



Reregistration Eligibility Document (RED)

Inorganic Nitrate/Nitrite (Sodium and Potassium Nitrates)

INORGANIC NITRATE/NITRITE REREGISTRATION ELIGIBILITY TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
CAS	Chemical Abstracts Service
EP	End-Use Product
Agency	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
LD50	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
MP	Manufacturing Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.

Executive Summary

The first registered pesticide product containing sodium or potassium nitrate dates from 1948. Currently, there are a total of six registered products for these two active ingredients. All currently registered products are pyrotechnic fumigants designed to be ignited and placed in burrows thereby delivering lethal doses of toxic gases for the control of various rodents, coyotes and ground wasps, as well as skunks.

Based on the results of its reregistration review, the U.S. Environmental Protection Agency (E.P.A.) has determined that the data bases for these two active ingredients are substantially complete and sufficient to allow E.P.A. to conduct a reasonable risk assessment. There are some outstanding requirements for potassium nitrate concerning product chemistry. These are, however, seen as confirmatory and not essential for the Agency's risk assessment.

Accordingly, E.P.A. has determined that the registered uses of sodium and potassium nitrates are eligible for reregistration. The decision to reregister specific products will be made after appropriate labeling and product specific data are submitted and/or cited. After reviewing these data and labels the E.P.A. will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product labeling and composition are acceptable and their uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met, E.P.A. will reregister the products. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products, section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," under section 4(g)(2)(C) and (D). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA, section 3(c)(5).

This document presents the Agency's decision regarding the reregistration case inorganic nitrate/nitrite, which covers products containing the active ingredients sodium and potassium nitrates. No registered pesticide products now contain nitrites. The document consists of five sections. Section I is this introduction. Section II describes sodium and potassium nitrates, their uses and regulatory history. Section III discusses the human health and environmental assessments based on the data available to the Agency. Section IV discusses the reregistration decision for sodium and potassium nitrates and Section V discusses product reregistration. Additional details concerning the Agency's review of available data are available on request.

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EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St. S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION
ELIGIBILITY DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENTS

1. Chemical Name: Sodium Nitrate

CAS Number: 7631-99-4

Office of Pesticide Programs Chemical Code Number:
076103

Empirical Formula: NaNO_3

2. Chemical Name: Potassium Nitrate

CAS Number: 7757-79-1

Office of Pesticide Programs Chemical Code Number:
076104

Empirical Formula: KNO_3

B. USE PROFILE

Type of Pesticide: Rodenticide, predacide, insecticide

Pests Controlled: Moles, ground squirrels, prairie
dogs, ground-nesting wasps,
woodchucks, gophers, pocket
gophers and skunks.

Registered Use Groups: (See Appendix A for detailed
specific use sites).

For Sodium Nitrate:
Terrestrial Food/Feed
Terrestrial Feed
Terrestrial Non-food
Forestry
Residential Outdoor

For Potassium Nitrate:
Terrestrial Feed
Terrestrial Non-Food
Residential Outdoor

Formulation Types Registered:

For Sodium Nitrate: Ready-to-use cartridge formulated with sulfur and carbon; designed to be ignited and placed in pest burrow.

Sodium nitrate is used with other components as an active ingredient to control mammals such as woodchucks, ground squirrels, and coyotes in open fields, non-crop areas, rangelands, lawns and golf courses. The three end-use products, two containing 65% a.i. sodium nitrate and one with 46.2% sodium nitrate, are all used as fumigant gas cartridges designed to be placed in burrows. The sodium nitrate supports the combustion of charcoal in the formulation of each product. The label instructions for application state that the applicator should obtain enough material to plug the entrance of the burrow and then use a nail with at least a 1/8" diameter to puncture the cap at the end of the cartridge, where marked; insert the fuse, with a minimum of 3" exposed, in one of the center holes. The applicator then should ignite the fuse (holding cartridge away from face and body), and place it into the burrow and immediately close the burrow entrance. The minimum burn time for the fuse is 5 seconds.

For Potassium Nitrate: Ready-to-use cartridge formulated with sulfur and carbon; designed to be ignited and placed in pest burrow.

Potassium nitrate, an active ingredient in two registered end-use products (45% potassium nitrate and 46.2% potassium nitrate), is employed in the same manner as sodium nitrate with the following exceptions: the 45% formulation lists gardens as a site and the 46.2% formulation is used on ground wasps.

The smaller cartridges, containing either sodium or potassium nitrate, are approximately four inches in length and one inch in diameter and weigh 1-3 ounces. The larger cartridge, formulated with sodium nitrate, weighs 8.5 ounces and is approximately 12.5 inches long and 1.5 inches in diameter. They are designed to produce, upon combustion, large amounts various gases which act as toxicants to the pest inhabiting the burrow.

C. REGULATORY HISTORY

The first pyrotechnic cartridge products containing the active ingredients sodium and potassium nitrates were registered in 1948.

In the last thirty years, the Agency has received nine reports of injuries to applicators for registered gas cartridge products, including one fatality attributed to gross misuse. In 1982, in response to concern over the safety of these products, the Agency issued a Notice of Intent to Cancel (NOIC) all products unless registrants submitted upgraded labeling and data on fuse and cartridge burn times. Subsequent to compliance with the NOIC and labeling improvement program, there have been four reports of injuries, all involving misfiring of ignited cartridges. The Agency has contacted the two registrants of these particular products regarding these incidents to determine the cause of these accidents, and is including new data requirements which are intended to address the issue of quality control and product safety. These are contained in Appendix D.

III. AGENCY ASSESSMENT OF ACTIVE INGREDIENT

The Agency has conducted a review of the scientific data base for sodium and potassium nitrates, primarily relying on the studies and information from published literature submitted by registrants. These are cited in Appendices B and C, respectively. The findings are summarized below:

A. DESCRIPTION OF ACTIVE INGREDIENTS

Sodium nitrate, known also as cubic niter, Chile niter or soda niter, is a naturally occurring compound with a molecular weight of 85.00. It is a colorless, odorless solid forming transparent crystals, and is incorporated into the cartridges as a white powder. It has a melting point of 306°C and explodes when heated to 1000°F, producing toxic fumes of NO and Na₂O.

Potassium Nitrate, known also as saltpeter or niter, has similar properties when heated and is also a colorless, odorless compound incorporated as an oxidizer into the cartridge products. It has a molecular weight of 101.11 and a melting point of 334°C.

Both active ingredients have other industrial uses. Sodium nitrate is used in the production of other chemicals, glass, fertilizer and fireworks. Potassium nitrate also is used in the production of fireworks, blasting powders and gunpowder.

B. HUMAN HEALTH ASSESSMENT

The Agency has determined that only a minimal data set is necessary to assess the potential health hazards, exposures and risk for sodium and potassium nitrates and their registered uses. Both are common chemical compounds with very limited uses as pesticides.

Toxicology Data Base

The toxicological data base on the active ingredients potassium and sodium nitrate is adequate and will support reregistration eligibility.

A. Acute Toxicity

ACUTE TOXICITY VALUES FOR SODIUM NITRATE

<u>Test</u>	<u>Result (mg/kg)</u>	<u>Toxicity Category</u>
<u>Acute Oral LD50-Rat</u>	<u>3,700</u>	<u>III</u>
<u>Acute Dermal LD50-Rabbit</u>	<u><2,000</u>	<u>III</u>
<u>Primary Eye Irritation</u>	<u>Corneal Opacity reversible within 7 days; irritation</u>	<u>II</u>
<u>Primary Dermal Irritation</u>	<u>Mild or slight irritation at 72 hours</u>	<u>IV</u>

ACUTE TOXICITY VALUES FOR POTASSIUM NITRATE:

<u>Acute Oral LD50-Rat</u>	<u>3,750</u>	<u>III</u>
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(References 1, 2, 3, EPA 417860-01, EPA 417860-03)

Published data (4) estimate the minimum lethal dose of sodium nitrate in cattle to be 650-750 mg/kg and for potassium nitrate in sheep and cattle a lethal dose was 1,000 mg/kg.

Other published studies indicate values of 5,000 and >3,000 mg/kg for acute oral LD50 in rats and 2,680 mg/kg in rabbits for sodium nitrate. For potassium nitrate, other available studies indicate an acute oral toxicity in rats to be 4,300 mg/kg and 1,901 mg/kg for the acute oral LD50 in rabbits.

B. Subchronic Toxicity

No applicable studies are available.

C. Metabolism

It is believed that nitrate is converted in food or in the digestive system into nitrite. In large doses, nitrite converts the hemoglobin in the blood to methemoglobin, which cannot carry oxygen (4).

D. Chronic Toxicity

A 14-month study with male rats given 4000 ppm sodium nitrate in their drinking water indicated possible lower plasma vitamin E levels and higher red cell reduced glutathione than the control group (5).

Available information on the carcinogenic potential of nitrates is equivocal. The results of some studies suggest nitrates may cause tumors in laboratory animals, while others do not. (2, 8)

E. Mutagenicity

Both sodium nitrate and potassium nitrate are reported to cause mutagenic effects in various genetic toxicity tests (2, 6).

F. Other Toxicity Information

An epidemiology study conducted in Chile states that there is a significant association between the rate of nitrate fertilizer used per unit area of land and the mortality rates from gastric cancer in different provinces. This report hypothesized that carcinogenic nitrosamine was synthesized in the stomachs of humans from the nitrates and nitrites of the fertilizers (7).

1. Dietary Exposure

There are no pesticidal food uses for potassium or sodium nitrate. However, both are permitted, under 21 CFR, part 172, as food additives or preservatives. These

clearances include: curing premixes, with conditions against nitrosamine formation; potassium nitrate may be used as a curing agent on cod roe, not to exceed a final level of 200 ppm; sodium nitrate, at a level not to exceed 500 ppm in the finished product, as a color fixative in smoked, cured sablefish, salmon, or shad, and as a preservative and color fixative for home curing of meat and meat products. Also, 21 CFR Part 181 cites prior sanctions issued by the U.S. Department of Agriculture for the use of sodium and potassium nitrates in cured red meat products and cured poultry products.

Some of the products containing sodium and potassium nitrates are registered for use in rangeland and/or agricultural areas and are therefore classified by the Agency as food/feed uses. Due to the nature of their action, however, there is no reason to expect any contact with food or feed crops. Therefore, there is no likelihood of residues in or on food or feed crops and tolerances in or on agricultural commodities are not required.

3. Occupational Exposure

The Agency believes that any human exposure from the intended use of these products is limited to applicators. The Agency further believes that any such exposure is minimal for several reasons. As described above in section II.B., these products are cartridges, similar to flares, in which the ingredients are totally encased. Unlike many pesticide products, there is little opportunity for splashing, spillage, inhalation or dermal contact with spray or dust particles. Once ignited, these devices produce noxious gases which are directed into the pest burrow, which is sealed or covered. Inhalation exposure to the applicator should therefore be negligible. Incidents reported to the Agency in the past have largely involved dermal burns. The only fatality associated with these products has been attributed to gross misuse and inhalation of a smoke produced by a phosphorus-containing cartridge. This product is being reformulated and will no longer contain phosphorous. The Agency has received reports of dermal burns caused by ignited cartridges. These were largely due to improper handling of ignited cartridges or defective cartridges. The 1982 notice was intended to address these safety concerns. There have been four reports of injuries to applicators since then, due mainly to defective cartridges. The Agency is addressing the issue of defective cartridges in the attached data call in notice.

4. Human Risk Assessment

Risks associated with the registered uses of potassium and sodium nitrates are believed to be negligible. This is due to the limited exposure potential to humans, as described in the above section "Occupational Exposure."² Applicators of these products are largely protected from exposure to these chemicals by the product packaging. Further, the application method of these products precludes exposure to these chemicals. Once the cartridges are ignited, they are quickly placed in the burrow and covered, so that the gases are directed into the burrow. Improperly covered burrows could result in potential inhalation exposure to the gases, if the applicator remains in close proximity to the burrow. [To assess the toxicity of these gases, the Agency is requiring acute toxicity data, through this document, section V.B and Appendix D. Upon receipt of these data, the Agency will determine whether these products should be reregistered.] Registrants are also required, under section 6(a)(2) of FIFRA, to submit to the Agency any information regarding injuries to humans associated with the use of these products.

There are some studies which suggest possible carcinogenic effects for nitrate compounds. However, the Agency does not believe that this potential toxicological effect is relevant here because of the absence of chronic exposure.

In conclusion, at this time the Agency believes, based on data and information reviewed, that the pesticide active ingredients sodium and potassium nitrates, as registered for use in products covered by this document, do not present any unreasonable adverse effects to humans. After all of the product specific data has been reviewed, a final determination will be made.

C. ENVIRONMENTAL ASSESSMENT

The Agency has not required and does not intend to require any generic environmental fate or ecological effects data on the active ingredients sodium and potassium nitrates considering the registered product formulations and uses. All data requirements for these disciplines that are specified in 40 CFR Part 158 are waived. The rationale for this decision is presented below in the "Ecological Effects Assessment" and the "Environmental Fate Assessment."

²Available data on these two chemicals suggest moderate to low acute toxicity, as described in the above section Toxicology Data Base.

1. Ecological Effects Assessment

The intended purpose of products containing these active ingredients is to kill certain vertebrates and wasp pest species inhabiting burrows. Pest species are not exposed to sodium and potassium nitrates, but rather to the products of their pyrolysis. Application is subsurface and precludes exposure to avian populations and aquatic organisms. The Agency realizes, however, that any organism in a properly treated burrow will likely be killed and is concerned about potential impact to populations of non-target and endangered species.

The open literature indicates that several types of non-target organisms, including burrowing owls, may inhabit the burrows of target pests (9, 10). Due to the potential risk to non-target organisms, the Agency is currently developing more extensive labeling regarding timing of application and observation of signs indicating the presence or absence of target and non-target organisms. These instructions will be explicit concerning actions users must take before applying the product.

The use of these products may also result in a potential impact on endangered species which utilize burrows. Gas cartridges have been the subject of several formal and informal consultations with the U.S. Fish and Wildlife Service, and as a result, six endangered or threatened species that utilize burrows have been identified as being at risk. Current labeling detailed in Appendix A includes provisions to protect these species.

The Agency is currently in consultation with the U.S. Fish and Wildlife Service to re-evaluate the existing Biological Opinions, incorporate species newly identified as threatened or endangered and account for incidental take provisions³. A new Biological Opinion is expected in March 1992. After this Opinion is issued, any necessary changes in labeling will be identified and registrants will be required to revise their labels.

Registrants are reminded of their responsibility, under section 6(a)(2) of FIFRA, to submit any data

³Indicates the number of individual non-target species that are permitted to be harmed as a result of, or incidental to, the Agency's action.

regarding unreasonable adverse effects, including incidents involving non-target organisms, to the Agency. As more information becomes available regarding endangered and non-target species, the Agency may address this issue further.

2. Environmental Fate Assessment

Sodium and potassium nitrates are naturally occurring substances whose physical properties are well understood. It is the Agency's belief that the pyrolysis of these products results in simple organic and inorganic compounds, mostly in the form of gases, which eventually diffuse through burrow openings or into the soil. Exposure to the environment can be characterized as limited and localized rather than widespread or broadcast. Additionally, the Agency normally requires many of the environmental fate studies on pesticides in order to assist with its assessment of risk to living organisms. Given the Agency's ecological effects assessment, there is no need for such data. All environmental fate data requirements have therefore been waived.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required or waived the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing sodium or potassium nitrate as an active ingredient. The Agency has completed its review of these generic data and information from published literature, and has determined that the data are sufficient to support reregistration of products containing sodium or potassium nitrate. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of sodium and potassium nitrates, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B are sufficient to allow the Agency to conduct a reasonable risk assessment for the registered uses of sodium and potassium nitrates. The data available to the Agency support the belief that the registered uses of sodium and potassium nitrates will not result in unreasonable adverse effects to the environment.

particular products is addressed in section V of this document ("Product Reregistration").

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, various articles available in the public literature which are identified in Appendix C and the data identified in Appendix B. Although the Agency has found that products containing sodium and potassium nitrates are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support reregistration of products containing sodium or potassium nitrate, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing sodium nitrate has been reviewed and determined to be complete. The data base for potassium nitrate is substantially complete. The following generic data for potassium nitrate have not been submitted and are still required:

- o A copy of all available technical specifications, data sheets and other documents by which the manufacturer, producer or supplier describes the composition information.
- o A description of the recovering and refining process if any of the material is obtained from natural sources.
- o A discussion of the impurities present in technical potassium nitrate.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING SODIUM OR POTASSIUM NITRATE

No manufacturing-use products are registered.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredients, sodium and potassium nitrates, the

products containing them are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data when they have been submitted and/or cited and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are listed in Attachment D.

4 C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING SODIUM OR POTASSIUM NITRATE

The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

The Agency is currently developing detailed guidance on labeling for gas cartridge products which will further address concerns about applicator safety and potential impact to endangered and non-target organisms. This guidance will be sent to registrants prior to submission of labeling which is required eight months after issuance of this document. Registrants will be required to follow this guidance in revising their labels.

APPENDIX A

**USE PATTERNS SUBJECT TO REREGISTRATION
FOR
INORGANIC NITRATE/NITRITE
(SODIUM AND POTASSIUM NITRATES)**

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR CASE 4052: INORGANIC NITRATE/NITRITE

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (a)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
							Allowed	Disallowed	
active ingredient - POTASSIUM NITRATE									
FOOD/FEED USES									
RANGELAND (UNSPECIFIED)									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	5	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law
NONFOOD USES									
AGRICULTURAL UNCULTIVATED AREAS									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	not spec	not spec	none	none	use on woodchucks may be restricted by state law
GOLF COURSE TURF									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	5	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law
HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	5	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law
NONAGRICULTURAL UNCULTIVATED AREAS									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	not spec	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law
ORNAMENTAL LAWNS AND TURF									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0217 lb a/cartridge ¹	not spec	not spec	5	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (a)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
							Allowed	Disallowed	
active ingredient - SODIUM NITRATE									
FOOD/FEED USES									
AGRICULTURAL CROPS (UNSPECIFIED) (CROPLAND) Fumigation, When needed, Hand placed cartridge									
	IMPR	0.3439 lb a/cartridge ¹	not spec	not spec	not spec	not spec	not spec	none	none
RANGELAND (UNSPECIFIED) Fumigation, When needed, Hand placed cartridge									
	IMPR	0.3439 lb a/cartridge ¹	not spec	not spec	not spec	not spec	not spec	none	none
NONFOOD USES									
AGRICULTURAL UNCULTIVATED AREAS Fumigation, When needed, Hand placed cartridge									
	IMPR	0.3439 lb a/cartridge ¹	not spec	not spec	not spec	not spec	not spec	none	none
FOREST PLANTINGS (REFORESTATION PROGRAMS) Fumigation, When needed, Hand placed cartridge									
	IMPR	.0813 lb a/cartridge ¹	not spec	not spec	not spec	not spec	not spec	none	none
GOLF COURSE TURF Fumigation, When needed, Hand placed cartridge									
	IMPR	.0813 lb a/cartridge ¹	not spec	not spec	not spec	not spec	not spec	none	none

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (a)	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
							Allowed	Disallowed	
NONAGRICULTURAL UNCULTIVATED AREAS									
Fumigation, When needed, Hand placed cartridge	IMPR	0.3439 lb a/cartridge ¹	not spec	not spec	not spec	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law; do not treat if nontarget species present in pest burrows
ORNAMENTAL LAWNS AND TURF									
Fumigation, When needed, Hand placed cartridge	IMPR	.0813 lb a/cartridge ¹	not spec	not spec	not spec	not spec	none	none	endangered species restrictions; use in burrows only, not inside buildings; use on woodchucks may be restricted by state law; do not treat if nontarget species present in pest burrows

Abbreviations used

Header: max. = maximum; min. = minimum; apps. = applications; not spec. = not specified

Form: IMPR = impregnated material

Rate: a = active ingredient

Footnotes

1. Number of cartridges used per burrow varies with size of animal and burrow.

APPENDIX B

**Generic Data Requirements for Reregistration
of Sodium and Potassium Nitrates and Data Citations
Supporting Reregistration**

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix B contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to the following format:

1. Data Requirements (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. The following letter designations are used for use patterns:

- A Terrestrial food
- B Terrestrial feed
- C Terrestrial non-food
- J Forestry
- K Residential

Any other designations will be defined in a footnote to the table.

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF SODIUM NITRATE
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
<u>Product Chemistry</u>			
61-1	Product Identity	ABCJK	417600-01
61-2(a)	Begin. Mat. and Mfg.Process	ABCJK	417600-02
61-2(b)	Discussion of Impurities	ABCJK	417600-03
62-1	Preliminary Analysis	ABCJK	417600-04
62-3	Analytical Method	ABCJK	417600-06 417931-01
63-2	Color	ABCJK	417600-07
63-3	Physical State	ABCJK	417600-08
63-4	Odor	ABCJK	417600-09
63-5	Melting Point	ABCJK	417600-10
63-7	Density	ABCJK	417600-11
63-8	Solubility	ABCJK	417600-12

63-10	Dissociation Constant	ABCJK	417600-13
63-12	pH	ABCJK	417600-14
63-13	Stability	ABCJK	417600-15

Ecological Effects:

EPA waived all of these guideline as discussed in section C.1.

Toxicology

81-1	Acute oral tox - rat	ABCJK	417860-01
81-2	Acute dermal tox - rabbit	ABCJK	417860-02
81-4	Primary eye irritation - rabbit	ABCJK	417860-04
81-5	Primary dermal irritation - rabbit	ABCJK	417860-03

Environmental Fate:

EPA waived all of these guideline requirements as discussed in section C.2.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF POTASSIUM NITRATE
AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
<hr/> <u>Product Chemistry</u>			
61-1	Product Identity	ABCK	417667-01
61-2a	Begin. Mat. and Mfg Process	ABCK	DATA GAP
61-2b	Discussion of Impurities	ABCK	DATA GAP
62-1	Preliminary Analysis	ABCK	DATA GAP
62-2	Certification of Limits	ABCK	WAIVED
62-3	Analytical Method	ABCK	WAIVED
63-2	Color	ABCK	417667-01
63-3	Physical State	ABCK	417667-01
63-4	Odor	ABCK	417667-01
63-5	Melting Point	ABCK	417667-01
63-6	Boiling Point	ABCK	WAIVED
63-7	Density	ABCK	417667-01

63-8	Solubility	ABCK	417667-01
63-10	Dissociation Constant	ABCK	WAIVED
63-11	Oct/Water Partition Coef.	ABCK	WAIVED
63-12	pH	ABCK	WAIVED
63-13	Stability	ABCK	417667-01

Ecological Effects:

EPA waived all of these guideline requirements as discussed in section C.1.

Toxicology

81-1	Acute oral tox - rat	ABCK	WAIVED
81-2	Acute dermal tox - rabbit	ABCK	WAIVED
81-3	Acute Inhalation - rat	ABCK	WAIVED
81-4	Primary eye irritation - rabbit	ABCK	WAIVED

Environmental Fate:

EPA waived all of these guideline requirements as discussed in section C.2.

APPENDIX C

SODIUM AND POTASSIUM NITRATES BIBLIOGRAPHY

**Citations Considered to be Part of the
Data Base Supporting Reregistration**

GUIDE TO APPENDIX C

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or MRID number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as

author. As a last resort, the Agency has shown the first submitter as author.

- b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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<p>EPA is directed by the Federal Insecticide, Fungicide, and Rodenticide Act as amended in 1988 (FIFRA '88) to review all pesticide products containing active ingredients initially registered before November 1, 1984, and to reregister those products that have a substantially complete data base and do not pose unreasonable adverse effects to people or the environment. This pesticide reregistration program is to be completed by the late 1990's.</p> <p>The Reregistration Eligibility Document (or RED) discusses the scientific data and other information supporting EPA's regulatory conclusion that products containing a pesticide do not pose unreasonable risks when used as directed by Agency-approved labeling, and are eligible for reregistration.</p>			
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