US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Sodium Carbonate Peroxyhydrate (PC Code 128860)

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
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BIOPESTICIDE REGULATORY ACTION DOCUMENT TEAM

Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

Biochemical Pesticides Branch

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I. EXECUTIVE SUMMARY

A. IDENTITY

The technical grade (TGAI) algaecide and fungicide product, Technical Sodium Carbonate Peroxyhydrate, consists of 85% of the active ingredient (a.i.) sodium carbonate peroxyhydrate, and 15% of other ingredients. The end-use product, TerraCyte™ consists of 40% Technical Sodium Carbonate Peroxyhydrate and 60% other ingredients. This is equivalent to nominal concentration of 36% of the a.i. and 66% other ingredients. Both products are in the form of a free-flowing, white granular powder.

B. USE

The technical grade product is to be used in the formulation of end-use pesticide products. The end-use product is to be used as an algaecide and fungicide on turf grasses, ornamental plants, terrestrial landscapes, in commercial greenhouses, garden centers, nurseries and storage areas. There are no food uses.

C. RISK ASSESSMENT

The Agency has determined that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of sodium carbonate peroxyhydrate when label instructions are followed. Sodium carbonate peroxyhydrate is very unstable in the presence of moisture, and there is little likelihood exposure to the a.i. itself. Therefore, the risks to humans and the environment is low.

1. Human Health Risk Assessment

a. Toxicological Endpoints

Mammalian toxicology data requirements were submitted and satisfy the data requirements in support of the registration of products containing sodium carbonate peroxyhydrate. Submitted data indicate Toxicity Category III for Acute Oral Toxicity, Acute Dermal Toxicity, and Primary Dermal Irritation. The results of the eye irritation study demonstrated that the product causes severe, irreversible eye damage and was accorded Toxicity Category I. A data waiver was requested and granted for the Acute Inhalation Study on the basis of the large particle sizes in the granular product. The substance is not a dermal sensitizer.

b. Human Exposure

Exposure to the general population would be minimal but worker exposure is expected. Due to the

corrosive characteristics of the product (a severe eye irritant), appropriate protective wear and precautionary label language will mitigate worker vulnerability.

c. Risk Assessment

The Agency has considered sodium carbonate peroxyhydrate in light of the mode of action of the chemical and the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of sodium carbonate peroxyhydrate when label instructions are followed.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

EPA has waived all Tier 1 ecological studies for registration of registration of products containing sodium carbonate peroxyhydrate because no ecological toxicity endpoints are expected if the product is applied in accordance with label directions.

b. Ecological Exposure

When the pesticide is applied in accordance with label directions, no hazard to birds or other terrestrial animals, freshwater fish and invertebrates. No harm to non-target plants is foreseen if the label notice is observed to test the plants for phytotoxicity before application, and to prevent the elevation of the pH of the soil. Precautionary label statements are present to prevent exposure to non-target insects, including honey bees.

c. Risk Assessment

Risk to other organisms is expected to be minimal, given the unstable character of the chemical when water is applied and given the appropriate precautionary and advisory statements present on the label.

D. DATA GAPS/LABELING RESTRICTIONS

There are no data gaps. Labeling restrictions and precautionary labeling, which are required to mitigate risks, are detailed in the **LABELING RATIONALE** section below**.**

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common and Chemical Name: Sodium Carbonate Peroxyhydrate

Chemical Formula: $2Na_2CO_3 \cdot 3H_2O_2$

CAS number: 15630-894

Trade and other names: Sodium Carbonate Peroxide, FB® Sodium Percarbonate, PCS

OPP Chemical Code: 128860

Basic Manufacturer: Solvay Interox Inc.
333 Richmond Avenue
Houston, Texas 77098-3099

B. USE PROFILE

Proposed uses and application methods for sodium carbonate peroxyhydrate products are included in the following summary:

Type of Pesticide: Algaecide and fungicide

Use Sites: The manufacturing-use product, technical sodium carbonate peroxyhydrate produced by Solvay Interox, Inc. may be formulated into end-use products.

The single end use product is to be used to control algae, moss, liver worts, slime molds and their spores on turf grasses, ornamental plants, terrestrial landscapes, around residences, in commercial greenhouses, garden centers, nurseries and storage areas. The pesticide is to be used on well-established plantings only (not for seed bed preparations, new plantings, or seedlings).

Formulation Types: Solid, free flowing, white granular powder (describes both the manufacturing-use and the end-use product)

Methods and Rates of Application:

Application of the granular is by a lawn spreader or other applicator that will ensure uniform coverage. Since sodium carbonate peroxyhydrate is activated by moisture, all applications must be made over wet conditions or must be watered immediately after spreading the product. The optimum application time is early morning or late afternoon.

The sodium carbonate peroxyhydrate end use product is applied in greenhouses, storage areas, and nursery yards, on soil surfaces containing growing plants, and on turf grasses. Treatment for

heavy contamination requires 4 pounds per 1000 square feet. Subsequent preventive treatments require 2-4 lbs per 1000 square feet. Applications should be repeated every 5 to 7 days to control new or established conditions.

For plant beds and bench areas, the dose is 1¼ pound over 1000 sq ft. and applications are repeated every 4 weeks.

On potted plants, the dose is ¼ ounce or 1 level teaspoon over the surface of 8-inch pots, and 1½ level teaspoons over the surface of 10-inch pots. The treatment is repeated every 4 weeks.

For use on turf grasses, such as well-established golf course fairways, greens and tees, the pesticide is applied at the rate of 8 pounds per 1000 square feet. Subsequent applications (as needed) can be made on consecutive days at the rate of 2 to 4 pounds per 1000 square feet. Application is to be immediately followed by sprinkler irrigation for 8-10 minutes to a depth of ⅛ to $^{1}/_{10}$ of an inch.

Use Practice Limitations: Workers must not enter treated areas for 4 hours following application.

Timing: Optimum treatment time is early morning or late afternoon. For curative applications on turf grasses, apply in either the spring or fall when temperatures are 50^{0}F or above.

C. ESTIMATED USAGE

Estimates based on existing commercial use cannot be made since the manufacturing-use product is to be incorporated into the first registered product.

D. DATA REQUIREMENTS

EPA reviewed data requirements for granting these registrations under Section 3(c)(5) of FIFRA. Product analysis data requirements and mammalian toxicology data requirements are adequately satisfied. All of the data requirements for ecological effects were waived.

E. REGULATORY HISTORY

On February 2, 1999, EPA received an application from BioSafe Systems for registration of an end use product containing a new active ingredient, sodium percarbonate (sodium carbonate peroxyhydrate). A notice of receipt of that application was published in the Federal Register, (OPP-30481), on August 11, 1999 with a 30-day comment period. No comments were received as a result of this publication.

On January 30, 2002, EPA received an application for registration of Technical Sodium Carbonate Peroxyhydrate from Solvay Interox, Inc.

F. CLASSIFICATION

The mode of action of the pesticide, sodium carbonate peroxyhydrate, is to kill the target organisms by oxidizing critical components, such as the cellular structure of the target organism. Thus, it does not qualify to be classified as a biochemical pesticides. However, the Agency has classified sodium carbonate peroxyhydrate ($2\,Na_2CO_3 \cdot 3H_2O_2$) as eligible for reduced data requirements. It is a non-complex chemical and its physical and chemical characteristics are well understood. In the presence of water, the granules or crystals of sodium carbonate peroxyhydrate are dissolved and transformed into hydrogen peroxide and sodium carbonate. Upon contact the hydrogen peroxide oxidizes its target, then breaks down into water and oxygen, neither of which engender toxicological concern.

G. FOOD CLEARANCES/TOLERANCES

There are no food uses associated with this active ingredient.

III. SCIENCE ASSESSMENT

A. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for the technical grade/manufacturing-use product and the end-use product have been met.

1. Product Identity and Mode of Action

a. Product Identity

The active ingredient, sodium carbonate peroxyhydrate, is a free flowing, white crystalline powder having the chemical formula $2\ Na_2CO_3 \bullet 3\ H_2O_2$. Technical sodium carbonate peroxyhydrate consists of 85 % of the active ingredient, sodium carbonate peroxyhydrate. Other (inert) components make up the remaining 15%. The end-use product consists of 40% of the technical product and the remainder is an inert carrier.

b. Mode of Action

Sodium carbonate peroxyhydrate is transformed into hydrogen peroxide and sodium carbonate in the presence of water. The hydrogen peroxide oxidizes the critical cellular components of the target organism and thus kills them.

2. Physical And Chemical Properties Assessment

The product chemistry data which support the registration of the TGAI/MUP and the end-use product are summarized below in Table 1a, and their physical and chemical properties are shown in Table 1b.

Table 1a: Product Chemistry Data Requirements:

Product Chemistry	**TGAI/MP (MRID 44593001, 44593002, 44995601)**	**EP (MRID 44714101)**
151-10: Product Identity and Composition *880-1100	Technical sodium carbonate peroxyhydrate consists of 85% sodium carbonate peroxyhydrate and 15% of other ingredients	The EP consists of 40% Technical Sodium Carbonate Peroxyhydrate and 60% of an inert ingredient.
151-11:Manufacturing Process *880-1200	An acceptable description of the complex manufacturing process was submitted.	The product is manufactured by a simple mixing process of the TGAI and the inert ingredient without any chemical reactions.
151-12:Discussion of Formation of Impurities *880-1400	Small amounts of impurities formed *in situ* are reported in MRID 44593002	No impurities are likely to form during the manufacturing process (a simple mixing process).
151-13: Preliminary Analysis *830.1700	The producer submitted Certificates of Analysis for 10 production lots The available oxygen content is measured and the hydrogen peroxide content is calculated. The analysis is acceptable.	Five batch preliminary analysis was supplied for TGAI but not needed for end-use product which is manufactured by a simple mixing process.
151-15: Certified Limits *830.1750	Certified limits are consistent with 40CFR158.175(d)(2) and are acceptable as explained in MRID 44593002	Certified limits calculated in accordance with 40 CFR 158.175(b)(2) are acceptable.
151-16: Enforcement Analytic method *830-1800	An acceptable analytic method was submitted to detect the active ingredient	An acceptable analytic method was submitted to detect the active ingredient

Table 1b:.Physical/Chemical Properties-OPP151.17

Physical/Chemical Property	**TGAI/MP(MRID 44995601**	**EP (MRID 44714101)**
*830.6302:Color	White	White
*830.6303:Physical State	Free flowing granular powder, mean particle size =350-550µ	Free flowing granular powder, mean particle size =350-550µ
*830.6304: Odor	Odorless	Odorless
*830.6313:Stability at normal and elevated temperatures	Self-accelerating decomposition with oxygen release starting at 50^0 C (122^0 F)	Stability greater than 6 months at <50^0 C (122^0 F), longer at recommended storage conditions
*830.6314: Oxidation/Reduction Potential	Strong oxidizing agent	Oxidizing agent
*830.6315:Flammability	N/A-No flammable characteristics	N/A-No flammable characteristics
*830.6316: Explodability	N/A-No explosive characteristics	N/A- No explosive characteristics
*830.6317 Storage Stability	Avoid heat, moisture, water, acids, bases, salts of heavy metals, reducing agents, organic materials, flammable substances	Note: Requirement for storage stability data waived with appropriate labeling in response to registrant's subsequent request for waiver in letter dated June 10, 2002; Ref.7
*830.6319: Miscibility	N/A-Product is not intended to be mixed with water	N/A-Product does not require dilution
*830.6320: Corrosion Characteristics	Alkaline solid -can be stored in polymer lined or plastic containers	Moderately corrosive because of alkalinity-can be stored in polymer lined or plastic containers
*830.6321: Dielectric Breakdown Voltage	N/A-Product not intended to be used as an insulating material	N/A-Product not intended for use in or around electrical equipment

*830.7000: pH	In a 1% aqueous solution-10.5-10.6	10.4-10.6 for a 1% solution
*830.7100: Viscosity	N/A-Product is a solid	N/A- Product is a solid
*830.7300: Bulk Density	Ranges from 1.00 to 1.17 g/cm^3	1.00-1.17 g/cm^3

*=OPPTS Biochemical Guidelines
N/A = not applicable

B. HUMAN HEALTH ASSESSMENT

Information submitted to support the registration of the Technical Grade Sodium Carbonate Peroxyhydrate and the end-use product adequately satisfies the non-food use requirements set forth in 40CFR158.690 (c) for biochemical pesticides. The overall toxicological risk from human exposure to sodium carbonate peroxyhydrate is negligible.

1. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the products containing the active ingredient sodium carbonate peroxyhydrate.

a. Acute Toxicity

Results of the acute toxicity studies are summarized in Table 2. A summary of these studies are as follows:

Acute Oral Toxicity

Groups of 7-week-old fasted rats (5 of each sex) were given a single dose of the test substance at dose levels of either 700, 1000, and 1500 mg/kg. Rats were observed for 14 days post -treatment. All rats dosed at 1500 mg/kg died within one day of treatment. At the other test doses hypoactivity, ataxia, diarrhea, red-stained face, absence of pain reflex, excessive salivation, brown-stained urogenital area, dyspnea, prostration, and death were observed up to 3 days post-treatment (more so at the 1000 mg/km level than at the 700 mg/kg level). Necropsy showed that rats killed by treatment were most frequently found to have coloration changes in the glandular portion of the stomach and, in some cases, thickened stomach walls. Most rats surviving the tests had no visible G.I. tract effects, save for a few observed to have coloration and stomach thickening effects. The combined LD_{50} for males and females was 1,034 mg/kg. Based on this result, technical sodium carbonate peroxyhydrate is placed in Toxicity Category III and the study is acceptable.

Acute Dermal Toxicity

Groups of 14-week-old fasted rabbits (5 of each sex) were given a single dose of the test substance at 2000 mg/kg. The rabbits were observed for 14 days post treatment. No mortality or clinical toxicity was observed. Some dermal irritation and skin effects were observed. Necropsy findings revealed skin effects in the treated area which included multiple crusted areas of variable size and color and thickened skin in half the test animals (5/10). The combined LD_{50} for males and females was>2000 mg/km. Based on this result, technical sodium carbonate peroxyhydrate, is placed in Toxicity Category III and the study is acceptable.

Acute Inhalation Toxicity

A data waiver request was considered and granted for Acute Inhalation Toxicity (OPP 152.12) testing. The waiver was granted due to the fact that the product is a granular formulation with large particles (350-550 µm) that are not respirable (and difficult to test). In addition, an attrition resistance study to simulate shipping effects on particle size demonstrated that less than 1% of the

sample were frayed/pulverized into particles of less than106 µm (memo to M. Swindell, T. Kish, 10/6/00). EPA concluded that "any significant exposure by breathing is expected to be limited to the upper respiratory tract, where any harmful dose would likely be noticed right away... ." The waiver was granted and Toxicity Category IV was assigned, based on the submitted study, to support the registration of the end use product.

Primary Eye Irritation

Six adult rabbits (3 of each sex) were given a dose of 0.1 g of the test substance applied directly to one eye. Rabbits were observed at 1, 24, 48, 72, and 96 hours post-treatment. Test rabbits exhibited severe irreversible eye damage (conjunctival irritation including corneal and iridial effects) throughout the 96 hour observation period. The experiment was halted after 96 hours due to the level of irritation. The eye effects included pain response, blanching of the conjunctivae, petite hemorrhaging of the conjunctivae, necrosis of the conjunctivae and corneal epithelial pealing. Based on the severe eye irritation recorded in the study, technical sodium carbonate peroxyhydrate is placed in Toxicity Category I, and the study is acceptable.

Primary Dermal Irritation

Six adult rabbits were given a dose of 0.5 g of the test substance applied directly to the shaved back and flanks. Rabbits were observed at 4,24,48,72, 96 hours and at 7 and 14 days post-treatment. All test rabbits exhibited slight erythema after 4 hours which cleared in all rabbits by day 14. Slight edema was also observed in 4/6 test rabbits after 4 hours, which cleared in all but one rabbit after 24 hours and cleared in all rabbits by day 7. Based on the persistent (7-14 days in some rabbits) dermal irritation in this study, technical sodium carbonate peroxyhydrate is placed in Toxicity Category III and the study is acceptable.

Dermal Sensitization

Adult guinea pigs (including a test group of 10 individuals, a positive control group of 4, and a naive control group of 10) were tested using an induction phase/challenge phase protocol. During the induction phase, a dose of the test substance was applied to the test group (directly to the shaved back and flanks) as a 75% w/v mixture once per week for three weeks. Two weeks after the final treatment in the induction phase, the test group was given a challenge dose of sodium carbonate peroxyhydrate (85%) as a 25% w.v mixture (a naive control group was also tested in the challenge phase). In addition, a positive control group was tested during the induction (dosage = 0.3 % w/v 2,4-dinitrochlorobenzene (DNCB) in acetone) and challenge (dosage = 0.1 % w/v DNCB in acetone) phases. All the test animals were observed at 24 and 48 hours post treatment in both the induction and challenge phases for signs of erythema and edema. All guinea pigs in the test group exhibited slight erythema during the induction phase. During the challenge phase, none of the test animals (test and naive control groups) showed any reaction. The positive control group showed moderate to severe erythema in the induction phase and severe erythema in the challenge phase. Based on the lack of irritation observed in the challenge phase, technical sodium carbonate peroxyhydrate is not considered to be a dermal sensitizer. The study is acceptable.

Table 2. Acute Mammalian Toxicity:

Guideline	Study	Results	MRID No.
152-10 *870.1100	Acute Oral Toxicity-rat	Rat oral LD_{50} =1034 mg/kg. Accepted; Toxicity Category III, Ref.1	42489201
152.11 *870.1200	Acute Dermal Toxicity	Rabbit dermal LD_{50} >2000 mg/kg. Accepted; Toxicity Category III, Ref.1	42545403
152-12 *870.1300	Acute Inhalation Toxicity	Data waiver granted based on non-respirable large particle size in granular formulation Toxicity Category IV, Ref.2	NA
152-13 *870.2400	Primary Eye Irritation	Severe , irreversible eye irritation in rabbits. Accepted; Toxicity Category I, Ref.1	42545401
152-14 *870.2500	Primary Dermal Irritation	Slight edema and erythema in rabbits, cleared by the end of the test. Accepted; Toxicity Category III, Ref. 1	42545402
152-15 *870.2600	Dermal Sensitization	No reaction in guinea pigs after induction/challenge doses. Accepted; Not a Sensitizer, Ref.1	42545404

*=OPPTS Biochemical Pesticide Test Guideline Numbers.

b. Genotoxicity and Mutagenicity

These studies required or conditionally required for all food use biochemical pesticides, were not submitted by the registrant as the TGAI and end-use products both are non-food uses.

c. Effects on the Endocrine Systems:

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate". Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program,

the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in

wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for sodium carbonate peroxyhydrate and none are expected since the mode of action of the chemical is well defined.

2. Dose Response Assessment

Of the acute toxicity studies, the primary eye irritation study yielded a Toxicity Category I result, which was severe irreversible eye damage on the test animals. Otherwise, no toxicological endpoints were identified.

3. Aggregate Exposure and Risk Characterization

a. Dietary

i. Food

Risk from the consumption of residues of sodium carbonate peroxyhydrate is not expected for the general population including infants and children. The end-use product TerraCyte™ is not for use on food or animal feed.

ii. Drinking Water

Label directions require that treatment of turf with sodium carbonate peroxyhydrate be immediately followed by watering through a sprinkler system for 8 to 10 minutes. The dissolved granules are transformed into hydrogen peroxide and sodium carbonate. Hydrogen peroxide is, on contact with organic matter, broken down into water and oxygen, neither of which engender toxicological concern. Because of the instability of the sodium carbonate peroxyhydrate molecule in the presence of water, there is negligible risk that municipal drinking water will be affected, or that any possible runoff to surface or groundwater could result in any harmful (toxicological) effect.

4. Occupational, Residential, School, and Day care Exposure and Risk Characterization

Sodium carbonate peroxyhydrate is used for the control of algae, moss, and slime molds on grass. Significant human exposure to other than the pesticide applicators is not expected from uses of the pesticide on lawns around residences, schools and day care centers because of the instability of the granular product when used according to label directions (wet conditions). For pesticide applicators, the use of sodium carbonate peroxyhydrate on turf is subject to the Worker Protection Standards (WPS) requiring Personal
Protective Equipment (PPE), which are: protective eyewear (goggles or face shield), chemical resistant gloves, coveralls over long-sleeved shirt, long pants, and chemical resistant footwear

plus socks. These PPE will mitigate worker exposure and risk.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. Sodium carbonate peroxyhydrate is not labeled for food or animal feed use. Therefore, acute and chronic dietary risks are not expected.

6. Aggregate Exposure from Multiple Routes Including Oral, Dermal, and Inhalation

Aggregate exposure via these three routes are expected to be minimal when the product is applied in accordance with labeled directions and appropriate PPE is used as described above. If the product label directions are not followed, aggregate exposure to sodium carbonate peroxyhydrate contained in the end-use product by field workers and pesticide applicators could occur via oral, dermal and inhalation routes. The risks of worker exposure are measured by the results of the acute toxicity studies submitted to support registration. The acute oral toxicity was accorded a Toxicity Category III, with only a small expectation of toxicity from accidental ingestion of the pesticide.

Results of the acute dermal toxicity study indicated no toxicity at the highest dose tested. (The LD_{50} >2000 mg/kg, the highest dose tested) and the acute dermal test was accorded a Toxicity III Category. This chemical has been found not to be a dermal sensitizer. There was a data waiver requested and granted for the inhalation toxicity study based on the large particle size of the granular formulation. Acute inhalation toxicity was thus accorded a Toxicity Category IV.

7. Cumulative Effects

In view of the breakdown of the pesticide product in the presence of water to hydrogen peroxide and sodium carbonate, and the subsequent breakdown of hydrogen peroxide on contact to water and oxygen, cumulative effects are not expected.

8. Risk Characterization

The Agency has considered the active ingredient, sodium carbonate peroxyhydrate, in light of the use, mode of action of the chemical, and the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of TerraCyte™ when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The end-use product is to control algae, moss and slime molds and is sold for use on lawns and ornamental plants around residences, and for horticultural and commercial use, as shown on the label of the product. When applied in accordance with directions on the label, the unstable nature of the chemical accounts for the use of the product without harm to birds and other terrestrial animal species. In the presence of water, the active ingredient rapidly breaks down to hydrogen peroxide and sodium carbonate, and hydrogen peroxide rapidly breaks down, on contact, to water and oxygen, neither of which presents toxicological concern.

In the uses for which the product is intended, harm to aquatic species, freshwater fish and and freshwater aquatic invertebrates is not foreseen; however, mitigating language on the product label is provided.

For non-target plants, submitted data from the open literature allowed EPA to waive required studies as specified in OPP Guideline 154.10, provided the label directs that any turf grasses and plants to be treated must be tested for phytotoxicity prior to application, and that repeated applications may cause the possible elevation of the pH of the soil that may adversely affect plant growth.

A request for waiver of studies testing non-target insects and honey bee acute contact toxicities has been found acceptable by EPA, provided that precautionary statements or mitigating language is present on the label.

All the waivers of data requirements for eco-toxicology data are summarized in Table 3 below.

Table 3: Required Eco-Toxicology Studies; Requested Waivers of Data

Guideline No.	Study	Comments
154-6 *850.2100	Avian acute oral toxicity	Request of data waiver acceptable. The product label includes the following language: "..... water immediately following application.....Water to recommended amount for at least 10 minutes." References 9 and 10.
154-7 *850.2200	Avian dietary test	Request of data waiver acceptable provided there is label language as above. References 9 and 10.
154-8 *850.1075	Freshwater fish acute toxicity-LC_{50}	Request of data waiver acceptable. The product label includes the following language: "This product is toxic to birds and fish. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high mark. Do not contaminate water by cleaning of equipment or disposal of wash waters." Reference 2, Conclusion 6.
154-9 *870.1010	Aquatic invertebrate, acute toxicity-LC_{50}	Request of data waiver acceptable provided there is label language as above. Reference 2, Conclusion 6.
154-10 *850.4025	Non-target plant studies	Request of data waiver acceptable when the product is used according to proposed label directions that use sites (turf grasses) be tested for phytotoxicity and reference is made to the fact that repeat applications may raise soil pH to levels that may adversely affect plant growth. Reference 6, MRID No.4565900, and Reference 5.
154-11 *850.3020	Non-target insect testing Honey bee acute contact toxicity	Request of data waiver acceptable. The product label includes the following text: "This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops and weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Do not apply this product or allow it to drift to crops where beneficial insects are part of an integrated pest management strategy." Reference 2, Conclusion 8.

* = OPPTS Biochemical Pesticide Test Guideline Numbers.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, 40CFR 158.690(d)(2)) was not triggered because the Tier I studies were waived. Risk is minimal due to the use pattern, application methods, and the chemically unstable character of the product in the presence of water.

3. Ecological Exposure and Risk Characterization

Because of the chemical instability of sodium carbonate peroxyhydrate in the presence of water, there is little likelihood of ecological exposure and risk.

D. EFFICACY DATA

No efficacy data were submitted or reviewed since no public health uses are proposed for the product.

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A"above, Sodium Carbonate Peroxyhydrate is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, and is likely to provide protection as claimed, satisfying Criteria "C." Criteria "D"is satisfied in that the toxicological properties of this product are less toxic than other conventional pesticide products currently in use for this target pest.

Therefore, Sodium Carbonate Peroxyhydrate is eligible for registration. The uses are listed in Table 4, Appendix A.

B. REGULATORY POSITION

1. Unconditional Registration

All data requirements have been fulfilled and/or waived by the Agency and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products which contain sodium carbonate peroxyhydrate as their sole active ingredient.

2. Tolerances for food uses

The products containing sodium carbonate peroxyhydrate are not registered for food use.

3. CODEX Harmonization

There is no CODEX value for sodium carbonate peroxyhydrate

4. Non-food Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time. Currently, there are no non-food issues associated with this active ingredient. The non-food uses are listed in Appendix A, Table 4.

5. Risk Mitigation

Sodium carbonate peroxyhydrate is a strong oxidizing agent, and it is corrosive. The label instructs users to keep this substance out of contact with other pesticides, cleaners or oxidative agents. The label signal word is "Danger" because of its corrosive characteristics. Appropriate instructions are on the label to mitigate risks of environmental hazards. Risks to applicators and handlers are mitigated by label language requiring them to wear protective eyewear (goggles or face shield), chemical resistant gloves, coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Risk is further mitigated by the requirement of a 4-hour re-entry period.

6. Endangered Species Statement

Given the intended use pattern, the results of toxicity and exposure data from the public scientific literature and data submitted by the applicant, the Agency has determined that this action will have no adverse effects on currently listed endangered and threatened species.

C. LABELING RATIONALE

It is the Agency's position that the labeling of the pesticide products containing Sodium Carbonate Peroxyhydrate comply with current requirements.

1. Human Health Hazard

a. Worker Protection Standard

The end-use product comes under the provision of the Worker Protection Standards (WPS). Personal Protective Equipment (PPE) are protective eyewear (goggles or face shield), chemical resistant gloves, coveralls over long-sleeved shirt, long pants, chemical resistant footwear and socks, and a 4-hour re-entry interval (REI).

b. Non-Worker Protection Standard

Keep unprotected persons out of treated areas until sprays have dried.

c. Precautionary Labeling

The Agency has examined the toxicological data base for sodium carbonate peroxyhydrate and concluded that the proposed precautionary labeling (i.e. Signal Word, First Aid, and other Label Statements) adequately mitigates any risks associated with the proposed uses.

Technical product Precautionary Labeling: "DANGER"

Hazards to Humans and Domestic Animals:

Causes severe eye damage and skin irritations. Do not get in eyes, on skin, or clothing. Harmful if swallowed or inhaled. Avoid breathing dust. Wear protective eyewear (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. When prolonged or frequently repeated contact could occur, use chemically resistant gloves and full body clothing.

First Aid:

If in eyes:
- -Hold eye open and rinse slowly for 15-20 minutes.
- -Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.
- -Call a poison control center or doctor for treatment advice.

If inhaled:
- -Move person to fresh air.
- -if person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth
- -Call a poison control center or doctor for treatment advice.

If on skin or clothing:
- -Take off contaminated clothing.
- -Rinse skin Immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed
- -Call a poison control center or doctor immediately for treatment advice.
- -Have a person drink plenty of water if able to swallow.
- -Do not induce vomiting unless told to do so by a poison control center or doctor.
- -Do not give anything by mouth to an unconscious person.

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End-Use Product Precautionary Labeling: "DANGER"

Hazards to Humans and Domestic Animals:

CORROSIVE: Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing.

First Aid:

If in eyes:
- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye
- -Call a poison control center or doctor for treatment advice.

If on skin or clothing:
- -Take off contaminated clothing. J
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

If swallowed:

-Call poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by the poison control center.
-Do not give anything to an unconscious person.

If inhaled:

-Move person to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN- Probable mucosal damage may contraindicate the use of gastric lavage.

2.. Environmental Hazards Labeling:

End-use Product Environmental Hazards Labeling: FOR TERRESTRIAL USES. Keep out of lakes, ponds and streams. This pesticide is toxic to birds, fish and aquatic invertebrates, Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wash waters. This product is highly toxic to bees and other beneficial insects exposed to direct contact on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment. Do not apply this product or allow it to drift to crops where beneficial insects are part of an integrated pest management strategy.

3. Application Rate

It is the Agency's position, that the labeling for the pesticide products containing sodium carbonate peroxyhydrate must comply with the current pesticide labeling requirements. The Agency has not stipulated a maximum number of applications for the active ingredient. The label stipulates: All applications (of the granular pesticide) must be made over wet surfaces. For application in greenhouses, storage areas and nursery yards, apply 4 pounds per 1000 square fee. For application on plant beds and bench areas, distribute 1¼ lbs. uniformly over 1000-sq. ft. of bed or bench area.
For application on turf grasses, spread 8 pounds per 1000 square feet with subsequent applications of 2-4 pounds per 1000square feet..

D. LABELING

(1) Product name: **Technical Sodium Carbonate Peroxyhydrate**

Active Ingredient:
Sodium Carbonate peroxyhydrate.....85%
Other Ingredients.....15%
_____
Total.....100%.

(2) Product name: **TerraCyte™**

Active Ingredient:
Sodium carbonate peroxyhydrate.....34%
Other Ingredients.....66%
_____
Total.....100%

Signal Word is "DANGER". CORROSIVE, Eye irreversible damage, Harmful if swallowed, inhaled, absorbed through skin are appropriate warnings.

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (TGAI and End-Use Product-DANGER)

V. ACTIONS REQUIRED BY REGISTRANTS

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

VI. DATA GAPS

There are no data gaps.

VII. APPENDIX A

Table 4 lists the use sites for the products. The labels for the products are also attached.

Table 4. Use Sites

1): Technical Sodium Carbonate Peroxyhydrate Use Site: Formulation into end-use products 2): TerraCyte™ Use Sites: Ornamental Plants and Turf Grasses, and in Commercial Greenhouses, Garden Centers, Nurseries and their Storage Areas.	**Official date registered:** September 20, 2002

VIII. REFERENCES

MRID Numbers-PC Code 128860

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42489201 Glaza, S. (1990) Acute Oral Toxicity Study of FB Sodium Percarbonate S02544 in Rats: Final Report: Lab Project Number:HLA 90903986. Unpublished study prepared by Hazleton Labs America, Inc. 38 p.

42545400 Wexford Labs, Inc. (1992) Submission of toxicity data to support registration of Dri-Cide 256. Transmittal of 4 studies.

42545401 Glaza, S. (1990) Primary Eye Irritation Study of FB Sodium Percarbonate in Rabbits: Final Report: Lab Project Number: HLA 90903989. Unpublished study prepared by Hazleton Labs America, Inc. 28 p.

42545402 Glaza, S. (1990) Primary Dermal Irritation Study of FB Sodium Percarbonate in Rabbits: Final Report: Lab Project Number: HLA 90903988. Unpublished study prepared by Hazleton Labs America, Inc. 20 p.

42545403 Glaza, S. (1990) Acute Dermal Toxicity Study of FB Sodium Percarbonate in Rabbits: Final Report: Lab Project Number: HLA 90903987. Unpublished study prepared by Hazleton Labs America, Inc. 25 p.

42545404 Glaza, S. (1990) Dermal Sensitization Study of FB Sodium Percarbonate SO 2544 in Guinea Pigs--Closed Patch Technique:Final Report: Lab Project Number: HLA 90903990. Unpublished study prepared by Hazleton Labs America, Inc. 29 p.

44714100 BioSafe Systems (1998) Submission of Product Chemistry Data in Support of the Application for Registration of TerraCare Granular Algaecide /Fungicide. Transmittal of 1 Study.

44714101 Roberts, A. (1998) Product Chemistry of TerraCare Granular Algaecide /Fungicide. Unpublished study prepared by BioSafe Systems. 41 p. {OPPTS 830.1550, 830.1600, 830.1670, 830.1750, 830.1800, 830.6303, 830.6314, 830.6320, 830.7000, 830.7300}.

44893800 BioSafe Systems (1999) Submission of Product Chemistry Data in Support of the Application for Registration of GreenCleen Granular. Transmittal of 1 Study.

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45516400 NorAmTech Corp (2001) Submission of Efficacy Data in Support of the Application for

Registration of Wash 'N Bleach Extra. Transmittal of 1 Study.

45516401 Brown, K. (2001) Petrocci and Clarke Laundry Sanitizer Test: Wash N Bleach Extra: Final Report: Lab Project Number: 463-103.Unpublished study prepared by MicroBioTest, Inc. 29 pp.

45526400 Solvay Interox, Inc. (2001) Submission of Residue Data in Support of the Application for the Registration of PAK 27 and the Petition for the Threshold of Tolerance of Sodium Percarbonate for the Control of Algae in Drinking Water. Transmittal of 1 Study.

45526401 Moore, S. (1997) PAK 27: Residue in Water, Fish, Irrigated Crops. Unpublished study prepared by Burlington Chemical Co, Inc. 65 p. (OPPTS 860.1400).

45554900 BioSafe Systems (2001) Submission of Toxicity Data in Support of the Application for Registration of GreenClean Granular Algaecide . Transmittal of 1 Study.

45554901 Machado, M. (2001) GreenClean--Acute Toxicity to Rainbow Trout (Oncorhynchusmykiss) Under Static Conditions: Lab Project Number: 13780.6100. Unpublished study prepared by Springborn Laboratories. 35 p. (OPPTS 850.1075)

Other submitted studies-MRID Numbers

44593001 Sarvadi, D. and Boulos, N. (1998), PAK™ 27: Product Identity, Composition and Formulation, Prepared by Keller and Heckman , LLP; 16 pp.

44593002 Sarvadi, D. and Boulos, N. (1998), PAK™ 27: Preliminary Analysis and Certification of Limits, Prepared by Keller and Heckman LLP, 21 pp.

44995601 Heger, E., Boulos, N., Sarvadi, D. (1999), PAK™ 27: Product Description and Manufacturing Process, Prepared by Keller and Heckman LLP, 59 pp.

45659001 Roberts, A.P. (April 15, 2002), Compilation of Non-target Plant Testing on ZeroTol® Broad Spectrum Algaecide /Fungicide and TerraCyte™ Broad Spectrum Algaecide /Fungicide

Other References

1. USEPA; Science review in support of registration of TerraCare (TerraCyte™); MRID Nos. 44714101, 42489201, 42545401, 42545402, 42542545403, 42545404, and data waiver requests for ecological toxicity studies, memo from Alan Reynolds, Entomologist, thru Freshteh Toghrol, Ph.D., to Anne Ball, Nov. 22, 1999, 31 pp.

2. USEPA; Science review of resubmitted product chemistry information, CSF, and revised data waiver requests for ecotox studies, (Reference nos 3. and 4);Memo from Alan Reynolds, Entomologist, thru Freshteh Toghrol, Ph.D., Senior Scientist to Anne Ball, Regulatory Action Leader, June 7, 2001.

3. Amy Roberts, Consultant for BioSafe Products Inc.: Letter to A. Ball providing supplemental information in response to DER dated 11/22/1999 concerning deficiencies regarding requirements set forth in guidelines OPP 151-13 and 151-15 concerning CSF, Five Batch Analysis in manufacturing process, Storage Stability, as well waivers for ecotoxicity studies, June 6, 2000, 6 pp.

4. Amy Roberts, Consultant for BioSafe Products Inc.: Letter to A. Ball responding to Alan Reynolds who requested additional information regarding information in June 6, 2000 letter response to DER cited above, March 2, 2001, 11 pp.

5. USEPA: Recommendations on Meeting Between Agency and TSG, Inc on 11/08/2001. Regarding Nontarget Organism Waiver Request Proposals from Amy Roberts (TSG) for TerraCyte™ (EPA File Symbol No. 70299-G and GreenCleen Granular (EPA File Symbol No. 70299-U); Review proposals from Amy Roberts (TSG) regarding waivers from the requirements of certain nontarget organism studies avian acute oral and dietary, freshwater fish, aquatic invertebrates, and plant toxicity) for TerraCyte™ (EPA File Symbol No. 70299-G) and GreenCleen Granular (EPA File Symbol No. 70299-U); memo from Russell S. Jones, Ph.D., to Anne Ball, January 30, 2002, 3 pp.

6. USEPA: Science Review in Support of Nontarget Organism Waiver Request for TerreCyte™ (EPA File Symbol No. 70299-G), MRID 45659001, memo from Russell S. Jones, Ph.D., to Anne Ball, June 26, 2002, 3 pp.

7. USEPA: Science Review: CSF dated April 15, 2002; Request of Waiver of Storage Stability Data Requirement (OPPTS 830.6317) with required label statements, for TerraCyte ™ (EPA File Symbol No. 70299-G); memo from Paul Zubkoff, Ph.D. Chemist, to Anne Ball, June 20, 2002, 2pp.

8. USEPA: Science Review of Product Chemistry: (Product Identity, CSF, Certified Limits, Manufacturing Process) for Technical Sodium Carbonate Peroxyhydrate, Solvay Interox, Inc. (EPA File Symbol No. 68660-I), MRID Nos. 44593002, 44995601, 44593001, memo from Paul Zubkoff, Ph.D.,Chemist, to Anne Ball, July 30, 2002, 4 pp.

9. USEPA: Letter from Sheryl Reilly, Ph.D., Branch Chief, BPB to Amy Roberts, TSG concerning label revisions. The letter included the statement: "The text you have proposed with respect to watering in the product...is satisfactory in obviating the problem of hazard to birds." (This is in the context of correcting label deficiencies for registration of TerraCyte™, EPA File Symbol No. 70299-G); April 19, 2002, 2 pp.

10. USEPA: Letter from Sheryl Reilly, Ph.D., Branch Chief, BPB to Amy Roberts, TSG, consultant for BioSafe Products, Inc, granting acceptance of request for waiver of data requirements, Avian Acute Oral Toxicity and Avian Dietary Test (OPP 154-6 and 154-7) in connection with registration of TerraCyte™. (EPA File Symbol No.70299-G). Reference is made to USEPA letter dated April 19, 2002 in which proposed label revisions regarding instructions for application of the product were noted as satisfactory "...in obviating the problem of hazard to birds."; August 09, 2002, 2 pp.