

Regulatory Note



Anhydrous Ammonia

The active ingredient anhydrous ammonia and the associated end-use product, Anhydrous Ammonia for Use in the Gophinator Device (99.8%), to control Richardson's ground squirrels (*Spermophilus richardsonii* Sabine or gophers) and woodchucks (*Marmota monax* or groundhogs) in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till field) have been granted temporary registration under the Pest Control Products Regulations.

This Regulatory Note provides a summary of data reviewed and the rationale for the regulatory decision for these products.

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Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) has reviewed the technical grade active ingredient anhydrous ammonia and the associated end-use product, Anhydrous Ammonia for Use in the Gophinator Device (99.8%), to control Richardson's ground squirrels (*Spermophilus richardsonii* Sabine or gophers) and woodchucks (*Marmota monax* or groundhogs) in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields).

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. The Agency has concluded that the use of anhydrous ammonia and the end-use product, Anhydrous Ammonia for Use in the Gophinator Device, 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 anhydrous ammonia and the end-use product, Anhydrous Ammonia for Use in the Gophinator Device, to control Richardson's ground squirrels (*Spermophilus richardsonii* Sabine or gophers) and woodchucks (*Marmota monax* or groundhogs) in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields) is proposed for temporary registration, pursuant to the Pest Control Products Regulations.

Maze Innovations will be carrying out confirmatory air monitoring studies as a condition of this temporary registration. Following the review of this information, the PMRA will publish a proposed regulatory decision document and request comments from interested parties before proceeding with a final regulatory decision.

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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		Anhydrous ammonia
Function		Rodenticide
Chem	ical name	
1.	International Union of Pure and Applied Chemistry	Ammonia
2.	Chemical Abstracts Service (CAS)	Ammonia
CAS number		7664-41-7
Molecular formula		NH ₃
Molecular weight		17.03
Structural formula		$H \sim \bigvee_{H}^{N} H$
Nominal purity of active		99.8%
Identity of relevant impurities of toxicological, environmental or other significance		Technical grade anhydrous ammonia does not contain any impurities or microcontaminants known to be Toxic Substances Management Policy (TSMP) Track 1 substances.

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

Technical Product: Anhydrous Ammonia

Property	Result
Colour and physical state	Colourless
Odour	Penetrating, pungent, suffocating odour
Melting point or range	N/A

Property	Result
Boiling point	-33.4°C at 760 mm Hg
Density	0.6 g/ml at 20°C
Vapour pressure at 25°C	7510 mm Hg
Henry's Law constant at 20°C	$1.869 \times 10^{-1} \text{ atm} \cdot \text{m}^{3}/\text{mole}$
Solubility in water at 0°C	89.9 g/100 ml
<i>n</i> -Octanol–water partition coefficient (K_{ow})	$\log K_{\rm ow} = 0.23$
Dissociation constant (pK_a) at $25^{\circ}C$	p <i>K</i> _a = 9.25
Stability (temperature, metal)	Reactive; reacts vigorously with fluorine, chlorine, hydrochloric acid, hydrobromic acid, nitrosyl chloride, chromyl chloride, trioxygen difluoride and nitrogen trichloride.

End-use Product: Anhydrous Ammonia for Use in the Gophinator Device

Property	Result
Colour	Colourless
Odour	Penetrating, pungent, suffocating odour
Physical state	Gas
Formulation type	Gas
Nominal guarantee	99.8%
Formulants	The product does not contain any United States Environmental Protection Agency (USEPA) or PMRA List 1 and 2 formulants. It does not contain formulants known to be TSMP Track 1 substances.
Container material and description	Stainless steel tanks
Density	0.6 g/ml at 20°C
pH of 10% solution in water	12
Oxidizing or reducing action	Extremely reactive with acids. Highly reactive with oxidizing and reducing agents.

Property	Result
Storage stability	Stable when stored in tanks, or nurse tanks or applicator tanks
Explodability	Slightly explosive in the presence of reducing materials (hypochlorites or other halogenated compounds). Non-explosive in the presence of open flames and sparks, shocks, heat, oxidizing materials, combustible
	materials, organic materials, metals, acids, alkalis or moisture.
Corrosion characteristics	Highly corrosive to copper and its alloys. Slightly corrosive to aluminium and zinc, very slightly corrosive to mild steel and non-corrosive to glass and stainless steel.

1.3 Details of Uses

Anhydrous ammonia (NH₃) is proposed for use as a fumigant with the Gophinator device to control Richardson's ground squirrels, *Spermophilus richardsonii* Sabine (gophers), and woodchucks, *Marmota monax* (groundhogs), in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields). The rate is to inject anhydrous ammonia into burrow until vapour is visible at the secondary entrances of the burrow system, up to a maximum complete injection time of 5 seconds; an injection period of 5 seconds will result in the release of 450 ml of anhydrous ammonia down a burrow. Anhydrous ammonia is applied by placing the applicator wand into the primary burrow entrances. Soil is then packed around the wand, filling the entrance to provide a seal that will prevent the vapour from escaping from the burrow. The product may be re-applied when re-infestation is observed.

Anhydrous ammonia is a commercially available commodity that is commonly used as a nitrogen fertilizer. Anhydrous ammonia vapour reacts strongly with any water. It is also strongly alkaline in the presence of water. Therefore, contact with any tissue, especially mucosal tissues, can cause caustic burns. As well, water can be absorbed from tissues that come in contact with anhydrous ammonia, causing dehydration of the affected areas. Because liquid anhydrous ammonia boils at -13.9°C, direct contact with it can cause frostbite. Anhydrous ammonia kills with a combination of these effects (i.e., burning and destroying tissues).

2.0 Methods of Analysis

Anhydrous ammonia is manufactured by reacting nitrogen from the air with hydrogen derived mainly from natural gas (methane) in presence of an iron catalyst. Submission of the analytical method has been waived as it is a well-known method.

3.0 Impact on Human and Animal Health

3.1 Effects Relevant to Human and Animal Health Arising from Exposure

Due to the inherent corrosive nature of the technical grade active ingredient, the requirement for toxicology studies was waived. The toxicological properties of anhydrous ammonia have been well documented in the published literature, which was referenced for the assessment below. As the end-use product is a re-pack of the technical grade active ingredient, all comments relating to the technical grade active ingredient also pertain to the end-use product.

Anhydrous ammonia is a clear, colourless gas at standard temperature and pressure conditions and has a characteristic pungent odour that has an odour threshold of 0.6 to 53 ppm. Anhydrous ammonia is a liquid when compressed or cooled, and must be stored under pressure to prevent vaporization. When anhydrous ammonia is released from compression in a storage tank, the temperature drops rapidly from 37.8 to -33.4°C. At this temperature, anhydrous ammonia will freeze-burn the skin upon contact. Anhydrous ammonia reacts with moisture in the mucous membranes to produce an alkaline solution that is corrosive. Eye and nose irritation is noted at low airborne concentrations (100 ppm, ATSDR 2004), and contact with concentrated aqueous solutions may cause serious corrosive injury, including skin burns, permanent eye damage or blindness. Inhalation of anhydrous ammonia may cause nasopharyngeal and tracheal burns, bronchiolar and alveolar edema, coughing, an accumulation of fluid in the lungs as well as airway destruction, resulting in respiratory distress or failure.

The American Conference of Governmental Industrial Hygienists (ACGIH) has set the threshold limit value (TLV) for anhydrous ammonia at 25 ppm (17.5 mg/m³) for an 8-hour time-weighted average (TWA) concentration (ACGIH 2004). A short-term exposure limit (STEL) of 35 ppm (24.5 mg/m³) was also established for periods not to exceed 15 minutes. The National Institute for Occupational Safety and Health (NIOSH) recommends that the level in workroom air be limited to 50 ppm (35 mg/m³) for 5 minutes of exposure, with a concentration of 300 ppm (210 mg/m³) considered immediately dangerous to life or health. These limits are based upon critical irritation effects to the eyes, skin and respiratory tract.

Both human and animal studies indicate that acute exposure to ammonia gas or concentrated liquid ammonia solutions result in irritation and corrosive effects consistent with the caustic nature of an alkaline solution. Results of acute inhalation testing in rats generated a 2-hour lethal concentration to 50% (LC₅₀) value of 5137 mg/m³. Ammonia gas is easily detectable at low levels due to its low odour threshold, which allows users to avoid prolonged exposure. However, ammonia causes olfactory fatigue or adaptation, making its presence difficult to detect when exposure is prolonged. Repeated exposure to ammonia may cause chronic irritation of the respiratory tract.

3.2 Toxicological Endpoint for Assessment of Risk Following Long-term Dietary Exposure—Acceptable Daily Intake

The lack of proposed food uses precludes the establishment of an acceptable daily intake level.

3.3 Toxicological Endpoint for Assessment of Risk Following Acute Dietary Exposure— Acute Reference Dose

The lack of proposed food uses also precludes the establishment of an acute reference dose.

3.4 Toxicological Endpoint for Assessment of Occupational, Residential and Bystander Risks

For risk assessment purposes, the primary endpoint of concern for anhydrous ammonia is its corrosiveness. Anhydrous ammonia is a gas at standard temperature and pressure conditions; it must be stored under pressure to prevent vaporization. Upon release from compression, the temperature of anhydrous ammonia drops rapidly and any contact with the chemical at this point will freeze-burn the skin upon contact. Anhydrous ammonia reacts with moisture in the mucous membranes to become a corrosive agent. At low concentrations, it is severely irritating to the eyes, skin and mucous membranes, and may cause more pronounced and possibly permanent damage following sustained exposure. Eye or skin contact with higher concentrations may cause skin burns, permanent eye damage or blindness. Exposure via the inhalation route may cause coughing, swelling in the lungs and airway destruction resulting in respiratory distress or failure, with death a possible outcome after intense over-exposure.

The ACGIH recommended exposure limits for ammonia gas include a TLV-TWA of 25 ppm for an 8-hour exposure and a STEL of 35 ppm for periods not to exceed 15 minutes. All limits are based upon critical irritation effects to the eyes, skin and respiratory tract.

Handler exposure would be short- to intermediate-term duration (i.e., up to six months/year) and would be predominately via the inhalation route, with some potential for dermal exposure. Due to its corrosive properties, mitigation measures are considered necessary to protect against the acute hazards of anhydrous ammonia.

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

3.5.1 Occupational Exposure and Risk

3.5.1.1 Handler Exposure and Risk

Anhydrous ammonia (guarantee 99.8%), packaged under pressure, is proposed for use as an outdoor fumigant to control Richardson's ground squirrels and woodchucks (groundhogs) in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields).

The Gophinator device is a 227 L (60 gallon) compressed gas tank with 15.24 m (50 feet) of hose and a specially built wand. Injection of ammonia in a rodent burrow is manually controlled by opening and closing a spring loaded valve on the wand.

Farmers and custom applicators will inject anhydrous ammonia into an active rodent burrow for 5 seconds, releasing 450 ml of anhydrous ammonia. An applicator wand with a 2.4 mm (3/32 inch) flow regulator and application pressure 414 kPa (60 psi) will give a flow rate of 5.4 L/min (90 ml/sec). After application, primary burrow entrances will be packed with dirt around the wand to provide a seal, preventing the vapour from escaping. After injecting the end-use product for 5 seconds (450 ml), the hose can be left in a burrow for up to 20 seconds to allow time for the anhydrous ammonium to dissipate into the burrow. Ammonia injected in the burrow either will exit from secondary entrances and dissipate into the ambient air outside, or will disperse and bind to the soil moisture due to its strong attraction for water.

The number of burrows in an area depends on the density of the population; this number could vary from 20 to 500 per acre (0.4 ha) in a high infestation area. The amount of ammonia required for a severe infestation of gophers would be up to 227 kg/ha (200 lbs/acre). Compared to the use of anhydrous ammonia as a fertilizer at a rate of 85–112.5 kg/ha (75–100 lbs/acre), farmers could handle approximately twice as much under the proposed use. Burrows can be three to five metres long. An applicator can treat up to 500 burrows in a day, which will require one full tank (227 L) of ammonia per day. One operator working full time (8 hrs/day for 5 days/week) with a Gophinator device would use 3 metric tonnes (3000 kg) of ammonia per month and 15 to 18 metric tonnes (13 607–16 329 kg) of ammonia per year. The end-use product will be used only during the spring and summer for a maximum of six months in a year. Thus, the exposure potential for handlers is of a short- to intermediate-term duration, mainly from exposure to ammonia vapour or gas via inhalation and the dermal route.

If ammonia tanks are filled only at licensed farm dealers who are certified and licensed to store and handle ammonia, the mixer/loader exposure potential is relatively low. However, if untrained farmers fill Gophinator tanks from an anhydrous ammonia nurse tank already present on the farm for fertilizer use, the mixer/loader exposure potential could be significant.

An exposure potential exists mainly for applicators during and after application if there is any leakage of ammonia from the primary entrances of the treated burrow or the secondary entrances, located three to five metres away from the primary entrance. After injecting the anhydrous ammonia into the burrow, the applicator will approach these primary and secondary entrances of burrows to seal them with dirt, preventing the vapour from escaping. No air monitoring data was provided to estimate air concentration of ammonia near a treated burrow. The concentrations that could be attained in an average size burrow with the application rate of 450 ml of ammonia were estimated between 3800 ppm and 19 000 ppm. Anhydrous ammonia is classified as a dangerous good under the *Transportation of Dangerous Goods Act* as well as a controlled product under the Workplace Hazardous Materials Information System (WHMIS). Anhydrous ammonia is classified as a dangerous good due to its nature as a compressed gas and a corrosive gas.

Ammonia has a low odour threshold (0.6–53 ppm) and can easily be detected by the applicator; however, the odour threshold is not a reliable warning property as it is in the TLV's range. Air concentrations \geq 300 ppm are considered to be immediately dangerous to human life.

A sudden high exposure could occur unexpectedly from accidents, including these situations.

- When the valves present on wand or on the tank to the hose are opened or closed, anhydrous ammonia can escape from the hose or valves.
- When equipment fails or valves, connectors or hoses malfunction, anhydrous ammonia could spray in any direction with a force greater than that of a fire hydrant. Hoses exposed to sunlight, constant rubbing, or those that are stretched are subject to failure.
- When ammonia is transported or stored in confined spaces.
- When a change in temperature occurs. Outside temperature changes can affect the vapour pressure of ammonia in the tank. If the hose ruptures, the tank, hose or connectors leak, or a valve is unintentionally opened, the high pressure from the tank can cause ammonia to spray into eyes, face and other parts of body of an individual in the area. When pressure is released, liquid anhydrous ammonia quickly converts to a gas, which increases chances of inhalation exposure.

Exposure to ammonia and safety of handlers, especially farmers, is of concern. Users of the end-use product require a high level of specialized knowledge in the safe use of compressed gases, such as anhydrous ammonia. Several mitigation measures, as noted below, are required to address these concerns:

- restricting product users;
- requiring training in handling anhydrous ammonia;
- requiring extensive personal protective equipment for handlers;
- listing accidental/spillage measures on the label; and
- requiring users to adhere to equipment safety measures.

3.5.1.2 Postapplication Exposure and Risk

After application, the handlers of this product or other workers/farmers may re-enter treated areas for the following reasons:

- to monitor or mark treated burrows and confirm death of target species;
- to check for re-infestation of target species; and
- to perform agricultural activities.

As rodent burrows are generally located in pastureland, in hayland, rangeland or in cultivated fields (including in field perimeters and in no-till fields), cultivated land crop agriculture activities are not expected, except for collecting/stacking hay and grazing animals.

Any amount of anhydrous ammonia injected into the burrow will either escape from the burrow entrances and dissipate into the ambient air outside the treated burrow, or will disperse and bind to the soil moisture due to its strong attraction for water. However, air concentrations and dissipation rates are unknown. Thus, during postapplication activities, it is possible that ammonia levels in the air may or may not be higher than the acceptable exposure levels. Therefore, until data on air concentrations are available, treated areas must be posted for 24 hours to mitigate postapplication exposure potential.

3.5.2 Residential Exposure and Risk

As the end-use product is supported only for outdoor uses in agricultural settings in hay fields, in rangeland, in pastureland and in cultivated land (including field perimeters and no-till fields), exposure and risk for handlers during application and postapplication in residential settings would be minimal. Any concerns for indoor or outdoor residential settings, including playgrounds and parks, will be mitigated by label statements.

3.5.3 Bystander Exposure and Risk

As the end-use product would be applied inside rodent burrows in pastureland, in hay fields or in rangeland and away from people, exposure and risk potential for bystanders are low. Any concerns for bystanders exposure will be mitigated by a label statement and a requirement to post signs in the treated area to keep children, bystanders and pets well away from the application area.

3.5.4 Residues Relevant to Consumer Safety—Aggregate Exposure and Risk Assessment

There are no proposed residential uses. Therefore, an aggregate risk assessment was not required.

4.0 **Residues**

Residue data are not required.

5.0 Fate and Behaviour in the Environment

Ammonia is a gas that occurs naturally in the environment. Ammonia also occurs naturally when urine, manure, plants and dead organisms degrade in the environment. Ammonia dissolves readily in water where, at pH 7, approximately 90% ionizes to form ammonium ion $(NH_3 + H_2O \neq NH_4^+ + OH^-)$. The total content of ammonia in water is generally expressed as the sum of non-ionized (NH_3) and ionized (NH_4^+) forms. Ammonia is also widely used as a nitrogen fertilizer in agriculture. According to the applicant, 650 000 metric tonnes of ammonia is used annually in the prairies (87.5 to 112.5 kg NH₃/ha).

5.1 Summary of Physical and Chemical Properties Relevant to the Environment

Ammonia is alkaline and very soluble in water (899 g/L). The high values of vapour pressure (7510 mm Hg at 25°C) and Henry's Law constant (0.187 atm m³/mole) indicate that ammonia is very volatile under field conditions and rapidly lost into the atmosphere from the moist soil and from water surfaces. The dissociation constant of ammonia, pK_a, is 9.24 at 25°C, which indicates that ammonia exists mostly as undissociated molecule in the environmentally relevant pH conditions. The log K_{ow} of 0.23 indicates that ammonia has a low potential for bioaccumulation.

5.2 Summary of Fate and Behaviour in the Terrestrial Environment

Ammonia is highly volatile and volatilizes into the atmosphere. Ammonia is a part of the nitrogen cycle in the environment. It volatilizes into the atmosphere where it may undergo a variety of reactions such as photolytic reactions. A part of ammonia in the air may react

with compounds such as sulfur dioxide forming ammonium sulphate or nitrates, which return to the earth's surface as a wet or dry deposition.

In most soils, ammonia exists as the ammonium ion. Ammonia is also assimilated by several microorganisms as a source of nitrogen for cellular nutrition. Nitrifying organisms derive energy from the oxidation of ammonium to nitrate (IPCS 1986).

Ammonium is rapidly transformed (oxidation) in soils by microorganisms (bacteria) into nitrates (nitrification) under aerobic conditions. Nitrates are very soluble in water and are not adsorbed by soil particles. Nitrates have, therefore, a high potential to leach and to contaminate groundwater. Nitrates are also converted by denitrification to nitrogen gas or nitrous oxide, which may escape into the atmosphere.

Ammonium is strongly adsorbed to soil particles and is relatively immobile in soils. However, when transformed into nitrates, ammonia is mobile.

According to the 2003 Material Safety Data Sheet for aqua ammonia, ammonium does not bioaccumulate in organisms. Ammonia does not build up in the food chain, but serves as a nutrient source for plants and bacteria (ATSDR 2002).

5.3 Summary of Fate and Behaviour in the Aquatic Environment

In surface waters, ammonium may undergo microbiological nitrification under aerobic conditions. This process uses oxygen and releases hydrogen, which may result in oxygen depletion and acidification, respectively, in aquatic systems. Ammonium may be assimilated by aquatic plants as a source of nitrogen, adsorbed to the sediments or volatilized (IPCS 1986).

5.4 Summary of Fate and Behaviour in Air

Ammonia is highly volatile and volatilizes into the atmosphere, where it exists in the gas phase. Under normal atmospheric conditions, ammonia does not undergo any primary photochemical reactions at wavelengths greater than 290 nm. However, ammonia undergoes a secondary reaction when exposed to radicles or other photochemically excited species:

 $\begin{array}{l} NH_3+OH^{-}\rightarrow NH_2^{-}+H_2O\\ NH_3+O\rightarrow NH_2^{-}+OH^{-} \end{array}$

When ammonia is subjected to gas-phase reaction with photochemically produced hydroxyl radicals, the calculated half-life was two months (NPISP 2004). Ammonia also undergoes decomposition to nitrogen and hydrogen when exposed to an electric discharge. Ammonia can form explosive mixtures in the air at atmospheric temperature and pressure, and the products of combustion are mainly nitrogen and water, with trace

amounts of ammonium nitrates and nitrogen dioxide. Another important reaction is the catalytic oxidation of ammonia to nitric oxide (NO) and nitrous oxide (N₂O). Ammonia is also subjected to reaction with gaseous nitric acid to form particulate ammonium nitrate.

5.5 Expected Environmental Concentrations

As the active ingredient is injected into sealed rodent burrows by means of a wand attached to the Gophinator device, the expected environmental concentrations in soil, water and air were not estimated.

6.0 Effects on Non-target Species

6.1 Summary of Effects on Terrestrial Organisms

No data are available on the toxicity of ammonia to terrestrial organisms such as bees, predators and parasites, wild birds and mammals.

Non-target Terrestrial Plants

Plants use ammonium as a nutrient, but high levels can be toxic. Atmospheric levels greater than 75 μ g a.i./m³ will result in reduced growth and reduced vitality of terrestrial plants.

6.2 Summary of Effects on Aquatic Organisms

Ammonia (not the ammonium ion) is moderately toxic to very highly toxic to freshwater and marine aquatic organisms (Table 6.2.1). The toxicity of ammonia depends on factors such dissolved oxygen, temperature and pH. The acute toxicity of ammonia increases as the pH decreases (IPCS 1986).

Table 6.2.1 Effects on Aquatic Organisms

Organism	Exposure	Endpoint value	Degree of toxicity ^a
Freshwater species			
Invertebrates Acute		NOEC ^b : 0.08 mg a.i./L LC ₅₀ : 1.10–22.8 mg a.i./L	Moderately toxic
	Chronic	NOEC: 0.23 mg a.i./L	

Organism	Ex	posure	Endpoint value	Degree of toxicity ^a
Fish	Acute		NOEC: 0.09 mg a.i./L LC ₅₀ : 0.16–1.1 mg a.i./L	Very highly toxic
	Chronic	Early life- stage	NOEC: 0.0012 mg a.i./L	
		Full life cycle	NOEC: 0.012 mg a.i./L	
Bluegill sunfish	Acute		LC ₅₀ : 0.024–4.6 mg a.i./L	Very highly toxic
Bioconcentration in fish	No data av	ailable		
Freshwater algae: green algae	Acute		NOEC: 2.5 mg a.i./L	
Plants			NOEC: 0.15 mg a.i./L	
Marine species				
Invertebrates	Acute		NOEC: 0.17 mg a.i./L LC ₅₀ : 0.34–2.2 mg a.i./L	Highly toxic
Fish	Acute		NOEC: 0.04 mg a.i./L LC ₅₀ : 0.5 mg a.i./L	Highly toxic
Benthic diatoms	cation where		NOEC: <0.24 mg a.i./L	

^a USEPA classification, where applicable

NOEC: no observed effect concentration

Data were collected from the IPCS Report on ammonia, EHC 54, 1986

6.3 Effects on Biological Methods of Sewage Treatment

Not required by the PMRA

6.4 Risk Characterization

6.4.1 Environmental Behaviour

With the proposed use, ammonia is injected into rodent burrows by means of a wand attached to the Gophinator device, and the burrows are sealed immediately with top soil, which limits the movement of ammonia into the atmosphere. In most soils, ammonia is rapidly converted to ammonium, which strongly binds to soil particles, limiting its escape

into the atmosphere. Exposure to terrestrial and aquatic organisms is, therefore, limited with the proposed use.

6.4.2 Terrestrial Organisms

No data on ammonia toxicity to terrestrial organisms are available. With the proposed use, exposure of ammonia to terrestrial organisms such as wild birds and mammals is limited and, therefore, the proposed use of ammonia is not expected to pose a risk to these organisms.

However, a label statement is required to minimize the exposure to non-target organisms in and around the burrows.

6.4.3 Aquatic Organisms

Ammonia is highly toxic to fish and other aquatic organisms. Aquatic environments that receive ammonia may be acidified and nitrogen enriched. As the exposure to aquatic systems is limited with the proposed use, these aquatic organisms are not at potential risk.

A precautionary label statement is, however, required not to contaminate the aquatic habitats when cleaning and rinsing equipment or containers.

6.5 Data Gaps

No data gaps were identified.

6.6 Risk Mitigation

The following statement, which will help to minimize the risk to non-target organisms including species at risk, must appear on the label of the end-use product under "USE RESTRICTIONS":

Apply to burrows occupied by only Richardson's ground squirrel and woodchucks. Do not apply to unoccupied burrows.

The following measures will mitigate the risk of unintentionally killing non-target organisms, including species at risk.

• Applicators of anhydrous ammonia should observe the potential treatment area before treating burrows to confirm the presence of activity of Richardson's ground squirrels and woodchucks to ensure there is no evidence of species at risk activity or presence in burrows. • For information on species at risk in your area, contact your provincial or federal wildlife officials.

In addition, the following label statement is required to minimize the potential for aquatic exposure:

This product is toxic to fish and other aquatic organisms. Do not contaminate aquatic habitats, such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands, when cleaning and rinsing equipment or containers.

7.0 Efficacy

7.1 Effectiveness Against Target Organisms or with Respect to the Effect Achieved

7.1.1 Intended Use

Anhydrous ammonia for use in the Gophinator device is for use as a fumigant with the Gophinator applicator to control Richardson's ground squirrels and woodchucks in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields). The rate is to inject anhydrous ammonia into burrow until vapour is visible at the secondary entrances of the burrow system, up to a maximum complete injection time of 5 seconds; an injection time of 5 seconds will result in the release of 450 ml of anhydrous ammonia down a burrow. Re-application is when re-infestation is observed. Anhydrous ammonia is applied by placing the applicator wand into the primary burrow entrances. Soil is then packed around the wand, filling the entrance to provide a seal that will prevent the vapour from escaping from the burrow.

7.1.2 Mode of Action

Anhydrous ammonia vapour reacts strongly with any water. It is also strongly alkaline in the presence of water. Therefore, contact with any tissue, especially mucosal tissues, can cause caustic burns. As well, water can be absorbed from tissues that come in contact with anhydrous ammonia, causing dehydration of the affected areas. Because liquid anhydrous ammonia boils at -13.9°C, direct contact with it can cause frostbite. Anhydrous ammonia kills with a combination of these effects (i.e., burning and destroying tissues).

7.1.3 Crops/Pests

7.1.3.1 Crops

Anhydrous ammonia is for use with the Gophinator applicator in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields).

7.1.3.2 Pests

Richardson's Ground Squirrel

The Richardson's ground squirrel (*Spermophilus richardsonii* Sabine), is also called the gopher, prairie gopher, yellow gopher, flickertail or picket pin. They are found on the prairies (southern regions of Alberta and Saskatchewan and southwestern region of Manitoba). According to Alberta Agriculture, Food and Rural Development (AAFRD 2000), Richardson's ground squirrels can cause direct productivity losses in annual crops such as cereals, pulses and oilseeds as well as in forage land and pastures. They can also cause damage in more urban areas such as parkland and golf courses. Because ground squirrels eat a wide variety of grasses and broadleaved plants, they may compete with livestock for forage. In addition, mounds of soil excavated from burrows can damage crops, livestock and farm machinery. Ground squirrels are an important food source for badgers, and the burrowing activity of badgers attracted to areas with ground squirrels can also contribute to overall damage.

Richardson's ground squirrels spend the majority of their life underground, with many activities (e.g., mating, raising litters) taking place within the burrows. They live in complicated burrow systems consisting of a maze of galleries, with various openings (an average of eight) and several chambers (Mallis 1997). Burrow tunnels are 7.6 cm in diameter, between 3.7–14.9 m in length, and located 0.75–2.0 m deep. The main entrance is marked with a mound of dirt. Richardson's ground squirrel prefer high rolling hills of gravely or sandy soils, and hibernate for seven months each year, from September or October to April or May. During hibernation, these animals live off fat reserves they accumulate during the active portion of the year.

After emerging from hibernation, males establish territories of about 0.058 ha. This area usually encompasses three to five female burrows. After mating has occurred, females establish their own territory, which averages 0.016 ha within the male's territory. The female's territory remains the same each year, being passed on from mother to daughter. Richardson's ground squirrel has three daily activity periods: during the first two hours after sunrise; the hours between 10:00 a.m. and 2:00 p.m.; and from 4:00 p.m. until sunset.

Woodchucks

Woodchucks (*Marmota monax*), also known as groundhogs, are the largest member of the squirrel family. Woodchucks are 40–50 cm long, with males being slightly larger than females (Towers 1995; Thurston and Brittingham 1997).

Woodchucks are found in fields, clearings, edges of wooded areas, and rocky or brushy slopes across Canada and the eastern United States. They take advantage of suitable habitats created by humans along railroad tracks, roads, and highway ramps (Towers 1995). They will build burrows under buildings such as barns, porches, sheds and

building foundations (Bollengier 1994; Curtis and Sullivan 2001). Home-range sizes may vary from 16 ha to 65 ha, depending on age, sex, and food supply (Towers 1995).

Woodchucks excavate extensive, irregular burrow systems (Bollengier 1994; Towers 1995). Burrows may be as deep as 1.5 m and between 2.4 and 19.8 m long (Bollengier 1994). Their burrows usually have two to three entrances, but as many as five can be present (Curtis and Sullivan 2001). Tunnel diameter depends on the size of the occupant, the tunnels are on average 1.2 to 1.5 m deep and 8 to 9.5 m in length (Banfield 1974; Burt 1976). The main opening is approximately 25 to 30 cm in diameter and is surrounded by a large mound of excavated earth (Bollengier 1994). This main entrance opens into narrower tunnels. Other entrances are dug from below and do not have mounds of earth beside them, so these entrances are well hidden and difficult to locate (Thurston and Brittingham 1997). A single chamber, used for sleeping and rearing the young, is formed at the end of the main burrow (Thurston and Brittingham 1997). Woodchucks clean the burrow and use them for several seasons (Bollengier 1994).

7.1.4 Effectiveness Against Pest

Richardson's Ground Squirrel

Two efficacy studies on Richardson's ground squirrel were submitted to support the use of anhydrous ammonia in the Gophinator applicator. The results of these studies indicated that anhydrous ammonia when applied with the Gophinator applicator until vapour is visible from secondary burrow entrances, will kill Richardson's ground squirrel at least as well as 0.4% strychnine baits. Control in the anhydrous ammonia plot was 99% two days post-treatment, compared to 95% in the strychnine plot.

Woodchucks

Because of the extreme toxicity of an anhydrous ammonia saturated atmosphere to organisms, it is quite reasonable to assume that anhydrous ammonia is also toxic to woodchucks. Extrapolation to control of woodchucks from the submitted data on Richardson's ground squirrel is possible because of the similarity in the structure of burrows made by these two species.

Use Directions

The Gophinator device has an applicator wand with a flow regulator with a 2.4 mm (3/32 in.) sized orifice, and an application pressure of 414 kPa (60 psi), to give a flow rate of 5.4 L/minute (90 ml/sec). With these specifications, an injection period of 5 seconds will result in the release of 450 ml of anhydrous ammonia down a burrow. With an average burrow size ranging from 24 to 118 L in volume (based on a burrow diameter of 10 cm and a burrow length of 3 to 15 m), this amount of anhydrous ammonia would result in a fumigant concentration between 19 000 and 3800 ppm. Anhydrous ammonia is injected until vapour is visible at secondary entrances, up to a maximum complete injection time of 5 seconds.

Monitoring for the presence of pests prior to control (e.g., monitor for pest presence several days prior to treatment to ensure empty burrows are not treated) is required to determine which burrows are occupied or unoccupied (e.g., the presence of debris and cobwebs in a burrow entrance is indicative of an abandoned burrow). Post-treatment monitoring is required to determine re-establishment of pest populations (e.g., fill all burrow entrances after treatment and monitor for fresh digging).

7.1.5 Total Spray Volume

N/A

7.2 Phytotoxicity to Target Plants or Target Plant Products

The Gophinator dispenses a bulk volume of anhydrous ammonia into an open burrow system rather than injecting a carefully calibrated amount as when it is used as a fertilizer. Anhydrous ammonia can cause adverse effects to crops when used as a fertilizer, usually due to improper placement or depth of application, soil moisture levels and timing of fertilization. This suggests that localized adverse effects caused may occur when anhydrous ammonia is used in a manner that is not closely calibrated and controlled, i.e., as a fumigant applied with the Gophinator. For example, localized adverse effects may include burning of roots in or plants foliage near burrow openings. However, the damage caused by an infestation of pests such as the Richardson's ground squirrel would be far more detrimental to a crop than the potential adverse effects of the anhydrous ammonia. Therefore, a suitable warning to the user about potential adverse effects is required.

7.3 Impact on Succeeding Crops, Adjacent Crops and on Treated Plants or Plant Products Used for Propagation

N/A

7.3.1 Impact on Succeeding Crops (OECD 7.5.1)

N/A

7.3.2 Impact on Adjacent Crops (OECD 7.5.2)

N/A

7.3.3 Impact on Seed Viability (OECD 7.5.3)

N/A

7.4 Economics

No information was provided.

7.5 Sustainability

7.5.1 Survey of Alternatives

7.5.1.1 Non-chemical Control Practices

Non-chemical control methods currently used for the proposed pests include trapping and shooting. The proposed pests can also be controlled via exclusion (e.g., excluding pests from buildings by sealing entrances) or flooding infested fields.

7.5.1.2 Chemical Control Practices

Target Pest	Product Type	Active Ingredient
Richardson's	Poison bait	Chlorophacinone
ground squirrels		Strychnine
		Zinc phosphide
		2-diphenylacetyl-1,3-indandione
	Fumigant	Aluminum phosphide
		Gaseous oxides of sulphur
	Physical/chemical drowning	Mustard seed powder + α -olefin sulfonate
Woodchucks	Fumigant	Gaseous oxides of sulphur
		Aluminum phosphide

7.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

Anhydrous ammonia is compatible with current management practices (fumigation, trapping, poisoning, drowning, shooting and exclusion).

7.5.3 Contribution to Risk Reduction

Anhydrous ammonia has the potential to reduce the risk to non-target animals associated with poisoned baits such as strychnine. While the potential for accidental fumigation of

non-target species in burrow remains, there is no risk to scavengers from eating poisoned carcasses or to non-target animals from consuming poisoned baits.

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

Due to the mode of action of this chemical (fatal physical injury via a combination of burning and destroying tissues), the development of resistance to this method of control is not likely to occur.

7.6 Conclusions

The two efficacy studies conducted on Richardson's ground squirrel burrows demonstrated that anhydrous ammonia, when injected into burrows with the Gophinator device until vapour is observed at secondary burrow exits, will control Richardson's ground squirrel (99% control).

Because of the extreme toxicity of an anhydrous ammonia saturated atmosphere to organisms, it is quite reasonable to assume that anhydrous ammonia is also toxic to woodchucks. Extrapolation to control of woodchucks from the submitted data on Richardson's ground squirrel is possible because of the similarity in the structure of burrows made by these two species.

The Gophinator device has an applicator wand with a flow regulator with a 2.4 mm (3/32 in.) sized orifice, and an application pressure of 414 kPa (60 psi), to give a flow rate of 5.4 L/minute (90 ml/sec). With these specifications, an injection period of 5 seconds will result in the release of 450 ml of anhydrous ammonia down a burrow. With an average burrow size ranging from 24 to 118 L in volume (based on a burrow diameter of 10 cm and a burrow length of 3 to 15 metres), this amount of anhydrous ammonia is injected until vapour is visible at secondary entrances, up to a maximum complete injection time of five seconds.

Monitoring for the presence of pests prior to control (e.g., monitor for pest presence several days prior to treatment to ensure empty burrows are not treated) is required to determine which burrows are occupied or unoccupied (e.g., the presence of debris and cobwebs in a burrow entrance is indicative of an abandoned burrow). Post-treatment monitoring is required to determine re-establishment of pest populations (e.g., fill all burrow entrances after treatment and monitor for fresh digging).

The Gophinator applicator dispenses a bulk volume of anhydrous ammonia into an open burrow system rather than injecting a carefully calibrated amount as when it is used as a fertilizer. Anhydrous ammonia can cause adverse effects to crops when used as a fertilizer, usually due to improper placement or depth of application, soil moisture levels and timing of fertilization. This suggests that, when used in a manner which is not closely calibrated and controlled, i.e., as a fumigant applied with the Gophinator, localized adverse effects caused by anhydrous ammonia may occur (e.g., burning of roots in, or plants foliage near, burrow openings). However, the damage caused by an infestation of pests such as the Richardson's ground squirrel would be far more detrimental to a crop than the potential adverse effects of the anhydrous ammonia. Therefore, a suitable warning to the user about potential adverse effects is required.

The supported control claims are control of Richardson's ground squirrels and woodchucks in hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields). The recommended application rate is to inject anhydrous ammonia into burrow until vapour is visible at secondary entrances of the burrow system, up to a maximum complete injection time of five seconds (an injection period of 5 seconds will result in the release of 450 ml of anhydrous ammonia down a burrow). Re-application is when re-infestation is observed.

	Recommendation (based on value assessment)
Pests	Richardson's ground squirrel (Spermophilus richardsonii Sabine or gopher) Woodchuck (Marmota monax or groundhog)
Application timing	Observe the intended application area and inspect burrows to be treated prior to application in early morning and late evening of a 24-hour period before treating to confirm the target pest is actively using the site. It is preferable to treat burrows during the spring breeding season. DO NOT treat unoccupied or inactive burrows.
Number of applications	Re-apply when re-infestation is observed
Application method	With Gophinator Device. The applicator wand must have a flow regulator with a 2.4 mm (3/32 in.) sized orifice, and the application pressure must be 414 kPa (60 psi), to give a flow rate of 5.4 L/minute (90 ml/sec).
Crops	Hay fields, rangeland, pastureland and cultivated land (including field perimeters and no-till fields)

Table 7.6.1Summary	Use Directions
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	Recommendation (based on value assessment)
Application rate	Inject anhydrous ammonia into burrow until vapour is visible at secondary entrances of the burrow system, up to a maximum complete injection time of 5 seconds; an injection period of 5 seconds will result in the release of 450 ml of anhydrous ammonia in a burrow.

8.0 Toxic Substances Management Policy Considerations

During the review of anhydrous ammonia, the PMRA has taken into account the federal Toxic Substances Management Policy and has followed Regulatory Directive <u>DIR99-03</u>, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Ammonia naturally occurs in the environment. According to the TSMP criteria, elements and naturally occurring inorganic compounds are not candidates for virtual elimination from the environment. Anhydrous ammonia, therefore, does not fall under TSMP Track 1 criteria.

The active ingredient, anhydrous ammonia, does not contain any by-products or microcontaminants that meet the TSMP Track 1 criteria. Impurities of toxicological concern are not expected to be present in the raw materials, nor are they expected to be generated during the manufacturing process.

The formulated product does not contain any formulants that are known to contain TSMP Track 1 substances.

9.0 Regulatory Decision

9.1 Regulatory Decision

The PMRA has carried out an assessment of available information in accordance the Pest Control Products Regulations and has found it sufficient to allow a determination of the safety, merit and value of anhydrous ammonia and the associated end-use product, Anhydrous Ammonia for Use in the Gophinator Device. The Agency has concluded that the use of anhydrous ammonia and the associated end-use product, Anhydrous Ammonia for Use in the Gophinator Device, 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 anhydrous ammonia and the associated end-use product, Anhydrous Ammonia for Use in the Gophinator Device, has been granted temporary registration under the Pest Control Product Regulations for control of Richardson's ground squirrels (*Spermophilus richardsonii* Sabine or gophers) and woodchucks (*Marmota monax* or groundhogs) in hay fields, rangeland, pastureland and cultivated land (including field perimeters and notill fields) subject to the provision and review of confirmatory information.

9.2 Confirmatory Requirement

Confirmatory air concentration data for anhydrous ammonia.

List of Abbreviations

AAFRD	Alberta Agriculture, Food and Rural Development
ACGIH	American Conference of Governmental Industrial Hygenists
a.i.	active ingredient
atm	atmosphere
H_20	water
Hg	mercury
K_{ow}	<i>n</i> -octanol–water partition coefficient
kPa	kilopascal(s)
IPCS	International Programme on Chemical Safety
LC_{50}	lethal concentration to 50%
Ibs	pounds
mg	milligram(s)
min	minute(s)
ml	millilitre(s)
mm	millilitre(s)
N_2O	millimetre(s)
NH_3	nitrous oxide
NH_4^+	anhydrous ammonia (non-ionized ammonia)
NIOSH	ammonium (ionized ammonia)
nm	National Institute for Occupational Safety and Health
NO	nanometer
NOEC	nitric oxide
O	no observed effect concentration
O	oxygen
OH ⁻	hydroxide ion
ppm	parts per million
psi	pounds per square inch
sec	second
STEL	short-term exposure limit
STEL	short-term exposure limit
TLV	threshold limit value
TWA	time-weighted average

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