A compound, as per the United States Environmental Protection Agency (USEPA), and is food grade, as per the Food Chemicals Codex (FCC).

3.2 Determination of Acceptable Daily Intake

This is a non-food application. An acceptable daily intake is not required.

3.3 Acute Reference Dose

This is a non-food application. An acute reference dose is not required.

3.4 Toxicological Endpoint Selection: Occupational and Bystander Risk Assessment

The risk assessment anticipates exposure to the mixer, the loader, the applicator and, potentially, the bystander. In a typical 8-hour workday, a crew could treat up to 40 km of right-of-way (20 km each side), assuming a continuous population of ragweed. The

typical width of roadside spray swath of 1.5 m yields a total area of 6 ha. The range of active ingredient (a.i.) handled would be (6.0 ha \times 1200 L/ha \times 120 kg/1000 L) 864 kg a.i. to (6.0 ha \times 1400 L/ha \times 120 kg/1000 L) 1008 kg a.i. Bystander control during application will be sufficient to mitigate the need for further risk assessment. The primary routes of exposure are by dermal and inhalation routes.

Evaluation of acute studies and available literature of sodium chloride did not yield any concerns based on acute oral, dermal and inhalation toxicity. Sodium chloride was determined to be non-irritating to slightly irritating to the skin and minimally irritating to the eyes. There was no apparent potential for skin sensitization associated with sodium chloride.

An evaluation of sodium chloride as a developmental, reproductive or nervous system toxicant, carcinogen or genotoxicant was not carried out because sodium chloride is a List 4A compound, as per the USEPA, and is food grade, as per the FCC.

Dermal absorption was not evaluated. Therefore, adequate personal protective equipment and hygiene have been recommended to mitigate the need for such a study.

3.5 Impact on Human and Animal Health Arising from Exposure to the Active Substance or to its Impurities

3.5.1 Operator Exposure Assessment

There is a potential for exposure to the applicator when applying AdiosAmbros Water Soluble Granule (12.0% aqueous solution) to ragweed along roadsides, highways, walkways, vacant lots and industrial sites. Application is by hand-held spray nozzle or a conventional tractor or spraymount fixed boom. A spot treatment will likely be used for patch treatment along the roadsides. Exposure estimates were not evaluated for mixers, loaders or applicators, but it is anticipated that the use of appropriate eyewear should be sufficient to minimize the risk due to exposure of AdiosAmbros Water Soluble Granule.

3.5.2 Bystanders

There is a potential for bystander exposure; however, as a result of the low toxicity, an exposure assessment of bystanders is not necessary. As for mitigating any potential ocular exposure to the salt solution, it is recommended that the label instruct that bystanders not be exposed to any product drift.

3.5.3 Workers

The label does not indicate any postapplication activities. As such, an exposure assessment of workers was not necessary.

4.0 Residues

4.1 Residue Summary

The proposed use is for a non-food application. A food residue exposure assessment is not required.

5.0 Fate and Behaviour in the Environment

Several published sources of information were used to address the fate and behaviour of sodium chloride in the environment. In particular, the Environment Canada and Health Canada assessment report for road salts (Environment Canada and Health Canada 2001) was used extensively for this review. Other useful sources of information were reviews and documentation prepared for the above report, primary research articles as well as academic studies. Registrant-submitted data were used wherever possible; however, only existing information was submitted.

5.1 Fate and Behaviour Summary

Sodium chloride can be found in the environment either in its salt form or dissociated into sodium and chloride ions in the presence of water. Once dissociated, sodium will move through soil to some extent, but will tend to bind with soil particles depending on the cation exchange capacity of the soil. Alternatively, chloride does not readily bind or adsorb to soil surfaces and leaches through soil layers at the rate of the percolating water containing the dissolved ion. Sodium chloride is highly soluble in water and will not bioaccumulate. Based on the vapour pressure (0.1 kPa at 865°C) and Henry's law constant (4.3×10^5) , it is relatively non-volatile under field conditions from water and moist soil surfaces. Since sodium chloride is an inorganic molecule, no breakdown beyond dissociation of the molecule will occur. Sodium chloride is not subjected to other transformation. Dissipation of sodium and chloride ions can occur through leaching and runoff and to some extent through plant uptake. Under most Canadian conditions, accumulation of sodium and chloride ions in soil and/or contamination of surface water from the use of AdiosAmbros is not expected for this use pattern.

5.2 Expected Environmental Concentrations

The expected environmental concentration (EEC) of sodium chloride from the use of AdiosAmbros in soil and water was estimated using maximum-exposure scenarios. These estimations are considered as Tier I and do not account for any potential dissipation.

In addition to AdiosAmbros, the PMRA determined the EECs of sodium chloride (in soil and water) based on the use of road salt for comparative purposes. A principal source of exposure to sodium chloride in the environment is through the use of road salt, where it is used to melt ice and snow from driving surfaces for safety concerns. Road salts consist of several components; however, by far the greatest component is NaCl (up to 99% of the historical use). Environment Canada and Health Canada have assessed the environmental concern associated with this use and have concluded that road salt, including sodium chloride, is "toxic" under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). As a result, the environmental effects of sodium chloride released through the use of AdiosAmbros are assessed and compared to the environmental effects of sodium chloride released through the use of road salt. The EECs calculated for road salt application are presented in Appendix II, Tables 1 and 2.

5.2.1 Soil

Assuming a soil bulk density of 1.5 g/cm³, a soil depth of 15 cm and a scenario in which the maximum Canadian label rate (150 kg a.i./ha) is applied once per season to bare soil by direct overspray, and assuming no dissipation, the EEC of residues of NaCl in soil due to application of AdiosAmbros would be 66.7 mg a.i./kg soil (approximately 26.2 mg Na/kg soil and 40.5 mg Cl/kg soil) (Appendix II, Table 2).

5.2.2 Aquatic Systems

Direct Overspray

Assuming an agricultural scenario in which a body of water of 30-cm depth is oversprayed once only per season with the maximum Canadian application rate of 150 kg a.i./ha, the EEC of sodium chloride residues in water due to application of AdiosAmbros would be 50.0 mg a.i./L or 30.3 mg Cl/L (Appendix II, Table 2).

Runoff

The Tier I risk assessment of NaCl from AdiosAmbros using direct overspray-based EECs did not trigger investigation of potential contribution through runoff. In addition, the type of area where AdiosAmbros is intended to be applied is relatively small and narrow (e.g., along roadsides), and the timing of application is intended to occur during periods of no precipitation (as per label directions). Therefore, investigation of runoff of NaCl to surface waters was not considered necessary under the proposed use pattern. Alternatively, all assessments for the Environment Canada's Priority Substances List report for road salt assumed a runoff scenario.

Drinking Water

Drinking water estimates were not conducted. The current use pattern does not include application to food crops.

5.2.3 Vegetation and Other Food Sources

The EECs of sodium chloride in vegetation and food sources are calculated based on the maximum annual label rate of application. No transformation on the foliage occurs. Direct overspray scenario (at maximum application rate of 150 kg NaCl/ha, once per season) using a nomogram developed by the USEPA from the data of Hoerger and Kenaga (1972), Kenaga (1973), and modified according to Fletcher et al. (1994) for use

in ecological risk assessment (Urban and Cook 1986) was used (Appendix II, Tables 3 and 4).

6.0 Effects on Non-target Species

Several published sources of information were used to address effects of sodium chloride on non-target organisms. As with the environmental chemistry and fate assessment, the Environment Canada and Health Canada assessment report for road salts (Environment Canada and Health Canada 2001) was drawn upon extensively for this review. Other useful sources of information were reviews and documentation prepared for the Environment Canada and Health Canada report, primary research articles and academic studies. Registrant-submitted data were used wherever possible; however, only existing information was submitted.

6.1 Effects on Terrestrial Organisms

Terrestrial Invertebrates

Kaplan et al. (1980) exposed earthworms (*Eisenia foetida*) to sodium chloride over 14 days. All test species died at the 5000 mg NaCl/kg level; however, the LC_{50} was between 1000 mg NaCl/kg and 5000 mg NaCl/kg. The no observed effect concentration (NOEC) was estimated, as 10% of the LC_{50} (i.e., lowest concentration used in this test 1000 mg NaCl/kg) or 100 mg NaCl/kg.

Addison (2002) assessed the effects of sodium chloride on earthworm (*Eisenia fetida/andrei*) reproduction and mortality over 28 days using a draft Organisation for Economic Co-operation and Development (OECD) guideline (OECD 2000). The 28-day EC_{50} for hatched cocoons of *Eisenia fetida/andrei* is 906 mg NaCl/L. The NOEC (90.6 mg NaCl/L) was estimated as 10% of the EC_{50} .

Mammals and Birds

No data were submitted by the registrant addressing potential toxic effects of sodium chloride to mammals and birds. The proposed use is by direct spray application; therefore, no granules are available for ingestion. Consumption of vegetation or water containing sodium chloride is not expected to provide a high enough dose to cause any harm to mammals or birds because uncontaminated drinking water is expected to be readily available during time of application (late spring through to early fall). A selected summary of some published literature investigating toxic effects is included hereafter.

Oral toxicity of sodium chloride to rats and mice has been recorded at an LD_{50} of 3000 mg/kg bw and 4000 mg/kg bw, respectively (Bertram 1997, as cited in Environment Canada and Health Canada 2001). Repeated small doses of sodium chloride in drinking water have not been reported to cause ill effects when access to uncontaminated drinking water was unrestricted. For risk assessment purposes, 10% of the above minimum LD_{50} is used to estimate the no observed effect limit (NOEL); this is 300 mg/kg bw for rats.

Wickstrom et al. (2001, as cited in Environment Canada and Health Canada 2001) recorded an acute LD_{50} of 3000–3500 mg NaCl/kg-bw on house sparrows. The study prevented access to fresh drinking water for six hours postdose. For risk assessment purposes, 10% of the above minimum LD_{50} was used to estimate the NOEL; this is 300 mg/kg dw for house sparrows.

Vascular Plants

For the purposes of assessing the proposed use pattern of sodium chloride on terrestrial plants, data pertaining to soil or solution culture application on herbaceous plants are most applicable (Appendix II, Table 5). The EC_{25} (root elongation) of 202 ppm for sodium, based on soil concentration, was the most sensitive endpoint value observed. This translates into an application rate of 455 kg Na/ha or 1155 kg NaCl/ha.

Arambasic et al. (1995; registrant-submitted) assessed the effects of sodium chloride on root growth in onion bulbs (*Allium cepa*) and garden cress seeds (*Lepidium sativum*). The 48-hour IC₅₀ for root growth was 11205 mg NaCl/L and 6305 mg NaCl/L for onion and cress, respectively. An EC₂₅ was not reported. Based on these results, a NOEL was estimated (10% of IC₅₀) as 631 mg NaCl/L for root growth in cress seeds, which is equivalent to an application rate of 1420 kg NaCl/ha.

The Environment Canada and Health Canada assessment report used several endpoint values for the assessment of the effects of road salts towards terrestrial plants (Environment Canada and Health Canada 2001). Included within this are the lowest EC_{25} values reported above by Cain et al. (2001) of 67.5 ppm sodium and 215 ppm chloride in soil for causing foliar injury on ponderosa pine. These values translate into an application rate of 152 kg/ha and 484 kg/ha for sodium and chloride, respectively.

6.2 Effects on Aquatic Organisms

Freshwater Invertebrates

Laboratory studies have indicated that sodium chloride is practically non-toxic to cladocerans (Appendix II, Table 6). The 48-hour LC_{50} was for *Ceriodaphnia dubia* at 2308 mg NaCl/L (1400 mg Cl/L) (Cowgill and Milazzo 1990, as interpreted by Evans and Frick 2001). The 7-day LC_{50} value of 2019 mg NaCl/L (1225 mg Cl/L) was also reported (Cowgill and Milazzo 1990, and as cited in Environment Canada and Health Canada 2001), and used by Environment Canada and Health Canada (Environment Canada and Health Canada 2001). Using 10% of the LC_{50} , from these values, a 48-hour and 7-day NOEC were estimated as 231 mg NaCl/L (140 mg Cl/L) and 202 mg NaCl/L (123 mg Cl/L), respectively.

Chronic effects of sodium chloride to cladocerans have been assessed. Birge et al. (1985) in a laboratory test using NaCl in reconstituted water observed a 21-day NOEC for chloride on *Daphnia pulex* of 314 mg/L. Biesinger and Christensen (1972, as reported in Evans and Frick 2001) reported impairment in reproduction of 16% for *Daphnia magna* over 21 days at a concentration of 1730 mg/L sodium chloride. The most sensitive chronic endpoint is 314 mg Cl/L.

Freshwater Fish

Laboratory studies have indicated that sodium chloride is practically non-toxic to freshwater fish species (Appendix II, Table 7). The most sensitive LC_{50} value was observed by Adelman et al. (1976) for *Carassius auratus* (goldfish) at 7341 mg NaCl/L or 4453 mg/L as chloride. Using 10% of this LC_{50} value, the estimated NOEC was 734 mg NaCl/L or 445 mg/L chloride.

For chronic effects of sodium chloride to freshwater fish, a 33-day early life-stage test (Birge et al. 1985) determined a NOEC for fathead minnow of 252 mg Cl/L for mortality. In an early life-stage test of unspecified duration, Spehar (1987, as stated in USEPA 1988a) observed 54% survival with rainbow trout exposed to 1324 mg/L chloride and 97% survival at 643 mg Cl/L. No survival was observed at 2740 mg Cl/L. The most sensitive chronic end point selected for risk assessment is the estimated NOEC value of 252 mg Cl/L from Birge et al. (1985).

Freshwater Plants

Stanley (1974, as cited in Evans and Frick 2001) observed a 50% reduction in dry weight of Eurasian milfoil, *Myriophyllum spicatum*, exposed over 32 days to a sodium chloride concentration of 5963 mg/L (3617 mg Cl/L) (as cited in USEPA 1988a). Teeter (1965, as cited in Evans and Frick 2001, and USEPA 1988a) reported a reduction in germination for seeds of *Potamogeton pectinatus* when exposed to 3000 mg NaCl/L (1820 mg Cl/L) for 28 days; however, the amount of reduction was not reported. The same study reported reduced dry weight (for 9-week old plants) and shoots (13-week old plants) of *Potamogeton pectinatus* (as cited in USEPA 1988a) when exposed to 3000 mg NaCl/L (1820 mg Cl/L) for 35 days, and the amount of reduction was not reported.

Wilcox (1984, as cited in Environment Canada and Health Canada 2001) observed a 43% reduction in growth of *Sphagnum fimbriatum* over 45 days of exposure to 2471 mg/L sodium chloride (1500 mg Cl/L). As a conservative estimation, 10% of this value is considered the most sensitive endpoint for macrophytes or 247 mg NaCl/L (150 mg Cl/L).

Freshwater Algae

Patrick et al. (1968, as cited in Evans and Frick 2001) reported a 50% reduction in number for the diatom *Nitzschia linearis* exposed to 2430 mg NaCl/L (1475 mg Cl/L) for 120 hours. Mohammed and Shafea (1992, as cited in Evans and Frick 2001) attained a cell concentration of the freshwater alga species *Scendesmus obliquus* of 43% of the controls at a sodium chloride concentration of 11690 mg/L. Reynoso et al. (1982, as cited in Evans and Frick 2001) observed a 49% reduction in growth of *Chlamydomonas reinhardtii* exposed to 4965 mg/L NaCl over six days. Shitole and Joshi (1984) observed reduction in growth for freshwater species *Pithophora oedogonia* and *Spirogyra setiformis* exposed to sodium chloride.

Evans and Frick (2001) and Environment Canada and Health Canada (Environment Canada and Health Canada 2001) determined that the IC_{50} endpoint (2430 mg NaCl/L or 1475 mg Cl/L) from the Patrick et al. (1968) study as the most appropriate for their risk

assessment purposes and, similarly, 10% of this endpoint will also be used as an estimate of the NOEL or 243 mg NaCl/L (147 mg Cl/L).

6.3 Risk Characterization

6.3.1 Environmental Behaviour

The application of AdiosAmbros will result in the rapid dissociation of the NaCl molecule to sodium and chloride in the presence of water. Sodium chloride is not subjected to other transformation processes such as hydrolysis, phototransformation and biotransformation. The chloride ion is the predominant component expected to be found in surface and groundwater after percolation through soil media, while the sodium component will generally remain bound to soil or sediment particles depending on the cation exchange capacity of the soil. Based on the proposed use pattern the potential contamination of aquatic systems through runoff is minimal.

For the purposes of a Tier I aquatic risk assessment for sodium chloride (initial assessment of the EEC against endpoints), the EEC is based on the most conservative scenario of concentration due to direct overspray of water bodies at the proposed rate of 150 kg NaCl/ha. Based on the above environmental behaviour of sodium chloride, the chloride ion is generally considered to have the greatest potential for toxicity in fresh surface waters. For this reason, calculated chloride concentrations (based on reported NaCl concentrations; as a proportion of the molecular mass) are presented in addition to NaCl for aquatic studies. In the case of a terrestrial plant study, both the reported sodium concentration in soil and the calculated NaCl concentration are provided; all other terrestrial data are reported as NaCl concentration.

6.3.2 Terrestrial Organisms

Earthworms

The risk posed to earthworms through the proposed use of sodium chloride is low (Appendix II, Tables 8 and 9). The risk quotient (RQ) for the sublethal endpoint (90.6 mg NaCl/kg dw soil— reproductive) and lethal endpoint (100 mg NaCl/kg dw soil) was 0.67 and 0.74, respectively.

Mammals and Birds

The acute risk of sodium chloride to mammals through oral exposure was assessed (Appendix II, Table 9). The level of risk to rat was determined by dividing the acute oral NOEL per individual (300 mg NaCl/kg bw × standardized body weight of 0.35 kg/individual, from USEPA 1988b) by the daily intake of sodium chloride in food. This daily intake was calculated by multiplying the standardized food consumption rate of rats (0.06 kg dw/ind/day, from USEPA 1988b) by the EEC of sodium chloride in the rat diet (75 674 mg a.i./kg diet). The NOEL per individual was 105 mg a.i, and the daily intake of sodium chloride was 4540 mg. The resulting number of days required for an individual rat to ingest enough sodium chloride through 100% contaminated diet in order

to reach the NOEL was 0.02. The following risk criteria were used: Days > 1 = Negligible risk; Days < 1 = Risk.

The acute risk of sodium chloride to birds through oral exposure was assessed (Appendix II, Table 9). The level of risk to the house sparrow was determined by dividing the acute oral NOEL per individual (300 mg/kg bw × standardized body weight of 0.027 kg/individual, from Dunning 1993) by the daily intake of sodium chloride in food. This daily intake was calculated by multiplying the standardized food consumption rate of house sparrows (0.0066 kg dw/ind/day from equation for passerine species, in USEPA 1993) by the EEC of sodium chloride in the field sparrow bird diet (17602 mg a.i./kg diet). Information pertaining to the house sparrow diet was not available; therefore, the known diet of the field sparrow was used as a surrogate value and assumed to be similar. Based on this, the NOEL per individual was 8.10 mg a.i., and the daily intake of sodium chloride was 116 mg. The resulting number of days required for an individual bird to ingest enough sodium chloride through 100% contaminated diet in order to reach the NOEL was 0.07. The following risk criteria were used: Days > 1 = Negligible risk; Days < 1 = Risk.

Therefore, based on the above calculations for the rat and the sparrow, there is a potential for risk to wild mammals and birds through oral ingestion of sodium chloride if the animals were to consume 100% contaminated food. However, under field conditions this assessment is not considered valid because mammals and birds are able to move to different foraging locations and can readily access fresh drinking water. Repeated small doses of sodium chloride in drinking water have not been reported to cause ill effects in mammals when access to uncontaminated drinking water was unrestricted (Bertram 1997, as cited in Environment Canada and Health Canada 2001). Similarly, Wickstrom et al. (2001) generated the above endpoint value for birds by restricting drinking water intake for 6 hours postdose. The proposed use pattern of sodium chloride will occur during summer months when ample uncontaminated drinking water is expected to be available to off-set any potential toxicity due to an acute intake of sodium chloride. The end-use product is applied as a spray solution; therefore, no exposure to concentrated granular salt is possible (as with road salts). In addition, the relative frequency of mammals and birds in areas proposed for use (e.g., near highways and roadways) is not expected to be great because food sources will be limited and human activity will be high. Consequently, the risk posed to mammals and birds from sodium chloride through the use of AdiosAmbros is expected to be minimal.

Vascular Plants

Non-target plant species are likely to be exposed to sodium chloride through uptake from contaminated soil, or through direct spray exposure, or indirect spray drift, of the applied end-use product. The EC_{25} value (202 ppm Na) that translated into an application rate of 455 kg Na/ha for root elongation in various prairie plant species is higher than the intended maximum application rate of 59 kg Na/ha (i.e., 150 kg NaCl/ha). The estimated NOEL for root elongation in cress seeds (631 mg NaCl/L) that translated into an application rate of 1420 kg NaCl/ha is also higher. Therefore, based on these data, the

risk posed by sodium chloride to terrestrial plant species through contaminated soil is considered negligible (Appendix II, Tables 8 and 9).

The most sensitive terrestrial woody plant endpoints used by Environment Canada and Health Canada (67.5 ppm Na, 215 ppm Cl—ponderosa pine test species) represent application rates (152 kg Na/ha and 484 kg Cl/ha), which are less than the application rate for AdiosAmbros (59 kg Na/ha and 91 kg Cl/ha) (Appendix II, Table 9). Therefore, risk is considered to be low to woody plants from the use of AdiosAmbros.

It should be pointed out that for the proposed use pattern of AdiosAmbros, it is not possible to reduce the spray drift to adjacent non-target terrestrial plants by observing terrestrial buffer zones because of the potential narrow width of the application areas (i.e., along roadsides, walkways, etc.). It is, however, possible to reduce the spray drift by avoiding spraying during certain meteorological conditions, as outlined in Section 6.4. For future use expansion, the registrant may be asked to submit information/data on the effects of direct overspray of NaCl on non-target plants.

6.3.3 Aquatic Organisms

Cladoceran

The most sensitive acute and chronic endpoints (NOECs) for aquatic invertebrates are for *Ceriodaphnia dubia* (mortality, 231 mg NaCl/L or 140 mg Cl/L) and for *Daphnia pulex* with 202 mg NaCl/L (123 mg Cl/L) and 518 mg NaCl/L (314 mg Cl/L). Based on these values, the risk to freshwater invertebrates is considered to be low (Appendix II, Tables 8 and 10). With respect to freshwater invertebrates, mitigative measures are not required for the application of sodium chloride.

Freshwater Fish

The most sensitive acute and chronic endpoints (NOECs) for freshwater fish are 734 mg NaCl/L (445 mg Cl/L; 96-hour mortality) for the goldfish, and 415 mg NaCl/L (252 mg Cl/L; 33-day life-stage) for the fathead minnow (Appendix II, Table 10). When comparing with the EEC for sodium chloride in water (50 mg/L, 30.3 mg Cl/L), there is negligible risk to goldfish (RQ of 0.07) and low risk to the fathead minnow (RQ of 0.12) exposed to sodium chloride under the intended use. Therefore, with respect to freshwater fish, mitigative measures are not required for the application of sodium chloride.

Freshwater Plants

The most sensitive endpoint (NOEC) for freshwater plants is for *Sphagnum fimbriatum* of 247 mg NaCl/L (150 mg Cl/L) (Appendix II, Table 10). When comparing with the EEC for sodium chloride in water (50 mg/L, 30.3 mg Cl/L), there is low risk to freshwater plant species exposed to sodium chloride applied under the intended use. With respect to freshwater plants, mitigative measures are not required for the application of sodium chloride.

Freshwater Algae

The most sensitive endpoint (NOEC) for freshwater algae are 243 mg NaCl/L (147 mg Cl/L) for *Selenastrum capricornutum* (number of cells) (Appendix II, Table 10). When comparing with the EEC for sodium chloride in water (50 mg/L, 30.3 mg Cl/L), the risk to freshwater alga species exposed to sodium chloride applied under the intended use is low. With respect to freshwater algae, mitigative measures are not required for the application of sodium chloride.

6.4 Risk Mitigation

Based on the proposed use of AdiosAmbros, no buffer zones are required for protection of terrestrial or aquatic organisms. However, due to the proposed use pattern of this pesticide, some label statements pertaining to minimizing spray drift are required. In addition, environmental disposal statements are required. The following label modifications are proposed.

Add to DIRECTIONS FOR USE:

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands).

Add to ENVIRONMENTAL HAZARDS:

"TOXIC to non-target terrestrial plants."

Add to DIRECTIONS FOR USE:

"<u>Field sprayer application</u>: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty.

DO NOT apply by air."

Add to DISPOSAL:

- "1. Make the empty container unsuitable for further use.
- 2. Dispose of the container in accordance with provincial requirements.
- 3. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill and for clean-up of spills."

AdiosAmbros Compared to De-icing Road Salt

Environment Canada and Health Canada (Environment Canada and Health Canada 2001) conducted a tiered risk assessment to determine risk to the environment due to the use of

road salts. The Environment Canada and Health Canada priority substances list assessment of road salts report (Environment Canada and Health Canada 2001) concluded that road salts, containing certain inorganic salts such as sodium chloride, used as a de-icing agent on roads during winter are entering the "[...] environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends." They concluded that road salts are "toxic" as defined in Section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Therefore, it is important to consider the proposed use of AdiosAmbros within the context of the existing use of road salt in order to assess the relative environmental impact it may have.

Approximately 4.75 million tonnes of sodium chloride as road salts were used in Canada during the winter of 1997–1998 (Environment Canada and Health Canada 2001), which is also considered a representative figure for road salts use in more recent years. The highest road salt loadings occur in Ontario and Quebec, followed by the Atlantic provinces, and the least amount of loadings occurs in the western provinces. The estimated road salt application per road lane and per hectare (calculated) in Ontario, Quebec and New Brunswick is outlined in Appendix II, Table 1. The PMRA calculated the EEC of NaCl in soil and water from road salt application using two measurements of road salt application rates and a conservative number of 20 applications per season; based on these values, the EECs for soil and water were approximately 2.8 g NaCl/kg and 2.1 g NaCl/L, respectively (Appendix II, Table 2). The second measurement of EECs was based on total salt loadings per winter season; the calculated EEC ranges were approximately 1.1 to 48.9 g NaCl/kg and 0.8 to 36.7 g NaCl/L in soil and water, respectively (Appendix II, Table 2).

In water, *in situ* environmental concentrations of chloride of up to 18 g/L have been recorded in runoff coming from roadways (Environment Canada and Health Canada 2001). Chloride concentrations up to 82 g/L have been observed in runoff coming from salt piles (Environment Canada and Health Canada 2001). Attributed to road salt use (Environment Canada and Health Canada 2001), elevated chloride concentrations have been recorded in ponds and wetlands (4 g/L), groundwater in areas adjacent to storage yards (2.8 g/L), watercourse (4.3 g/L) and impoundments (2 to 5 g/L). Highest loadings are often observed in the spring due to snowmelt and surface runoff; however, high values can also be observed during summer months due to travel time required for ions to reach surface waters. Soil concentrations of sodium chloride near patrol yards have been recorded as high as 13.1 g/kg for sodium and 14.5 g/kg for chloride; the average soil concentration was 2.1 and 2.6 g/kg for chloride and sodium, respectively (Environment Canada and Health Canada 2001). Sodium soil concentrations in situ sampled within 30 m of roadways have been recorded at 60 mg/kg, and chloride soil concentrations within 200 m of roadways have been recorded at 200 mg/kg (Environment Canada and Health Canada 2001).

A total of approximately 243 tonnes of AdiosAmbros is anticipated to be used per season in Canada (registrant data). This represents 0.005% of sodium chloride loadings to the environment when compared to the contribution through road salt use (4.75 million tonnes per year). Based on the proposed application rate of AdiosAmbros, expected environmental concentrations of NaCl in soil and water are estimated to be 66.7 mg a.i./kg and 50 mg a.i./L, respectively. These values are at least two orders of magnitude less than water and soil EECs of sodium chloride due to road salt use (Appendix II, Table 2) and the observed environmental concentrations (from literature). No significant addition of chloride to surface waters due to the use of AdiosAmbros is expected. Therefore, based on the expected amount of sodium chloride to be used by application of AdiosAmbros, minimal concern arises when put into the context of existing loadings into the environment due to road salt.

In addition, any additional risk posed to the environment through the proposed use of AdiosAmbros alone is low. The Tier I risk assessment, assuming the most conservative scenario, did not indicate a level of concern that would trigger further assessment.

Subsequent to the publishing of Environment Canada and Health Canada assessment report (Environment Canada and Health Canada 2001), a management plan was implemented to provide the tools for safely reducing the negative impacts of road salt. As a result, a Code of Practice document was published in April 2004 (Environment Canada 2004) that detailed the requirements to meet the reduction objective. Annex I of this document outlines concentrations of sodium and chloride in the environment that indicate environmental impact when exceeded. Organizations applying 500 tonnes of road salt or more per year (for example, municipalities and counties) are required to implement monitoring programs that will allow for comparison of water and soil concentrations of sodium and chloride to these concentration levels outlined in Annex I. The maximum levels suggested for surface waters are 140 mg Cl/L for protecting against short-term effects on aquatic organisms, and 35 mg Cl/L for protecting against long term effects on aquatic organisms (Table 6.4.1). The maximum levels suggested for soils for the protection of soil integrity, soil organisms and vegetation are 60 mg Na/L and 90 mg Cl/L (Table 6.4.1). As outlined in Table 6.4.1, the predicted Tier I EECs of sodium and chloride, based on the use of AdiosAmbros, will not exceed these values. In addition, the expected use of sodium chloride as AdiosAmbros (243 tonnes per year) is lower than the minimum value of 500 tonnes per year (per user organization), at which point the Code of Practice criteria apply.

Table 6.4.1Comparison of Tier I Sodium and Chloride EECs from AdiosAmbros
and Environment Canada Code of Practice (2004) Sodium and
Chloride Concentrations for the Protection of the Environment from
Road Salt Use

Medium	Sodium or Chloride EEC from Use of AdiosAmbros	Sodium or Chloride Guideline for Environmental Protection
Chloride in surface waters	30.3 mg Cl/L ¹	Short-term protection—140 mg Cl/L
		Long-term protection—35 mg Cl/L
Sodium in soil	26.2 mg Na/kg ¹	60 mg Na/L^2
Chloride in soil	40.5 mg Cl/kg ¹	90 mg Cl/L^2

From direct overspray (most conservative scenario).

Soil integrity, soil organisms and vegetation will "generally be protected" at, or below, this level (Environment Canada 2004). Level is reported in Environment Canada (2004) with units of mg/L.

As the EECs for NaCl and for AdiosAmbros are less than the guideline values, exposure from the proposed used pattern is expected to be less than through road salt use. Runoff of sodium chloride through the use of AdiosAmbros is expected to be minimal because the type of area where AdiosAmbros is intended to be applied is relatively small and narrow (e.g., along roadsides) and the timing of application is during periods of no precipitation (as per label directions). The above analysis indicated that the environmental inputs of sodium chloride through the application of AdiosAmbros are not considered to add significantly to any existing environmental effects from sodium chloride loadings due to road salt.

7.0 Efficacy

7.1 Mode of Action

The information provided suggests that sodium chloride may be classified as a contact herbicide and that only the plant parts that come into contact with the product become desiccated. The mode of action may be to reduce the water potential outside the cells on the leaves of the plant because the plant cells seek to achieve an equilibrium in osmotic potential through the process of osmosis, and water is drawn out of the plant, essentially desiccating the plant tissues. It is unclear whether sodium chloride actually enters the plant leaves, thus drawing water directly out of the cells through the same process of osmosis. It is also possible that the sodium chloride may be penetrating the cuticle, entering the leaves and thus translocating to some degree within the plant.

7.2 Nature of Pest Problem

Common ragweed is a nuisance species that is a weed in both crop and non-crop land, and also produces large quantities of highly allergenic pollen. Common ragweed is often found in highly disturbed habitats or waste areas including along roadsides or on medians and in vacant lots.

7.3 Effectiveness Against Pest

The results of efficacy trials conducted in Quebec between 1996 and 2002 support a directed application of AdiosAmbros to areas of high common ragweed density on roadsides, highways, walkways, vacant lots and other non-cropland sites.

The draft label indicates that for best results AdiosAmbros should be applied during periods of full sunshine with a minimum ambient temperature of 24°C. It appears common ragweed plants are more vulnerable to dessication under such conditions thus resulting in a more efficacious application.

7.4 Application Information

It was reported that applications of AdiosAmbros were made at various growth stages of common ragweed, from the 2- to 3-leaf seedling stage to mature plants up to half a metre in height, and no effect of timing of application was apparent in the data submitted for review. The draft label states 10-leaf stage to flowering. Due to the high degree of biological plasticity of common ragweed, flowering may occur in plants varying in height from as little as < 10 cm to as much as > 1 m. The growth stage or timing of application will therefore have to be more specific on the final label. One application per season is being requested.

7.5 Total Spray Volume

The application rate is based in part on the volume needed to provide thorough coverage of the target plants. The data provided for review demonstrates that common ragweed is controlled with applications of a 12% concentration of sodium chloride in 1250 L water/ha (150 kg of AdiosAmbros in 1250 L of water).

7.6 Non-safety Adverse Effects

Sodium chloride has the potential to negatively impact any plant species it is applied to because plant cells in general seek to achieve an equilibrium in osmotic potential through the process of osmosis, and water is drawn out of the plant, essentially desiccating the plant tissues, when sodium chloride is applied to the leaf surface.

The data submitted for review are adequate to support a directed spray of AdiosAmbros to areas including roadsides, highways, walkways, vacant lots and other non-cropland sites, where high densities of common ragweed may occur.

7.7 Economics

N/A

7.8 Sustainability

It is expected that the use of AdiosAmbros in providing an alternative with lower risks may result in a reduction in traditional chemical herbicide use in the proposed use pattern on roadsides, highways, walkways, vacant lots and other non-cropland sites for the control of common ragweed.

7.8.1 Survey of Alternatives

7.8.1.1 Non-chemical Control Practices

Mechanical mowing or hand-pulling techniques may be used in certain situations such as in vacant lots or along walkways. Mechanical mowing is the method of choice for larger areas such as roadsides, but, in recent years, re-vegetation (re-seeding) with desirable plant species and plant competition have become more frequently used methods of controlling undesirable vegetation, including common ragweed. Mechanical mowing is often ineffective because common ragweed plants will usually continue to grow after being mowed and will likely flower and produce seed.

7.8.1.2 Chemical Control Practices

No herbicides are presently registered for the selective control of common ragweed alone. Alternative herbicides for broad-spectrum weed control for use on roadsides, highways, walkways, vacant lots and other non-cropland sites include various formulations of glyphosate, glufosinate-ammonium, paraquat/diquat as well as several Weed Science Society of America Group 4 herbicides (synthetic auxins) including, but not limited to, 2,4-D, MCPA and dicamba.

7.8.2 Compatibility with Current Management Practices Including Integrated Pest Management

The most common management practices for vegetation control on roadsides, highways, walkways, vacant lots and other non-cropland sites are mechanical mowing and herbicide use. For areas of high common ragweed density, however, the use of a product with lower risks, such as AdiosAmbros, would be of benefit for the control of common ragweed. AdiosAmbros is applied with the same equipment as conventional herbicides; therefore, its use is compatible with current management systems.

7.8.3 Contribution to Risk Reduction

AdiosAmbros offers an alternative with lower risks to traditional chemical herbicides for the control of common ragweed in such areas as on roadsides, highways, walkways, vacant lots and other non-cropland sites. As such, this product may contribute to reduced chemical use these areas.

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

Based on the speculated mode of action of AdiosAmbros, the development of resistance is unlikely. The use of AdiosAmbros in conjunction with a conventional herbicide program may mitigate, in part, the development of resistance in common ragweed.

7.9 Conclusions

Adequate value data were provided to support the use of AdiosAmbros on roadsides, highways, walkways, vacant lots and other non-cropland sites for the control of common ragweed. The non-safety adverse effects data provided for review were limited and support the use of a directed spray of AdiosAmbros to areas of high common ragweed density only.

8.0 Toxic Substances Management Policy

The PMRA has taken into account the federal Toxic Substances Management Policy¹ and has followed its Regulatory Directive DIR99-03². It has been determined that this active ingredient and end-use product do not meet all the TSMP Track 1 criteria. This compound is considered a Track 2 substance.

9.0 Proposed Regulatory Decision

The PMRA has carried out an assessment of available information in accordance with the Pest Control Products Regulations and has found it sufficient to allow a determination of the safety, merit and value of the active ingredient sodium chloride and the end-use product AdiosAmbros. The Agency has concluded that the use of the active ingredient sodium chloride and the end-use product AdiosAmbros in accordance with the label has merit and value consistent with the Pest Control Products Regulations and does not entail

¹ The federal Toxic Substances Management Policy is available through Environment Canada's website at <u>www.ec.gc.ca/toxics</u>.

 ² Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply);
 Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla.gc.ca.

an unacceptable risk of harm. Therefore, based on the considerations outlined above, the use of the active ingredient sodium chloride and the end-use product AdiosAmbros for control of common ragweed on roadsides, highways, walkways, vacant lots and other non-cropland sites is proposed for full registration, pursuant to the Pest Control Products Regulations.

The PMRA will accept written comments on the proposal up to 45 days for the date of publication of this document to allow interested parties and opportunity to provide input into the proposed registration decision for this product.

List of Abbreviations

a.i.	active ingredient
AOAC	Association of Official Analytical Chemists
ASTM	American Society for Testing and Materials
bw	body weight
CEPA	Canadian Environmental Protection Act
CTV	critical toxicity value
cm	centimetre(s)
DMSO	dimethylsulfoxide
dw	dry weight
EC	effect concentration
EEC	expected environmental concentration
FCC	Food Chemicals Codex
fw	fresh weight
g	gram(s)
h	hour(s)
ha	hectare
IC ₅₀	inhibition concentration 50%
kg	kilogram(s)
K _{ow}	<i>n</i> -octanol–water partition coefficient
L	litre(s)
LC ₅₀	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)
mm Hg	millimetre mercury
nm	nanometer(s)
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
nm	nanometre
pН	-log10 hydrogen ion concentration
рКа	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
RQ	risk quotient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Toxicology Summary

Table 1 **Toxicology Table**

STUDY	SPECIES, STRAIN AND DOSES	NOAEL ¹ AND LOAEL ² mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES-	-TECHNICAL		
Oral	Rat—strain and doses unknown	LD ₅₀ > 2000 mg/kg	Low toxicity
Dermal	Rabbit—strain and doses unknown	LD ₅₀ 10 000 mg/kg	Low toxicity
Inhalation	Rat—strain and doses unknown	(1 h) LC ₅₀ 42 000 mg/L	Low toxicity
Skin irritation	Rabbit—strain	MIS: unknown	RTECS ³ notes mild irritation.
	unknown; 500 mg/24 n	MAS: unknown	Non-irritating to slightly irritating
Eye irritation	Rabbit—New Zealand white; 0.10 ml	MIS: Unknown MAS: 13	Minimally irritating
Skin sensitization (Human Repeat Insult Patch)	Human—0.3 ml of 10% and 30% w/w distilled water	No positive or control groups	Not a dermal sensitizer
ACUTE STUDIES-	-FORMULATION-AI	DIOSAMBROS WATER	SOLUBLE GRANULE
Oral	Rat—strain and doses unknown	LD ₅₀ > 2000 mg/kg	Low toxicity
Dermal	Rabbit—strain and doses unknown	LD ₅₀ 10 000 mg/kg	Low toxicity
Inhalation	Rat—strain and doses unknown	(1 hour) LC ₅₀ 42 000 mg/L	Low toxicity
Skin irritation	Rabbit—strain	MIS: unknown	RTECS ³ notes mild irritation.
	unknown; 500 mg/24 h	MAS: unknown	Non-irritating to slightly irritating
Eye irritation	Rabbit—New Zealand white; 0.10 ml	MIS: Unknown MAS: 13	Minimally irritating
Skin sensitization (Human Repeat Insult Patch)	Human—0.3 ml of 10% and 30% w/w distilled water	No positive or control groups	Not a dermal sensitizer

Ι NOAEL: no observed adverse effect level. 2

LOAEL: lowest observed adverse effect level.

3 RTECS: Registry of Toxic Effects of Chemical Substances.

Appendix IIEnvironmental Assessment

NaCl EECs in Soil Resulting from Application of Road Salts

Based on application data of sodium chloride per two-lane highway provided by Morin and Perchanok (2000, as cited in Environment Canada and Health Canada 2001), the PMRA-calculated single application rate of road salt on two lane highways in Ontario, Quebec and New Brunswick during the winter period is as follows:

Province	Mean kg Salt/ 2-Lane km of	kg Salt/ha for Lane Width of:		
	Highway (one application)	3.0 m (10 feet)	3.7 m (12 feet)	
Ontario	130	217	176	
Quebec	190	317	257	
New Brunswick	150	250	203	

Table 1Calculated Single Road Salt Application Rate per Hectare Based on
Application Rate per Two Lane Highway

These values represent single application rates and do not represent total loadings; total loadings are a function of the number of application rates that occur per kilometre of highway over the winter period. Road salt loadings in southern Ontario, southern Quebec and New Brunswick are estimated to be 20–50 tonnes per 2-lane kilometre per season (Environment Canada and Health Canada 2001).

Assuming a soil bulk density of 1.5 g/cm³, a soil depth of 15 cm and a scenario in which the maximum road salt application rate (317 kg NaCl/ha, Table 1) is applied 20 times per season (based on limitation of model parameter) to bare soil by direct overspray and assuming no dissipation (elemental molecule), the EEC of residues of NaCl in soil due to road salt application would be approximately 2820 mg NaCl/kg soil (approximately 1110 mg Na/kg soil and 1710 mg Cl/kg soil, Table 2).

Morin and Perchanok (2000) determined the grams of road salt used per square metre of provincial saltable road for the 1997–1998 winter de-icing season. As there is no degradation of applied salt, these data could be used towards an alternate Tier I estimation of the EECs for sodium chloride in soil and water, based on the rates of road salt application. These figures take into account the number of actual applications, whereas the previous calculation assumed 20 applications (limited by model parameters), which may be an underestimation. The seasonal range of application reported by Morin and Perchanok (2000) was between 250 and 11 000 g salt/m², with the highest loadings observed in Ontario and western Quebec. Sodium chloride is the major component of road salt; therefore, the above range is assumed to represent sodium chloride. Assuming a soil bulk density of 1.5 g/cm³, a soil depth of 15 cm, a scenario in

which the seasonal road salt application rate ranges from 2500 to 110 000 kg NaCl/ha roadway (based on 250 to 11 000 g salt/m²), application to bare soil by direct overspray and no dissipation (elemental molecule), the EEC of residues of NaCl in soil due to road salt application would be approximately 1110 to 48 900 mg NaCl/kg soil (approximately 437 to 19 200 mg Na/kg soil and 673 to 29 700 mg Cl/kg soil) (Table 2).

NaCl EECs in Water Resulting from Application of Road Salts

Assuming an agricultural scenario involving the above maximum single application rate of road salt applied as a de-icing agent (317 kg NaCl/ha, Table 1), in which a body of water of 30 cm depth is oversprayed directly 20 times per season (based on limitation of model parameter) and assuming no transformation in water, the EEC of sodium chloride residues in water due to road salt application would be approximately 2110 mg NaCl/L or 1280 mg Cl/L (Table 2).

Based on the seasonal application data provided by Morin and Perchanok (2000), described above, an alternate Tier I estimate of EECs in surface water due to road salt can also be determined. Assuming an agricultural scenario involving the above maximum single application rate ranges from 2500 to 110 000 kg NaCl/ha roadway (based on 250 to 11 000 g salt/m²), in which a body of water of 30 cm depth is oversprayed, and assuming no transformation in water, the EEC of sodium chloride residues in water due to road salt application would range from approximately 833 to 36 700 mg NaCl/L (approximately 328 to 14 400 mg Na/Kg soil and 505 to 22 300 mg Cl/Kg soil, Table 2).

Table 2Summary of EECs in Soil and Water Based on AdiosAmbros and Road Salt
Application Rates

Medium	EEC Based on AdiosAmbros (150 kg/ha × 1 application)	EEC Based on Road Salt (317 kg/ha roadway × 20 applications) ¹	EEC Based on Road Salt (seasonal application of 2500 to 110 000 kg NaCl/ha roadway) ²
Soil	66.7 mg NaCl/kg soil	2820 mg NaCl/kg soil	1110 to 48 900 mg NaCl/kg soil
Water	50 mg NaCl/L water	2110 mg NaCl/L water	833 to 36 700 mg NaCl/L water

Based on data from Environment Canada and Health Canada (2001).

² Based on data from Morin and Perchanok (2000).

³ Road salt data based on information provided in Environment Canada and Health Canada (2001), and Morin and Perchanok (2000).

Matrix	EEC (mg ai/kg fw) ^a	Fresh/Dry Weight Ratios	EEC (mg ai/kg dw)
Short-range grass	32 100	3.3 ^b	105 932
Leaves and leafy crops	16 800	11 ^b	184 799
Long grass	14 700	4.4 ^b	64 680
Forage crops	18 000	5.4 ^b	97 200
Small insects	7800	3.8°	29 640
Pods with seeds	1605	3.9 ^c	6260
Large insects	1335	3.8°	5073
Grain and seeds	1335	3.8°	5073
Fruit	2010	7.6 ^c	15 276

Table 3Maximum EEC in Vegetation and Insects after a Direct Overspray

^a Based on correlations reported in Hoerger and Kenaga (1972) and Kenaga (1973).

^b Fresh/dry weight ratios from Harris (1975).

^c Fresh/dry weight ratios from Spector (1956).

Table 4Maximum EEC in Diets of Birds and Mammals

Organism	Matrix	EEC (mg a.i./kg dw diet)
Bobwhite quail	30% small insects 15% forage crops 55% grain	26 262
Mallard duck	30% large insects 70% grain	5073
Rat	70% short grass20% grain/seeds10% large insects	75 674
Mouse	25% short grass50% grain/seeds25% leaves and leafy crops	75 219
Rabbit	25% short grass25% leaves and leafy crops25% long grass25% forage crops	113 152

Organism	Matrix	EEC (mg a.i./kg dw diet)
Sparrow	51% small insects 49% grain/seeds	17 602

Table 5Range of Threshold Values Estimated for Soil and Water for Various
Terrestrial Plant Species1

Form	Pathway	Plant Form	Endpoint Type and Value	Endpoint Range ppm (mg/kg or mg/L)
Na	Soil	Herbaceous	EC ₂₅	202–270
	Soil	Woody	EC ₂₅	67.5–300
	Root uptake	All species	EC ₂₅	67.5–300
Cl	Water solution	Wetland	LOEL ²	300–1500
	Soil	Woody	EC ₂₅	215-500
	Root uptake	All species	EC ₂₅ , LOEL	215-1500
NaCl	Soil	Woody	EC ₂₅	600–5500
	Solution culture	Herbaceous	EC ₂₅	< 2500-10 000
	Solution culture	Wetland	NOEL, LOEL	280-66 600
	Solution culture	Woody	EC_{25} , CTV^3	836–25 000
	Root uptake	All species	EC ₂₅ , CTV, NOEL, LOEL	280-66 600

¹ Data from Cain et al. 2001; summary table from Environment Canada and Health Canada 2001.

² LOEL: lowest observed effect level. ³ CTV: gritigel toxicity value A value f

CTV: critical toxicity value. A value that represents the lowest concentration of a substance that will cause an effect in a particular study.

Table 6Lethal and Sub-lethal Endpoint Values for Cladoceran Species Exposed to
Sodium Chloride^a

Species	Test Duration	NaCl (mg/L)	Cl (mg/L)	Reference	Degree of Toxicity ^b
Daphnia magna	48-hour LC ₅₀ —infusion water/test solution/ synthetic water	4746	2879	Arambasic et al. 1995	Practicall y non- toxic

Species	Test Duration	NaCl (mg/L)	Cl (mg/L)	Reference	Degree of Toxicity ^b
Daphnia magna	4-day LC ₅₀	3054	1853	Anderson 1948 (as cited in Environment Canada and Health Canada 2001)	Practicall y non- toxic
Ceriodaphnia dubia	4-day LC ₅₀	2630	1596	Wisconsin State Laboratory of Hygiene (WI SLOH) 1995 (as cited in Environment Canada and Health Canada 2001)	Practicall y non- toxic
Daphnia pulex	48-hour LC_{50} —reconstituted water	2423	1470	Birge et al. 1985	Practicall y non- toxic
Daphnia pulex	48-hour LC_{50} —natural stream water	5028	3050	Birge et al. 1985	Practicall y non- toxic
Ceriodaphnia dubia	48-hour LC ₅₀ —hardness adjusted Lake Huron water	2308	1400	Cowgill and Milazzo 1990, as interpreted by Evans and Frick 2001	Practicall y non- toxic
Ceriodaphnia dubia	7-day LC ₅₀	2019	1225°	Cowgill and Milazzo 1990, and as cited in Environment Canada and Health Canada 2001	Not applicable
Ceriodaphnia dubia	9-day NOEL (mean brood size)—hardness adjusted Lake Huron water	1296	786	Cowgill and Milazzo 1990	Not applicable
Daphnia magna	48-hour LC ₅₀ —hardness adjusted Lake Huron water	7754	4704	Cowgill and Milazzo 1990, as interpreted by Evans and Frick 2001	Practicall y non- toxic

Species	Test Duration	NaCl (mg/L)	Cl (mg/L)	Reference	Degree of Toxicity ^b
Daphnia magna	9-day NOEL (mean brood size)—hardness adjusted Lake Huron water	1296	786	Cowgill and Milazzo 1990	Not applicable
Daphnia pulex	21-day NOEC (reproduction, body length, survival)	518	314	Birgeet al. 1985	Not applicable

^a Toxicity values expressed as NaCl and Cl; test application as NaCl.

^b Based on the USEPA classification, where applicable.

 Value determined by the PMRA based on data from Cowgill and Milazzo 1990; value reported in Environment Canada and Health Canada (2001) is 1260 mg Cl/L.

Table 7Endpoint Values for Fish Species Exposed to Sodium Chloride^a

Species	Test Duration	NaCl (mg/L)	Cl (mg/L)	Reference	Degree of Toxicity ^b
<i>Gambusia affinis</i> (mosquito-fish)	96-hour, 50% mortality (median tolerance limit)	17 500	10 616	Wallen et al. 1957, as cited in Evans and Frick 2001	Practicall y non- toxic
<i>Lepomis macrochirus</i> (bluegill)	96-hour, 50% mortality (median tolerance limit)	12 964	7864	Trama 1954, as cited by Evans and Frick 2001	Practicall y non- toxic
Oncorhynchus mykiss (rainbow trout)	96-hour LC ₅₀	11 112	6743	Spehar 1987, as cited Environment Canada and Health Canada 2001	Practicall y non- toxic
<i>Pimephales promelas</i> (fathead minnow)	96-hour LC ₅₀	10 831	6570	Birge et al. 1985	Practicall y non- toxic
<i>Lepomis macrochirus</i> (bluegill)	96-hour LC ₅₀	9627	5840	Birge et al. 1985	Practicall y non- toxic

Species	Test Duration	NaCl (mg/L)	Cl (mg/L)	Reference	Degree of Toxicity ^b
Pimephales promelas (fathead minnow)	96-hour LC ₅₀	7681°	4600 ^c	WI SLOH 1995, as cited in Environment Canada and Health Canada 2001	Practicall y non- toxic
<i>Pimephales promelas</i> (fathead minnow)	96-hour LC ₅₀	7 650	4640	Adelman et al. 1976, and Environment Canada and Health Canada 2001	Practicall y non- toxic
<i>Carassius auratus</i> (goldfish)	96-hour LC ₅₀	7341	4453	Adelman et al. 1976, and Environment Canada and Health Canada 2001	Practicall y non- toxic
Oncorhynchus mykiss (rainbow trout); Perca flavescens (yellow perch); Pimephales promelas (fathead minnow); Salmo trutta (brown trout); Stizostedion vitreum (walleye); Lepomis macrochirus (bluegill); Ictalurus punctatus (channel catfish)	No mortality after 24-hour exposure	10 000	6066	Waller et al. 1996	Practicall y non- toxic
<i>Oncorhynchus mykiss</i> (rainbow trout)	7-day EC ₂₅ (egg/embryo)	1 630	989	Beak 1999, as cited in Evans and Frick 2001	Not applicable
Pimephales promelas (fathead minnow)	33-day NOEC (early life-stage)	415	252	Birge et al. 1985	Not applicable

Toxicity values expressed as NaCl and Cl; test application as NaCl. Based on the USEPA classification, where applicable. а b

с Value as reported in Environment Canada and Health Canada 2001.

Risk Quotient (EEC/NOEC)	Risk Category
< 0.1	Negligible risk
≥ 0.1-< 1.0	Low risk
≥ 1.0-< 10	Moderate risk
≥ 10-< 100	High risk
≥ 100-< 1000	Very high risk
≥ 1000	Extremely high risk

Table 8 Risk Characterization for Deterministic Risk Assessment

Table 9Risk Posed to Terrestrial Organisms Through the Proposed Canadian Use of
Sodium Chloride as AdiosAmbros

Organism	Exposure	Endpoint value	EEC	RQ	Risk				
	Invertebrates								
Earthworm	14-day acute	14-day NOEC ≥ 100 mg NaCl/kg	66.7 mg NaCl/kg soil	0.67	Low risk				
Earthworm	28-day reproductive	28-day estimated NOEC 90.6 mg NaCl/kg (hatched cocoons)	66.7 mg NaCl/kg soil	0.74	Low risk				
		Mammal	S						
Rat	Oral acute	10% of LD ₅₀ = 300 mg NaCl/kg bw	75674 mg NaCl/kg dw diet	0.02 days	Risk due to exposure from proposed use pattern is expected to be minimal to mammals				

Organism	Exposure	Endpoint value	EEC	RQ	Risk	
		Birds				
House sparrow	Oral acute	10% of LD ₅₀ = 300 mg NaCl/kg bw	17602 mg NaCl/kg dw diet	0.07 days	Risk due to exposure from proposed use pattern is expected to be minimal to birds	
Vascular Plants						
Vascular plant (combined data from various grassland prairie species)	Root elongation	EC ₂₅ 455 kg Na/ha (as based on test result) or 1155 kg NaCl/ha	150 kg NaCl/ha, maximum application of AdiosAmbros	0.14	Low risk	
Vascular plant garden cress seeds (<i>Lepidium</i> <i>sativum</i>)	Root elongation	48-hour NOEL 1420 kg NaCl/ha (based on 10% of IC ₅₀)	150 kg NaCl/ha, maximum application of AdiosAmbros	0.11	Low risk	
Vascular plants ponderosa pine (<i>Pinus</i> ponderosa)	Foliar damage	152 kg Na/ha, and 484 kg Cl/ha	59.0 kg Na/ha, and 91.0 kg Cl/ha	0.39 Na 0.19 Cl	Low risk	

Table 10Risk Posed to Aquatic Organisms Through the Proposed Canadian Use of
Sodium Chloride as AdiosAmbros

Organism	Exposure	Endpoint Value	EEC	RQ	Risk
Freshwater Species					
Freshwater invertebrate (<i>Ceriodaphnia</i> <i>dubia</i>)	48-hour acute	48-hour NOEC 231 mg NaCl/L or 140 mg Cl/L (10% of LC_{50})	50 mg NaCl/L (30.3 mg Cl/L)	0.22	Low risk
Freshwater invertebrate (Daphnia pulex)	7-day	7-day NOEC 202 mg NaCl/L or 123 mg Cl/L (10% of LC_{50})	50 mg NaCl/L (30.3 mg Cl/L)	0.25	Low risk
Freshwater invertebrate (Daphnia magna)	21-day	21-day NOEC 518 mg NaCl/L or 314 mg Cl/L	50 mg NaCl/L (30.3 mg Cl/L)	0.1	Low risk
Freshwater fish—goldfish (Carassius auratus)	96-hour acute	96-hour NOEC 734 mg NaCl/L or 445 mg Cl/L	50 mg NaCl/L (30.3 mg Cl/L)	0.07	Negligible risk
Freshwater fish—fathead minnow (Pimephales promelas)	33-day	33-day NOEC (early life-stage) 415 mg NaCl/L or 252 mg Cl/L	50 mg NaCl/L (30.3 mg Cl/L)	0.12	Low risk
Freshwater alga (Selenastrum capricornutum)	5-day acute	5-day NOEC 243 mg NaCl/L or 147 mg Cl/L, number of cells $(10\% \text{ of IC}_{50})$	50 mg NaCl/L (30.3 mg Cl/L)	0.21	Low risk
Vascular plant (<i>Sphagnum</i> <i>fimbriatum</i>)	45-day chronic	45-day NOEC 247 mg NaCl/L or 150 mg Cl/L	50 mg NaCl/L (30.3 mg Cl/L)	0.2	Low risk

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