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EPA

Reregistration Eligibility Document (RED)

Carbon and Carbon Dioxide

Carbon and Carbon Dioxide Reregistration Eligibility Team

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GLOSSARY OF TERMS AND ABBREVIATIONS

CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
EPA	U.S. Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
LEL	Lowest Effect Level
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the EPA.
MSHA	Mine Safety and Health Administration
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PEL	OSHA Permissible Exposure Level
ppm	Parts per Million
RED	Reregistration Eligibility Document
STEL	OSHA Short-term Exposure Level

Executive Summary

This Reregistration Eligibility Document addresses both elemental carbon and carbon dioxide. The first registered pesticide product containing carbon dates from 1948. Currently, all six products containing carbon as an active ingredient are registered for use as a rodenticide and predacide. These products are formulated as pyrotechnic cartridges which are designed to be ignited and placed in burrows inhabited by target animals. Gaseous pyrolysis products cause asphyxiation of animals in the burrow. Four products containing pressurized carbon dioxide as an active ingredient are presently registered for fumigation to control insects and rodents in enclosed areas.

The Environmental Protection Agency (EPA) has conducted a review of the scientific data base and other relevant information supporting the reregistration of carbon and carbon dioxide and has determined that the data base is sufficient to allow the EPA to conduct reasonable risk assessments. The data available to the EPA support the conclusion that the currently registered uses of carbon and carbon dioxide will not result in unreasonable effects to the environment or human health. No further generic data are required.

Carbon is used only for non-food uses so no tolerance under the FFDCA is required. Carbon dioxide is exempt from the requirement of a tolerance (40 CFR 180.1049). Also, carbon dioxide is classified as Generally Recognized As Safe (GRAS) (21 CFR 184.1240).

Accordingly, the EPA has determined that all products containing carbon or carbon dioxide as the active ingredient 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. Before reregistering each product, the EPA is requiring that product specific data and revised labeling be submitted by the registrants within eight months of the issuance of this document. EPA has "batched" products considered to be similar with respect to acute toxicity testing requirements. After reviewing these data and the revised labels, the EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product composition and labeling are acceptable and the product's uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met EPA will reregister the products. Any end-use products containing carbon or carbon dioxide in combination with other active ingredients will not be registered until EPA has determined that those other active ingredients are 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 EPA") 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, under section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action" under FIFRA section 5(g)(2)(C) and (D), respectively. Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the 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 EPA's decision regarding the reregistration eligibility of the active ingredients carbon and carbon dioxide. The document consists of five sections. Section I is this introduction. Section II describes carbon and carbon dioxide, their uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the EPA. Section IV discusses the reregistration eligibility decision for carbon and carbon dioxide and Section V discusses product reregistration requirements. Additional details concerning the review of available data are available on request.[1]

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[1] 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: Carbon

CAS Number: 7440-44-0

Office of Pesticide Programs Chemical Code Number: 16001

Empirical Formula: C

2. Chemical Name: Carbon dioxide

CAS Number: 124-38-9

Office of Pesticide Programs Chemical Code Number: 16601

Empirical Formula: CO_2

B. USE PROFILE

Carbon:

Type of Pesticide: Rodenticide/Predacide, Insecticide when used in combination with sodium or potassium nitrates.

Pests Controlled: Pocket gophers, moles, ground squirrels, rats, skunks, woodchucks, red foxes, coyotes, prairie dogs, and ground wasps.

Registered Use Groups: (See Appendix A for detailed specific use sites)
Terrestrial Food Crop
Terrestrial Feed Crop
Terrestrial Non-Food Crop
Forestry
Residential Outdoor

Formulation Types Registered:

Ready to use cartridge-type bomb formulated with other active ingredients. Designed to be ignited and placed in pest burrow. Combustion produces pyrolysis compounds which are toxic when inhaled by the pests inhabiting the burrow. The smaller cartridges (0.75 to

3.0 ounces) measure approximately four inches in length and one inch in diameter. The larger cartridge (8.5 ounces) measures 12.5 inches in length and 1.5 inches in diameter.

Methods of Application:

Use one cartridge per burrow system;
for larger animals, use more than one cartridge.
Puncture cap at the end of cartridge at points marked.
Insert fuse in one of the center holes. Hold cartridge away from face and body, then light. Immediately place lit cartridge inside and seal entrance to burrow.

Carbon Dioxide:

Type of Pesticide: Insecticide.

Pests Controlled: Insects

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

Indoor Food

Formulation Types Registered: Pressurized liquid: 99.95% to 100% active ingredient; pressurized gas: 99 to 99.9% active ingredient; aerosol spray: the registrant of this product has recently notified EPA of their intent not to support the reregistration of carbon dioxide for this particular use. EPA is not considering this use of carbon dioxide for reregistration.

Methods of Application:

Seal area to be fumigated. Adjust atmosphere in this area to 60% carbon dioxide and maintain for four or five days. Following fumigation, ventilate with monitoring to assure area is safe for reentry.

C. REGULATORY HISTORY

Carbon: The first pyrotechnic cartridge products containing the active ingredient carbon was registered in 1948.

In the last thirty years, the EPA has received nine reports of injuries related to use of cartridges, including one fatality attributed to gross misuse. In 1982, in response to concern over safety of these

products, the EPA issued a Notice of Intent to Cancel (NOIC) all products unless registrants submitted upgraded labeling and data on the burning characteristics of cartridges. Subsequent to compliance with the NOIC and labeling improvement program, there have been four reports of injuries, all involving misfiring of ignited cartridges. The EPA has contacted the two registrants of these particular products regarding these incidents.

Carbon dioxide: EPA first registered a carbon dioxide containing product, a pressurized gas product in 1981. Carbon dioxide was formulated with other active ingredients as an aerosol spray. This spray was used to control insects such as wasps. The registrant of this product has recently notified EPA of their intent not to support the reregistration of carbon dioxide for this particular use. The first product containing carbon dioxide for use as a fumigant was registered in 1982. The product is used as an insecticide and miticide in stored grain. In 1980 EPA exempted carbon dioxide from tolerances in or on raw agricultural commodities (40 CFR 180.1049). Carbon dioxide does not accumulate in treated raw agricultural commodities but rather diffuses into the atmosphere following application. Therefore, no residues of carbon dioxide are found in or on raw agricultural commodities. In 1981, EPA established a food additive regulation for carbon dioxide in or on all processed agricultural commodities when used post-harvest (40 CFR 185.650).

III. EPA ASSESSMENT OF ACTIVE INGREDIENT

The EPA has reviewed the scientific data base for carbon and carbon dioxide consisting of published literature studies cited in the Bibliography in Appendix C. The findings are summarized below:

A. DESCRIPTION OF ACTIVE INGREDIENT AND ASSESSMENT OF PRODUCT CHEMISTRY

Carbon

Carbon is a nonmetallic element with an atomic weight of 12.01. Pure carbon is found in three forms: amorphous black powder; black crystals known as graphite and the usually colorless diamond crystal. Carbon is found in many inorganic and all organic compounds. It is the principal component in charcoal, coal, and soot. The melting point for carbon ranges from 3652-3697°C. The dust may explode when exposed to

heat or flame or various chemical components including nitrates, oxides, peroxides, and halogens (9).

Carbon, in the form of charcoal or sawdust, is used as a pesticide in combination with nitrates and sulfur in gas cartridges. These cartridges are used in burrows to kill coyotes, woodchucks, ground squirrels, prairie dogs, and pocket gophers and ground wasps. No data are required concerning generic product chemistry.

Carbon dioxide

Carbon dioxide is a colorless, odorless, noncombustible gas. Its molecular weight is 44.01. Solid carbon dioxide is known as dry ice and the sublimation temperature at atmospheric pressure is -74.5°C. The solubility of CO_2 in water is 0.14 g/100 g water; it is less soluble in organic solvents. The specific gravity relative to air at 24°C is 1.53. When added to alkaline solutions carbonates are formed (6).

Carbon dioxide is a naturally occurring gas found in the atmosphere which is required for plant and animal life. It is a product of animal metabolism and is essential for plant and animal respiration (6). It was first identified by Joseph Priestley about two hundred years ago and has been extensively studied since then.

Carbon dioxide is used for a wide variety of non-pesticide applications. Probably the best known use is for the carbonation of beverages. It may also be used in refrigeration, fire fighting, welding operations, rubber tumbling, mining operations, and oil well secondary recovery. Medical applications include use as a coma-inducing agent in psychiatric treatment and as a constituent of therapeutic oxygen.

Carbon dioxide is used as a pesticide for insect control in stored grain under modified atmospheres containing approximately 60% carbon dioxide.

B. HUMAN HEALTH ASSESSMENT

Carbon

1. Toxicology - Data Base

The toxicological data on carbon available in the open literature are adequate for assessing risk to humans. Carbon is a natural component of all organic chemicals and all living organisms. One form of carbon, activated charcoal, is given orally as an adsorbent for treatment of accidental drug poisoning

(4). Carbon, in the form of carbon black, is cleared by the Food and Drug Administration, for use in resinous and polymeric coatings as food-contact surfaces (21 CFR 175.300). It is also listed for use in paper and paperboard and polymers in contact with food.

The functional pesticidal active ingredients in animal control cartridges are the pyrolysis products of the carbon and other components of the formulation. The toxic properties of the carbon bear no relationship to the toxicity of the active compounds.

2. Occupational and Residential Exposure

Based upon available use data for carbon end-use products (016001), gaseous pyrolysis products are generated by oxidation of carbonaceous materials within flare-like containers for the purpose of controlling small mammals and coyotes in burrows and dens. When properly used for pest control in animal dens and burrows, the fuse of the flare is ignited, the flare is placed within the burrow within seconds after ignition, and the opening is immediately sealed with nonflammable material such as soil to prevent dissipation of combustion products. Based upon reported incidents, the primary hazard posed is dermal burns following premature flare ignition. With respect to inhalation and dermal exposure, gas cartridges should pose very low exposure hazards to humans.

3. Risk Assessment

The toxicity data usually necessary for pesticide registration are not required for this use of carbon. There are some factors unique to this case which indicate that specific studies to fulfill the usual data requirements are not necessary to regulate this substance as a pesticide. Carbon is a basic component of all organic chemicals and all living organisms, and is truly ubiquitous. Human exposure is expected to be negligible for carbon when it is used as one component in gas-producing cartridges placed in animal burrows. Ignited cartridges are to be quickly placed into burrows which are then covered to entrap the generated fumes. Improperly covered burrows could result in inhalation exposure to the fumes if the applicator remains in close proximity to the burrow.

CARBON DIOXIDE

1. Toxicology

All toxicology data requirements are satisfied. No further data are required by EPA. A number of studies have been conducted with carbon dioxide, but in most instances the purposes

of these studies were not to determine the major endpoints of toxicity by using the protocols recommended in EPA guidelines for evaluating these effects. However, there is a substantial volume of information on carbon dioxide in the literature which covers major biological considerations.

a. Acute Toxicity

EPA has a number of adequate acute toxicological studies on carbon dioxide. All the available acute studies use the inhalation route of administration. In one study (3) dogs were given 30 percent carbon dioxide for 2 hours, then 40 percent carbon dioxide, and then abruptly returned to normal air. Eleven dogs died within 10 minutes with ventricular fibrillation. Four survived with cardiac arrhythmias, and two had no cardiac symptoms (3).

In a second study rats exposed to an atmosphere containing 50 percent carbon dioxide died within 6 hours. Rats exposed to 25 percent died within 36 hours. Deaths were a result of pulmonary injury. Atmospheres as low as 20 percent carbon dioxide caused cerebral depression. All rats exposed to 10 percent carbon dioxide survived (3).

In a third experiment, rats were exposed to 20 percent carbon dioxide for 2 hours followed by increasing concentrations up to 43 percent. The animals died in 2.5 to 19.3 hours and showed severe brain and spinal cord damage in proportion to the exposure (3).

The first effect of human inhalation of excessive carbon dioxide occurs at concentrations of about 2 percent (20,000 ppm) when the breathing becomes deeper and the tidal volume is increased. At 4 percent the depth of respiration is markedly increased and at 4.5-5 percent breathing becomes labored and, for some individuals, distressing (2). Human inhalation of 8-10 percent concentrations for periods up to 1 hour showed no evident harmful effects (2). Other effects of increased carbon dioxide levels are increased heart rate, headache, sweating, shortness of breath, dizziness, shaking, convulsions, and unconsciousness (5). Deaths from accidental exposure to extremely high levels of carbon dioxide have been reported, but generally analyses of the atmospheres for carbon dioxide concentration or the possible presence of other deleterious gases have not been performed (3).

b. Subchronic Toxicity

Subchronic exposure of laboratory animal species to various concentrations of carbon dioxide have resulted in different effects. Guinea pigs exposed to 15 percent carbon dioxide for 7 days lost weight at first but later returned to normal weight. They also had higher blood corticosteroids, lower adrenal

epinephrine, decreased adrenal cholesterol, higher arterial free fatty acids, and decreased lymphocytes in the first 3 days of exposure (3).

Rats exposed to 10 percent carbon dioxide for 30 days had a weight loss of 14-27 percent; those exposed to 20-25 percent for 34 days had a 50 percent loss. The weight losses were attributed to the reduced food intake. The weight was regained when the rats returned to a normal atmosphere (3).

No effects were seen in male rhesus monkeys that spent 93 days in an atmosphere with 3 percent carbon dioxide (3).

c. Human Chronic Toxicity

A study on brewery workers suggests that there are no significant physiological effects from chronic intermittent exposures to carbon dioxide concentrations at about 1.08 percent (time-weighted-average) (3).

d. Other Chronic Toxicological Effects

Some deleterious effects were found when animals were given concentrated doses of carbon dioxide higher than the levels normally breathed in air. Deleterious effects on sperm of various animal species have been reported (3) following exposure to high carbon dioxide atmospheres. Also, when pregnant rats were exposed to 6 percent carbon dioxide for one full day, 23.4 percent of the offspring had cardiac abnormalities, and there was also an increased incidence of skeletal malformations (10.9 percent) (3). Vertebral column malformations were reported in rabbits when the pregnant dams were exposed to 10-13 percent carbon dioxide (3).

Pregnant guinea pigs exposed to 0.48 percent carbon dioxide for 10 minutes daily for 20 days had a high number of miscarriages and flaccid paralysis of the hind limbs in the pups carried to term. Another group exposed to 0.42 percent carbon dioxide for 1 hour daily for 30 days had no miscarriages, but many of the offspring were microsomic and many of these had neuromuscular defects of the hind limbs (3).

e. Metabolism

Carbon dioxide is produced by the body's metabolism and is always present in the body at about 6 percent concentration. An average adult human will produce more than 500 g of carbon dioxide daily under resting conditions, and will produce much more when active.

Additional carbon dioxide has several effects on the body, and responses are immediate. It stimulates breathing, which exhales the carbon dioxide carried to the lungs from the cells by the blood-stream. An increase in carbon dioxide concentration stimulates the heart rate, increases the blood pressure, increases adrenalin flow, and relaxes the vascular smooth muscles. In addition, carbon dioxide reacts with water in the body to form carbonic acid, which dissociates to hydrogen ion and bicarbonate. An increase in carbon dioxide in the body increases acidity, and then the kidneys act to restore normal acidity.

Studies on men exposed to 1.5 percent carbon dioxide in the atmosphere for 42 days showed uncompensated respiratory acidosis during the first 23 days. After this there was a compensatory phase during the rest of the exposure period (3).

2. Dietary Exposure

Carbon dioxide is exempt from the requirement of a tolerance when used post-harvest in modified atmospheres for stored insect control on raw agricultural commodities as listed in 40 CFR 180.1049. Carbon dioxide may be used as a food additive post-harvest in modified atmospheres for stored product insect control on all processed agricultural commodities as described in 40 CFR 185.650.

In 21 CFR 184.1240 carbon dioxide is listed as a substance Generally Recognized As Safe (GRAS) for use in food. Carbon dioxide has been consumed in naturally carbonated or "mineral" water for centuries, and in manufactured carbonated beverages for many years. Thus, humans naturally have continual exposure to carbon dioxide without any indications of toxic effects from such ordinary exposures to carbon dioxide. Furthermore, since carbon dioxide is a normal constituent of the atmosphere at about 0.03 percent (300 ppm), there is continuous human exposure by inhalation and on the skin.

3. Occupational and Residential Exposure

Indoor use of carbon dioxide end-use products as a fumigant for postharvest treatment of raw and processed food commodities and cargo areas poses potential exposure risks for workers. Primary exposure hazards are associated with worker reentry into confined/enclosed spaces. Carbon dioxide gas may collect and be present in significantly higher concentrations in poorly ventilated depressions in grain bins, shafts, etc. and sites where recirculation of air is minimal. Studies of workers exposed to high levels of carbon dioxide in other industries indicate that confirmatory air monitoring is essential in confined spaces. Even with ventilation systems present to purge areas of excess carbon dioxide, some system design may be inadequate to reduce levels to the OSHA permissible exposure

level (PEL) of 10,000 ppm. Ventilation systems need to be periodically tested to determine system adequacy.

Product labels must recommend air monitoring while treated areas are being ventilated to reduce ambient levels of carbon dioxide. This monitoring will permit determination of post-application inhalation exposure levels at indoor use sites. During and following ventilation activities, short-term reentry of more than 15 minutes into treated areas may not occur prior to carbon dioxide levels falling below the OSHA short-term exposure limit, STEL = 30,000 ppm, within the breathing zone for workers. Monitoring shall also be required for the lowest work areas within enclosed/confined spaces.

4. Human Risk Assessment

There are many factors unique to carbon dioxide which suggest that specific studies to fulfill the usual data requirements for pesticide registration are not necessary in order for EPA to regulate this substance as a pesticide. As discussed above there are many natural exposures to carbon dioxide from normal respiratory and metabolic processes, inhalation of normal ambient carbon dioxide, and consumption of carbonated beverages and other foods. In moderate increases of carbon dioxide exposure, the human body has rapid compensatory mechanisms to restore the normal balances through increased respiration to exhale it and restoration of normal acidity by the kidneys (8). Humans ordinarily consume carbon dioxide in foods and beverages daily.

Serious teratological effects from acute exposure to atmospheres containing more than 10% carbon dioxide have been reported in toxicological studies. However, such atmospheres are not likely to be encountered by applicators using this product in accordance with the label.

The only risk from pesticide usage is to workers who enter fumigated enclosures which have not received sufficient aeration. However, the EPA believes that this risk is low if proper product application and area ventilation are made.

C. ENVIRONMENTAL ASSESSMENT

EPA has not required and does not intend to require any generic environmental fate or ecological effects data on the active ingredient carbon considering the registered product formulations and uses. All data requirements for these disciplines that are specified in 40 CFR section 158 are waived. The rationale for this decision is presented below in the "Environmental Risk Assessment."

1. Environmental Fate Assessment

Carbon: The physical and chemical properties of carbon, a naturally occurring substance, are well understood. The pyrolysis of carbon in the presence of the other active ingredients such as sodium and potassium nitrates results in simple organic and inorganic compounds, mostly in the form of gases, which cause asphyxiation of pests in burrows. These pyrolysis products eventually diffuse through the burrow opening or into soil. Exposure to the environment can be characterized as limited and localized rather than widespread or broadcast. EPA normally requires many of the environmental fate studies on pesticides in order to assist with its assessment of risk to living organisms. Given EPA's ecological effects assessment, there is no need for such data. Therefore, all environmental fate data requirements have been waived.

Carbon dioxide: Carbon dioxide is also a naturally occurring substance whose physical and chemical properties are well understood. Carbon dioxide is used indoors as a fumigant to asphyxiate insects. Since carbon dioxide is used indoors, EPA believes its use will not adversely effect the environment. Therefore, all environmental fate data requirements have been waived.

2. Ecological Effects Assessment

Carbon: The gas cartridges are intended for control of woodchucks, ground squirrels, prairie dogs, pocket gophers, moles, red foxes, coyotes, and ground wasps. Carbon is formulated with other active ingredients, sodium or potassium nitrates and sulfur, during manufacture of the gas cartridges. Pest species are not exposed to carbon or to the other active ingredients, but rather to the products of their pyrolysis.

Carbon dioxide: Carbon dioxide is used as a gas fumigant for control of insects in raw and processed agricultural commodities in storage bins, trucks, trailers, and on ships. The products generally contain over 99% carbon dioxide.

Since this is an indoor use pattern, exposure to nontarget organisms is not expected. Therefore, no generic ecological effects data have been required or are being required.

4. Environmental Risk Assessment

Carbon: Application of the gas cartridges is subsurface, to burrows, and precludes exposure to avian populations and aquatic organisms. EPA realizes, however, that any organism in a properly treated burrow will likely be killed, and that there is a potential impact on endangered species which use burrows. Gas cartridges have been the subject of several formal and informal consultations with the US Fish and Wildlife Service (USFWS), which has identified six endangered or threatened species that use burrows have been identified as being at risk. Current labeling detailed in Appendix A includes provisions to protect these species.

The open literature indicates that several non-target organisms, including burrowing owls, may inhabit the burrows of target pests (10, 11). Due to the potential risk to non-target organisms, the EPA 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. The EPA is currently consulting with the USFWS to re-evaluate the existing Biological Opinions, incorporate species newly identified as threatened or endangered, and account for incidental take provisions[2]. EPA will inform affected registrants of any changes needed in their gas cartridge labeling at that time.

Registrants are reminded of their responsibility, under section 6(a)(2) of FIFRA, to submit any data regarding unreasonable adverse effects, including incidents involving non-target organisms, to EPA. As more information becomes available regarding endangered and non-target species, the EPA may need to address this issue further.

Carbon dioxide: Since use of carbon dioxide as a fumigant is an indoor use pattern, exposure to nontarget organisms is not expected. Therefore, no

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[2] Indicates the number of individuals that are permitted to be harmed as a result of, or incidental to, the EPA's action.

generic ecological effects data have been required or are being required.

IV. REREGISTRATION DECISION FOR ACTIVE INGREDIENT

A. DETERMINATION OF ELIGIBILITY

Section 4(g)(2)(A) of FIFRA requires EPA to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The EPA has previously identified and required submission of generic (i.e., active ingredient specific) data required to support reregistration of products containing carbon and carbon dioxide as an active ingredients. EPA has also consulted and relied upon published literature as a source for technical information. EPA has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of products containing carbon and carbon dioxide. Appendix B identifies generic data requirements that EPA reviewed as part of its determination of reregistration eligibility of carbon and carbon dioxide, and lists the submitted studies that EPA found acceptable.

The data identified in Appendix B as well as information from the open literature are sufficient to allow the EPA to conduct a risk assessment for the registered uses of carbon and carbon dioxide. The data available to the EPA support the conclusion that the registered uses of carbon and carbon dioxide will not result in unreasonable adverse effects to the environment. The EPA has determined that all products containing carbon or carbon dioxide as the active ingredient are eligible for reregistration. The reregistration of particular products is addressed in section V of this document ("Product Reregistration").

The EPA 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, and the data identified in Appendix B. Although the EPA has found that products containing carbon and carbon dioxide are eligible for reregistration, it should be understood that the EPA may take appropriate regulatory action, and/or require the submission of additional data to support reregistration of products containing carbon or carbon dioxide, if new information comes to the EPA'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 bases supporting the reregistration of products containing carbon and fumigation products containing carbon dioxide have been reviewed and determined to be complete for reregistration. Carbon dioxide is currently registered as an active ingredient in two aerosol spray products used for the control of insects such as wasps. One product is currently listed for cancellation due to non-payment of 1991 maintenance fees. The registrant of the remaining product has recently notified EPA of their intent not to support the reregistration of carbon dioxide for this particular use. EPA is not considering this use of carbon dioxide for reregistration. No further generic data are required.

C. LABELING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CARBON OR CARBON DIOXIDE

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. Any product label which allows both manufacturing and end use must be amended to specify either manufacturing or end use, not both. No product may bear both manufacturing and end use labeling. In this situation, if a registrant amends the label to specify manufacturing use only and wishes to retain end use registration, he/she must apply for a separate end-use product registration.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredients, carbon and carbon dioxide, the products containing this active ingredient are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the EPA to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The EPA 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 stated in Attachment C.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING THE ACTIVE INGREDIENT CARBON

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. Any product label which allows both manufacturing and end use must be amended to specify only manufacturing or end use. In this situation, if a registrant amends the label to specify manufacturing use only and wishes to retain end use registration, he/she must apply for a separate end-use product registration.

The EPA 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.

D. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING CARBON DIOXIDE

1. Any product label which allows both manufacturing and end use must be amended to specify only manufacturing or end use. In this situation, if a registrant amends his label to specify end-use registration and wishes to retain manufacturing use registration, he must apply for a separate manufacturing use product registration.

2. Required Human Hazard Precautionary Statements:

a) "After fumigation, aerate treated areas until the level of CO_2 as measured by [the registrant must identify one or more direct-reading detection devices suitable for use with the product and provide or reference instructions on its use], is below 10,000 ppm."

b) "Short term entry into the treated area is permitted when measured CO_2 levels are between 10,000 and 15,000 ppm; respiratory protection [registrant must specify a self-contained breathing apparatus (SCBA) or combination air-supplied/SCBA respirator approved by the National Institute for Occupational Safety and Health

(NIOSH) and the Mine Safety and Health Administration (MSHA)] must be worn if 15 or more minutes are spent in the treated area."

c) "If measured CO_2 levels exceed 15,000 ppm, no person shall enter the treated areas without a respiratory protection device [registrant must specify either a NIOSH/MSHA approved self-contained breathing apparatus (SCBA) or combination air-supplied SCBA respirator]."

2. Spill and Leak Procedure Statement

"Evacuate immediate area of leak. Use SCBA or combination air-supplied/SCBA respirator for entry into affected area to correct problem. Move leaking of damaged cylinders outdoors or to an isolated location, observing strict safety precautions. When completely empty, return to manufacturer if instructed or dispose of leaking or damaged cylinders or containers in accordance with State and Local waste disposal regulations."

"Do not permit entry into spill area by unprotected persons until concentration of carbon dioxide is determined to be less than 10,000 ppm."

4. Placarding Statement

The applicator must placard or post all entrances to the fumigated area with signs conforming to the following requirements:

a) The sign shall be at least 14 inches by 16 inches in size and the letters shall be at least 1 inch in height unless a smaller size sign is necessary because the treated area is too small to accommodate a sign of this size. Letters shall be clearly legible.

b) The signal word: "DANGER/PELIGRO" and the skull and crossbones symbol must be on the placard.

c) The statement, "Area under fumigation, DO NOT ENTER/NO ENTRE."

d) The date of fumigation.

e) The name of the fumigant (carbon dioxide).

f) Name, address and telephone number of the applicator or pesticide handler.

These signs must be posted at eye level and must be visible from all visible points of entry to the treated area. They must remain posted during application and throughout the restricted-entry interval until the concentration of carbon dioxide is below 10,000 ppm. Each separate treated area (i.e., boxcar, silo, ship container) must be posted or placarded with this sign.

The applicator or person responsible for monitoring levels of carbon dioxide may remove the placard when the concentration of carbon dioxide is at or below 10,000 ppm.

5. Precautionary Statements for End-Use Products Intended for Structural, Transportation, Space or Commodity Fumigation.

In addition to the placarding directions specified under Section 4 above, the following statements must appear on all end-use products intended for structural, transportation, space or commodity fumigation:

> "All persons working with this product should be knowledgeable of the hazards of this chemical, and trained in the use of required respirator equipment and detector devices, emergency procedures and use of the product. When used for fumigation of enclosed spaces, [boxcars, silos, ship containers, and other transport vehicles], two persons familiar with the use of this product must be present during introduction of the fumigant, initiation of aeration, and after aeration when testing for reentry. Two persons do not need to be present if monitoring is conducted remotely (outside of area being fumigated)."

6. Required Storage and Handling Statements

"Store in dry, cool, well-ventilated area under lock and key. Post as a pesticide storage area. Do not contaminate water, food or feed by storage."

"Store cylinders upright, secured to a rack or wall to prevent tipping. Cylinders should not be subjected to rough handling or mechanical shock such as dropping, bumping, dragging or sliding. Do not use rope slings, hooks, tongs or similar devices to unload cylinders. Transport cylinders

using hand truck or fork truck to which the cylinder can be firmly secured."

"Do not remove valve protection bonnet and safety cap until immediately before use. Replace safety cap and valve protection bonnet when cylinder is not in use."

"When cylinder is empty, close valve, screw safety cap onto valve outlet and replace protection bonnet before returning to shipper. Only the registrant is authorized to refill cylinders. Do not use cylinders for any other purpose. Follow registrant's instruction for return of empty or partially empty cylinders."

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION FOR CARBON AND CARBON DIOXIDE

APPENDIX A: USE PATTERNS SUBJECT TO REREGISTRATION FOR CASE 4019: CARBON AND CO2

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (al)	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 = **CARBON**									
FOOD/FEED USES									
AGRICULTURAL CROPS (UNSPECIFIED)(CROPLAND)									
Fumigation, When needed, Hand placed cartridge	IMPR	0.1852 lb al/cartridge [1]	not spec	not spec	not spec	not spec	none	none	endangered species restrictions;do not use inside buildings
RANGELAND (UNSPECIFIED)									
Fumigation, When needed, Hand placed cartridge	IMPR	0.1852 lb al/cartridge [1]	not spec	not spec	5	not spec	none	none	endangered species restrictions;do not use inside buildings
NONFOOD USES									
AGRICULTURAL UNCULTIVATED AREAS									
Fumigation, When needed, Hand placed cartridge	IMPR	0.1852 lb al/cartridge [1]	not spec	not spec	not spec	not spec	none	none	endangered species restrictions;do not use inside buildings
FOREST PLANTINGS (REFORESTATION PROGRAMS)									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0325 lb al/cartridge [1]	not spec	not spec	not spec	not spec	none	none	endangered species restrictions;do not use inside buildings
GOLF COURSE TURF									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0325 lb al/cartridge [1]	not spec	not spec	5	not spec	none	none	endangered species restrictions;do not use inside buildings
NONAGRICULTURAL UNCULTIVATED AREAS									
Fumigation, When needed, Hand placed cartridge	IMPR	0.1852 lb al/cartridge [1]	not spec	not spec	not spec	not spec	none	none	endangered species restrictions;do not use inside buildings
ORNAMENTAL LAWNS AND TURF									
Fumigation, When needed, Hand placed cartridge	IMPR	0.0325 lb al/cartridge [1]	not spec	not spec	5	not spec	none	none	endangered species restrictions;do not use inside buildings

SITE Application Type, Application Timing, Application Equipment	Form	Maximum Application Rate (ai)	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 = **CARBON DIOXIDE**									
FOOD/FEED USES									
COMMERCIAL TRANSPORTATION FACILITIES									
Fumigation, When needed, Cylinder	PRGS	60% (±10%) ai/treated volume	not spec	not spec	not spec	not spec	none	none	do not fumigate if grain temperature is less than 40 °F or 60 °F (depending on product)
FEED/FOOD CONTAINERS-EMPTY/FULL									
Stored commodity fumigation, When needed, Cylinder	PRGS	60% (±10%) ai/treated volume	not spec	not spec	not spec	not spec	none	none	do not fumigate if grain temperature is less than 40 °F or 60 °F (depending on product)
GRAIN/CEREAL/FLOUR BINS, FEED/FOOD-FULL									
Stored commodity fumigation, When needed, Cylinder	PRGS	60% (±10%) ai/treated volume	not spec	not spec	not spec	not spec	none	none	do not fumigate if grain temperature is less than 40 °F or 60 °F (depending on product)
PROCESSED FOOD AND FEED PRODUCTS									
Stored commodity fumigation, When needed, Cylinder	PRGS	60% (±10%) ai/treated volume	not spec	not spec	not spec	not spec	none	none	do not fumigate if grain temperature is less than 40 °F or 60 °F (depending on product)

Abbreviations used

Header: max. = maximum; min. = minimum; apps. = applications; not spec. = not specified
Form: IMPR = impregnated material; PRGS = pressurized gas
Rate: ai = 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 Carbon or Carbon Dioxide 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 Requirement (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 the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

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

3. Bibliographic citation (Column 3). If the EPA 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

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF CARBON

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION

PRODUCT CHEMISTRY

EPA waived 40 CFR 158 requirements for reasons discussed in section III.

ECOLOGICAL EFFECTS

EPA waived 40 CFR 158 requirements as discussed in section III.

TOXICOLOGY

EPA waived 40 CFR 158 requirements for reasons discussed in section III.

ENVIRONMENTAL FATE

EPA waived 40 CFR 158 requirements for reasons discussed in section III.

The citations listed in the bibliography (Appendix C) were used to support these decisions.

APPENDIX B

DATA SUPPORTING GUIDELINE REQUIREMENTS FOR REREGISTRATION OF CARBON DIOXIDE

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Product Identity	ABL	94049-999[1]
63-2	Color	ABL	94049-999
63-3	Physical State	ABL	94049-999
63-4	Odor	ABL	94049-999
63-5	Melting Point	ABL	94049-999
63-6	Boiling Point	ABL	94049-999
63-7	Density	ABL	94049-999
63-8	Solubility	ABL	94049-999
63-9	Vapor Pressure	ABL	94049-999
63-10	Dissociation Constant	ABL	94049-999
63-11	Oct./Water Part. Coef.	ABL	94049-999
63-12	pH	ABL	94049-999
63-13	Stability	ABL	94049-999

[1] Information was obtained from correspondence with Phase 3 package for company no. 51877. MRID no. for package is cited.

ECOLOGICAL EFFECTS

EPA waived 40 CFR 158 requirements as discussed in section III.

TOXICOLOGY

EPA waived 40 CFR 158 requirements as discussed in section III.

ENVIRONMENTAL FATE

EPA waived 40 CFR 158 requirements as discussed in section III.

The citations listed in the bibliography (Appendix C) were used to support these decisions.

APPENDIX C

CARBON AND CARBON DIOXIDE 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 EPA the EPA 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 EPA 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 EPA could confidently identify one, the EPA has chosen to show a personal author. When no individual was identified, the EPA has shown an identifiable laboratory or testing facility as author.

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

b. Document date. When the date appears as four digits with no question marks, the EPA 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 EPA was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for EPA 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 EPA 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.

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

The following are the sources of the references cited in this document:

(1) Carbon dioxide. 1989. Federal Register 54 (12):2650-2651. January 19 (Thursday), 1989.

(2) Clayton, G. D., and Clayton, F. E., eds., 1982. Patty's Industrial Hygiene and Toxicology, 3rd Revised Edition, Vol 2c. Wiley Interscience, NY.

(3) FASEB, 1979. "Evaluation of the Health Aspects of Carbon Dioxide as a Food Ingredient." NTIS 80-104615

(4) Gilman, A.G., Goodman, L. S., and Gilman, A. (1980) The Pharmacological Basis of Therapeutics, 6th Edition. Macmillan, New York, p. 954.

(5) Jacobs, D. E., and Smith, M. S. (1988). "Exposures to Carbon dioxide in the Poultry Processing Industry." American Industrial Hygiene Association Journal 49:624.

(6) The Merck Index. Eleventh edition, (1989), p. 274.

(7) National Institute for Occupational Safety and Health. NIOSH/OSHA Occupational Health Guidelines for Chemical Hazards DHHS Publication No. 81-123. Cincinnati, Ohio: National Institute for Occupational Safety and Health, 1981.

(8) NIOSH Pocket Guide to Chemical Hazards. 1990. U.S. Department of Health and Human Services, Public Health Service, Publication No. 90-117.

(9) Sax, N. I., and Lewis, R. J. SR. 1989. Dangerous Properties of Industrial Materials, 7th Edition. Van Nostrand Reinhold, New York, p. 710.

10) Schmeltz, L.L., and Whitaker, J.O., Jr. 1977. Use of Woodchuck Burrows by Woodchuck and Other Mammals. Trans. Kentucky Acad. Sci. 38(1-2):79-82.

11) Vaughan, T.A. 1961. Vertebrates Inhabiting Pocket Gopher Burrows in Colorado. J. Mammal. 42(2):171-174.

EPA'S BATCHING OF CARBON AND CARBON DIOXIDE END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing either the active ingredients carbon or carbon dioxide, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above. Frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table I lists 1 batch including 4 products containing the active ingredient carbon dioxide.

Table I.

Batch	EPA Reg. No.	% Carbon Dioxide	Formulation Type
1.	2548-82	99.0	Gas
	11491-7	99.9	Gas
	38719-5	99.9	Gas
	51877-1	99.9	Gas

Table II lists 4 products with the active ingredient carbon/charcoal/sawdust and other active ingredients and were considered to be a batch.

Table II.

Batch	EPA Reg. No.	% Carbon/Charcoal/Sawdust & Other Active Ingredients	Formulation Type
1.	192-49	8.0 Carbon 45.0 Sulfur 45.0 Potassium nitrate 2.0 Dextrin	Smoke Cartridge
	358-137	8.7 Sawdust 34.8 Sulfur 46.2 Potassium nitrate	Smoke Cartridge
	10551-1	8.7 Charcoal 34.8 Sulfur 46.2 Sodium nitrate	Smoke Cartridge
	56228-2	17.34 Charcoal 3.52 Sawdust 10.84 Sulfur 3.25 Red phosphorus 43.36 Sodium nitrate	Smoke Cartridge

Table III lists one product that was considered not to be similar for purposes of acute toxicity. The registrant of the product not batched is responsible for meeting the acute toxicity data requirements.

Table III.

EPA Reg. No.	% Carbon/Charcoal/Sawdust & Other Active Ingredients	Formulation Type
56228-21	35.0 Charcoal 65.0 Sodium nitrate	Smoke Cartridge

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4019 Carbon and CO2	PRODUCT SPECIFIC

4. Guideline Requirement Number	5. Study Title	Protocol	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKLMNO	EP	8 mos.	
61-2(a)	Descrip of starting materials,(1,2,50) production & formulation proc					ABCDEFGHIJKLMNO	EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-2	Color					ABCDEFGHIJKLMNO	EP	8 mos.	
63-3	Physical state					ABCDEFGHIJKLMNO	EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	EP	8 mos.	
63-7	Density					ABCDEFGHIJKLMNO	EP	8 mos.	
63-14	Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-16	Explodability (12)					ABCDEFGHIJKLMNO	EP	8 mos.	
63-17	Storage stability					ABCDEFGHIJKLMNO	EP	8 mos.	
63-20	Corrosion characteristics					ABCDEFGHIJKLMNO	EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

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SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4019 Carbon and CO2	PRODUCT SPECIFIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Subetance	8. Time Frame	9. Registrant Response
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKLMNO	EP	8 mos.	
61-2(a)	Descrip of starting materials,(1,2,50) production & formulation proc					ABCDEFGHIJKLMNO	EP	8 mos.	
62-2	Certification of limits (1,5)					ABCDEFGHIJKLMNO	EP	8 mos.	
62-3	Analytical method (1)					ABCDEFGHIJKLMNO	EP	8 mos.	
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63-3	Physical state					ABCDEFGHIJKLMNO	EP	8 mos.	
63-4	Odor					ABCDEFGHIJKLMNO	EP	8 mos.	
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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4019 Carbon and CO2	PRODUCT SPECIFIC

4. Guideline Requirement Number	5. Study Title		Rec'd	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Acute Toxic - Regular Chemical									
81-1	Acute oral toxicity-rat	(1,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat	(1,2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-3	Acute inhalation toxicity-rat	(3,51,52)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit	(2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-5	Primary dermal irritation	(1,2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-6	Dermal sensitization	(4,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Efficacy - Invertebrate Control Agents									
	Mosquito, Blackfly, Biting Midge Treatments									
95-8,9	Comparative field test	(51,53,54)					C K	EP	8 mos.	
	Efficacy - Vertebrate Control Agents									
96-8	Mole toxicants	(1,51,53,55)					C JK	EP		
96-13	Rodent fumigants	(1,51,53,56)					C JK M O	EP	8 mos.	
96-17	Mammalian predacides	(1,51,53,57)					C K	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
4019 Carbon and CO2

3. Date and Type of DCI
PRODUCT SPECIFIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Acute Toxic - Regular Chemical								
81-1	Acute oral toxicity-rat (1,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-2	Acute dermal toxicity-rabbit/rat (1,2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-3	Acute inhalation toxicity-rat (3,51,52)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-4	Primary eye irritation-rabbit (2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-5	Primary dermal irritation (1,2,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
81-6	Dermal sensitization (4,51)					ABCDEFGHIJKLMNO	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Mosquito, Blackfly, Biting Midge Treatments								
95-8,9	Comparative field test (51,53,54)					C K	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-8	Mole toxicants (1,51,53,55)					C JK	EP		
96-13	Rodent fumigants (1,51,53,56)					C JK M O	EP	8 mos.	
96-17	Mammalian predacides (1,51,53,57)					C K	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4019 Carbon and CO2

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product. [NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop
B - Terrestrial food feed crop
C - Terrestrial nonfood crop
D - Aquatic food crop
E - Aquatic nonfood outdoor
F - Aquatic nonfood industrial
G - Aquatic nonfood residential
H - Greenhouse food crop
I - Greenhouse nonfood crop
J - Forestry
K - Residential outdoor
L - Indoor food
N - Indoor nonfood
M - Indoor Medical
O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Regular Chemical

1 Requirements pertaining to product identity, composition, analysis, and certification of ingredients are detailed further in the following sections: *158.155 for product identity and composition (61-1); *158.160, 158.162, and 158.165 for description of starting materials and manufacturing process (61-2); *158.167 for discussion of formation of impurities (61-3); *158.170 for preliminary analysis (62-1); *158.175 for certification of limits (62-2); and *158.180 for enforcement analytical methods (62-3).
2 A schematic diagram and/or brief description of the production process will suffice if the pesticide is not already under full scale production and an experimental use permit is being sought.
5 Certified limits are not required for inert ingredients in products proposed for experimental use.
10 Required if product contains an oxidizing or reducing agent.
12 Required if product is potentially explosive.

50 61-2 Because of past incidents involving units exploding, rocketing, prematurely igniting, and burning excessively and in the wrong places, the Agency wants as detailed a description of the manufacturing process as possible. In addition, the Agency wants the registrants of these products to list any steps taken to insure quality control of the units, such as periodic sampling to insure that units meet the burning requirements imposed in 1982.

Acute Toxic - Regular Chemical

1 Not required if test material is a gas or highly volatile.
2 Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as Toxicity Category I on the basis of potential eye and dermal irritation effects.
3 Required if the product consists of, or under conditions of use will result in, an inhalable material (e. g., gas, volatile substances, or aerosol/particulate).
4 Required unless repeated dermal exposure does not occur under conditions of use.

51 Not required for CO_2 products

52 81-3 The test must be conducted on the ignition gases. A test protocol must be submitted to the Agency, and approved, before initiation of test.

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4019 Carbon and CO2

Footnotes (cont.):

Efficacy - Invertebrate Control Agents

51 Not required for CO_2 products.

53 For Gas Cartridge products, registrants must resubmit the data on burn times for fuses and the cartridges, originally requested in the Agency's 1982 Label Improvement Program and Data Call-In, so that these data can be assigned an MRID Number.

54 95-9 Field data are required on ground wasps because currently registered products appear to be too wide to fit into wasp entrances, thus creating an unnecessary risk to potential users, some of whom could have life-threatening reactions to stings. A protocol must be submitted within 3 months, and approved, before work is begun. As part of the protocol, the registrant must document the entrance sizes of major wasp species, and their geographic distribution, in the United States. If actual testing is done, any reports of units that malfunction, or were too big to fit into burrows, must be reported.

Efficacy - Vertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for vertebrate control agents unless the pesticide product bears a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The registrant must develop and maintain the relevant data upon which the determination of efficacy is based. The Agency reserves the right to require, on a case-by-case basis (e.g., significant new uses or benefits data in cases of special reviews) submission of efficacy data for any pesticide product, registered or proposed for registration when necessary.

51 Not required for CO_2 products.

53 For Gas Cartridge products, registrants must resubmit the data on burn times for fuses and the cartridges, originally requested in the Agency's 1982 Label Improvement Program and Data Call-In, so that these data can be assigned an MRID Number.

55 96-8 Field data are required on one species of mole. A protocol must be submitted within 3 months, and approved, before work is begun. Any reports of units that malfunction, or were too big to fit into burrows, must be reported.

56 96-13 Field data are required on Norway rat, ground squirrel, and woodchuck. If none of these species is claimed, field data will be required for one rodent species, if any are claimed. A protocol must be submitted within 3 months, and approved, before work is begun. Any reports of units that malfunction must be reported.

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FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4019 Carbon and CO2

Footnotes (cont.):

Efficacy - Vertebrate Control Agents

5796-17 Field data are required on the coyote, skunk, and red fox. A protocol must be submitted within 3 months, and approved, before work is begun. Any reports of units that malfunction must be reported.