

June 14, 2006

Bob Pooler
USDA / AMS / T&M / NOP
Room 4008 - S, Ag Stop 0268
1400 Independence Ave, SW
Washington, DC 20250

Re: Sodium Carbonate Peroxyhydrate Petition
Originally received by USDA NOP 12-20-05

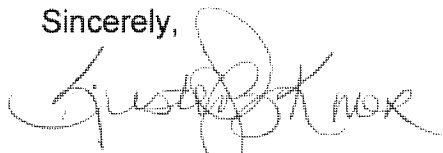
Dear Mr. Pooler:

Thank you very much for your quick response to our request to have the confidential business information contained within the above-referenced petition removed from the National Organic Program website. A good deal of this petition is comprised of proprietary lab testing results to support our product, and as we discussed, BioSafe Systems did not realize that any of this petition would be publicized.

Enclosed you will find a copy of the entire petition originally received at the NOP on December 20, 2005. I have gone through the petition and identified every page that should *not* be posted on the website for public viewing with a red "CONFIDENTIAL" stamp in the top right corner. These pages are all part of the lab test results or portions of the BRAD for Sodium carbonate peroxyhydrate that mention the test results and/or MRID numbers that correspond to specific tests.

If you require any further information, please do not hesitate to contact me at (860) 657-2211.

Sincerely,



Kristen Knox
Registration Manager

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2006 JUN 19 A 10:09

BiSafe Systems

P.O. Box 936
Glastonbury, CT 06033
Phone: 860.657.2211
Fax: 860.657.3388

E-mail: info@biosafesystems.com
Web: biosafesystems.com

BioSafe Systems Petition

And Support Documents

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2006 JUN 19 A 10: 09

2005 DEC 20 A 9: 20

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ITEM A

1. Synthetic substances allowed for use in organic crop production.

ITEM B.

1. Substance's common name:

Sodium Carbonate Peroxyhydrate. Also known as Sodium Percarbonate or commonly known as baking soda and peroxide.

2. The Manufacturer's name, address, and telephone number:

The manufacture of Sodium Carbonate Peroxyhydrate is Solvay Inc, 3333 Richmond Ave, Houston TX 77227. The name and address of the petitioner is BioSafe Systems, 36 Commerce St, Glastonbury, CT 06033

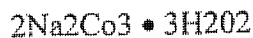
3. The intended or current use of the substance such as a pesticide, animal feed additive, processing aid, non-agricultural ingredient, sanitizer, or disinfectant:

The current use of the substance is for the control of algae in water gardens, ponds, lakes, and reservoirs as well as the control of invasive weeds such as moss, liverwort, and pearl wort.

4. The mode of action for Sodium Carbonate Peroxyhydrate (SPC) is through oxidation of the cell structure of algae and bryophytes. The SPC is a granular form of hydrogen peroxide that is a dry, white, granular substance with a particle size similar to table salt or sugar. The SPC goes into solution very readily and when applied in bodies of water that contain excess amounts of algae, it reacts with the proteins and enzymes that make up the cell structure of algae, and oxidizes the algae on contact. When SPC comes into contact with bryophyte organisms such as moss, liverwort, and pearl wort, it oxidizes the proteins and enzymes that makeup the cell structure of those plant pests, killing them on contact.

The source of the substance and a detailed description of the manufacturing process from the basic components to the final products:

SPC is a solid containing hydrogen peroxide bonded to a sodium carbonate (Soda ash) carrier. There are three molecules of H₂O₂ for every two molecules of sodium carbonate. This is expressed as

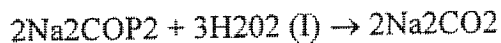


The manufacturing of SPC involves the mixing of two streams, sodium carbonate and hydrogen peroxide solutions, while heating in a fluid bed granulator. The

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water is evaporated to generate a dry, granular product. Approximately 155 excess sodium carbonate is present in the final product.



SPC is further formulated by mixing with sodium carbonate. The appropriate amount of SPC granules and Sodium Carbonate are metered into a stainless mixing tank. The ingredients are mixed for 20 minutes. After a thorough mixing, the product is bagged.

Description of Physical Conditions controlled during Manufacturing

The SPC and hydrogen peroxide are heated during mixing. No supplementary pH adjustment or control is necessary and no byproducts are produced. Fifty percent hydrogen peroxide is sprayed or applied onto soda ash particles. The soda ash receives the hydrogen peroxide and accepts a portion of the peroxide, which then converts the soda ash into the sodium peroxyhydrate compound. There are no waste products generated and all the components are used or consumed in the process.

Example: 50% soda ash by weight is combined with 50% hydrogen peroxide. The 50% hydrogen peroxide combines with the soda ash, is reduced in concentration from 50% to approximately 27%, and the balance of the peroxide breaks down into components of oxygen and water vapor.

- 6. A summary of any previous reviews by State or private certification programs or other organizations of the portioned substance.**

See Biopesticide Registration Action Document, HERA Document, and FAO Document.

- 7. Information regarding EPA, FDA, and state regulatory authority registrations, including registration numbers.**

See EPA Registration Documents

- 8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of the products that contain the petitioned substance.**

A. CAS Number- 15630-89-4

- 9. The substance's physical properties and chemical mode of action including:**

(a) Chemical interactions with other substances, especially substances used in organic production:

SPC is classified as an Oxidizer and will react with all compounds that typically sensitive to oxidation such as transitional metals such as copper, magnesium, iron. Typically SPC would not be used in conjunction with any product used in organic production. One would not mix a solution of SPC together with a copper solution or mix SPC with any fertilizer solution contain zinc, iron, or magnesium. SPC would react with biological inoculants, but again typical use patterns would not call for the biological inoculants to be mixed into a solution of SPC.

(b) Toxicity and environmental persistence:

SPC has been classified as a reduced risk pesticide by the US EPA and poses almost no concern with regard to environmental persistence. The hydrogen peroxide components of the SPC break down into oxygen and water and the soda ash component breaks down into carbon dioxide. The environmental persistence is estimated to be measured in minutes and not years.

See Acute Toxicity to Daphids, Acute Toxicity to Rainbow Trout, Wildlife International study, and the Hazleton studies.

(c) Environmental impacts from its use and manufacture:

The manufacturing process used to produce SPC is very clean and does not pose any threat to the environment. The soda ash receives the hydrogen peroxide and accepts a portion of the peroxide, which then converts the soda ash into the sodium peroxyhydrate compound. There are no wastes products generate and all the components are used and consumed in the process.

Example: 50% soda ash by weight is combined with 50% hydrogen peroxide. The 50% hydrogen peroxide combines with the soda ash, is reduced in concentration from 50% to approximately 27%, and the balance of the peroxide breaks down into components of oxygen and water vapor.

(d) Effects on human health:

See Biopesticide Registration Action Document, HERA Document, and FAO Document.

(e) Effects on soil organisms, crops, and livestock:

The application of SPC to the soil provides a limited impact on soil organisms. The initial application of SPC to the soil surface or by incorporation will result in a short-term reduction in soil organisms such as indigenous algae, bacteria, fungi, and bryophytes such as mosses and liverworts. The oxidizing power of the SPC will react with the enzymes and proteins that make up the cell walls and this

resulting oxidation reaction will kill these simple cell organisms. There has not been any evidence that the SPC compound has any other effect on more complex organism such as snails, worms, etc.

SPC applications made directly to plant material may result in significant necrosis of plant cell walls, which in turn causes phytotoxicity and may cause eventual death of the plant. Applications made to plant tissue by way off applying SPC granules directly to the foliar surfaces of a plant most often times result in marking a necrosis of the cell structure, but not always death of the plant.

See Biopesticide Registration Action Document, HERA Document, and FAO Document.

- 10. Safety information about the substance including a material safety data sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.**

See MSDS.

- 11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substances inclusion and or removal from the National List.**

The petitioner has not been able to find any research reviews by any outside parties that present contrasting positions concerning SPC.

- 12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:**

Sodium Carbonate Peroxyhydrate is a well-known compound that is formed by two well-known products used in organic agriculture: hydrogen peroxide and soda ash. Hydrogen peroxide is a compound that is already listed on the NOP list of approved compounds. Sodium carbonate, which is essentially the precursor to soda ash, is also a listed compound.

The resulting compound that is formed by spraying hydrogen peroxide onto soda ash produces a product that poses minimal threat to the environmental, or the health and welfare of the non-target organisms that come into contact with it. However, the potential benefits that can be derived from its use can offer the organic grower multitudes of advantages that include being used as an effective algaecide for water treatment, an effective herbicide for the control of algae, slime molds, mosses, and liverworts, as well as an effective biocide and sanitizer for the control of bacteria and fungi.

The products currently used in organic production include copper compounds to control bacteria, algae, and mosses. The copper compounds can bioaccumulate in the environment and also lead to mutational resistance issues. The oxidation power of SPC, does not allow for mutational resistance as previously outlined. SPC does not bioaccumulate in the environment.

In closing, the combined elements of low latent toxicity potential to both the environment and to humans and animals, coupled with chemical properties that do not allow the compound to bioaccumulate in the environment, and that the compound offers a substantial range of potential benefits to the organic industry that may and do include uses to control algae, bacteria, and fungi without posing environmental or safety issues and valid factors in approving SPC.

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U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Biopesticides and Pollution Prevention Division (7511C)
 1200 Pennsylvania Avenue NW
 Washington, DC 20460

EPA Reg. Number:

70299-4

Date of Issuance

5/30/03

Term of Issuance:

Unconditional

Name of Pesticide Product:

GreenClean Granular

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

BioSafe Systems LLC
 36 Commerce Street
 Glastonbury, CT 06033

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Make the following label change before you release the product for shipment:

Revise the EPA Registration Number to read, "EPA Reg. No. 70299-4"

Signature of Approving Official:

J. A.
 (See second page for signature)

Date:

5/30/03

EPA Form 8570-6


2005 DEC 20 A 9: 21

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2. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Sincerely,


Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention
Division (7511C)

Enclosures

GreenClean Granular

- * Algaecide
- * For use in Ponds, Lakes, Lagoons, Water Gardens, Ornamental Pools/Ponds, Ornamental Waterfalls, Fountains, Bird Baths, Irrigation Systems, Irrigation Ponds, Golf Course Ponds, Farm Ponds, Industrial/Commercial Ponds, Impounded Waters, Standing Water, Bilge Water, Non-Potable Water Reservoirs, Waterways, Conveyance Ditches, Canals, Laterals, Drainage Systems, Catch Basins, Flooded Areas, Sewage Systems, Drain Fields, Fire Ponds, Watering Tanks (Non-Potable Water), Storage Tanks, Water Collectors and Domestic/Commercial Non-Potable Waters
- * For use on Non-Painted: Floors, Walkways, Storage Areas, Patios, Decks, Railings, Roofs, Asphalt Shingles, Siding, Fiberglass, Boats, Piers, Docks, Stairs, Ramps, Ground Cover Mats, Weed Control Mats, Concrete, Brick, Tile, Slate, Granite, Statues/Monuments, Outdoor Furniture, Tennis Courts (non-grass), Nursery Yards, Shorelines, Gravel, Dirt Floors, Under Benches, and Other Non-Painted Surfaces
- * For indoor or outdoor horticultural, agricultural and commercial uses.

Active Ingredient:

Sodium Carbonate Peroxyhydrate*50.00%

Other Ingredients:.....50.00%

Total:100.00%

*Contains 27.60% Hydrogen Dioxide by weight.

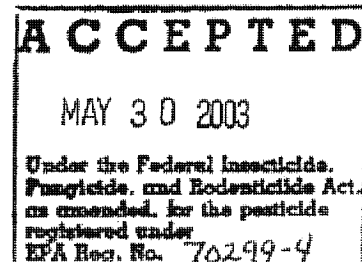
**KEEP OUT OF REACH OF CHILDREN
DANGER – PELIGRO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

EPA Registration No. (pending as EPA File Symbol 70299-U)
EPA Establishment No. 68660-TX-001

Manufactured by:
BioSafe Systems
36 Commerce Street
Glastonbury, CT 06033

Net Contents:



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2006 JUN 19 A 10:11

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • 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.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 for emergency medical treatment information.</p>	
NOTE TO PHYSICIAN	
<p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS – DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE): When handling wear protective eyewear (goggles or face shield) and chemical resistant gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply to treated, finished drinking water reservoirs or drinking water receptacles. 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 area. Do not apply this product or allow it to drift to crops where beneficials are part of an integrated pest management strategy.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. **Corrosive.** Do not bring in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted entry intervals (REI). The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

For enclosed environments:

There is a restricted entry of one (1) hour for this product when applied via spraying or foaming on hard surfaces in enclosed environments. PPE requirement for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, waterproof gloves and shoes plus socks.

There is a restricted entry of zero (0) hours for spreading, broadcasting, spot treatment, injection or other non-spraying or non-foaming application methods when used in enclosed environments.

For water treatment and applications in non-enclosed environments:

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

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

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

Apply GreenClean Granular to any water or surface sites except treated, finished drinking water reservoirs or drinking water receptacles.

* Some application sites include:

AGRICULTURAL

Farms, Sod Farms, and Irrigation Systems.

HORTICULTURAL & COMMERCIAL

Greenhouses, Nurseries, Golf Courses, Amusement Parks, Water Parks, Aquariums, Zoos, Botanical Gardens, National Parks, Recreational Areas, Non-Chlorinated Swimming Areas.

Raceways, Sports Facilities, Business Parks, Residential Developments, Indoor/Interiors, Malls, Hotels, Kennels, Cemeteries, Carwashes, Marinas, Boats, Docks, Garden Centers, Power Washing, Water Gardens, Landscapes, Municipalities, Waterways, Storm Waters, Drainage Systems, Impounded Waters, Wastewater, and Irrigation Systems.

WATER TREATMENT:

Use GreenClean Granular to treat, control, and prevent a broad spectrum of algae. Effects of treatment are immediately apparent (bubbling, bleaching/discoloration of algae, floating of dead organic matter). Waters treated with GreenClean Granular are permissible to be used without interruption.

DETERMINING WATER VOLUME

Measure length (L), width (W), and average depth (D) in feet (ft) or meters (m) and calculate volume using one of the following formulas:

Square/Rectangular:
 $L(ft) \times W(ft) \times D(ft) \times 7.5 = \text{Gallons}$
 $L(m) \times W(m) \times D(m) \times 1000 = \text{Liters}$

Circular/Elliptical:
 $L(ft) \times W(ft) \times D(ft) \times 5.9 = \text{Gallons}$
 $L(m) \times W(m) \times D(m) \times 786 = \text{Liters}$

1 acre-foot of water =

- water measuring 208.7 ft long x 208.7 ft wide x 1 ft deep
- 43,560 cubic feet
- 325,851 gallons
- 2,780,000 pounds

$$\frac{\text{Avg. Length (ft)} \times \text{Avg. Width (ft)} \times \text{Avg. Depth (ft)}}{43,560} = \text{acre-feet of water}$$

$$\frac{\text{Avg. Length (ft)} \times \text{Avg. Width (ft)}}{43,560} = \text{acres}$$

APPLICATION RATES

Full Water Volume Rates:

	HEAVY ALGAE GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR: Lg. Volume	90-500 pounds of GreenClean Granular per million gallons of water. - or - 30-170 pounds of GreenClean Granular per acre-foot of water.	9-50 pounds of GreenClean Granular per million gallons of water. - or - 3-17 pounds of GreenClean Granular per acre-foot of water.
For example: Lakes, ponds, lagoons		
GRANULAR: Sm. Volume	3-16 tablespoons of GreenClean Granular per 1000 gallons of water. (16 Tbs. = 1 Cup) (2 Cups = 1 lb.)	1-5 teaspoons of GreenClean Granular per 1000 gallons of water. (3 tsp. = 1 Tbs.)
For example: Indoor or outdoor water gardens, fountains, ornamental waterfalls		

Surface Water Volume Only Rates:

Use a "surface only" treatment for suspended algae and free-floating algae mats.

	HEAVY ALGAE GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR:	30-170 pounds of GreenClean Granular per acre-foot of water.	3-17 pounds of GreenClean Granular per acre-foot of water.
LIQUID:	<u>Solution Preparation:</u> Due to solubility limitations, use at least 1 gallon of water to fully dissolve each 0.5 pounds of GreenClean Granular. Dissolution of GreenClean Granular in cold water takes approximately 5 minutes.	
	<u>Treatment Rates:</u> Use the same rates as the granular application given above.	

GENERAL TREATMENT NOTES

- Control is most easily achieved when algae are not yet well established. Treat when growth first begins to appear. This is especially important in the prevention of clogged irrigation systems, pumps, filters etc.
- Apply early in the day under calm, sunny conditions, and when water temperatures are warm. Sunlight and higher temperatures both enhance GreenClean Granular activity.
- Apply in a manner that will insure even distribution of GreenClean Granular within the treatment area.
- Break up any heavy floating algae mats before or during application.
- Skim any dead algae and organic matter that rises to the water's surface after treatment. Allowing dead organics to sink and decay will provide a food source and additional nutrients that stimulate algae re-growth and further blooms.
- Use GreenClean Granular as an integral part of your water management system. If using in conjunction with other water additives (such as bacteria or enzymes), always apply GreenClean Granular first and wait several hours before adding any other products.
- Re-treat areas if re-growth begins to appear. Allow 48 hours between consecutive treatments.
- Maintain an algae free pond with GreenClean Granular maintenance rates at a frequency appropriate for your environmental conditions.
- In regions where water freezes in the winter, treatment with GreenClean Granular (including skimming) 6-8 weeks before expected freeze will help prevent masses of decaying algae under the ice cover.
- After application, do not allow undiluted granules to remain in an area where humans or animals are exposed.
- Non-target plants will suffer contact burn if undiluted granules are accidentally spilled on them. Do not apply in such a way that the concentrated product comes in contact with grass, ornamentals and other foliage.
- Do not tank mix with aquatic herbicides or algaecides containing copper or bromides. Always apply GreenClean Granular at least one day prior to the application of these products.
- 100 pounds of GreenClean Granular per million gallons of water = 4ppm of sodium.

EFFECTIVENESS FACTORS

- Effects of GreenClean Granular treatment are immediately apparent (bubbling, bleaching/discoloration of algae, floating dead organic matter).
- GreenClean Granular treatments are successful when contact of the pesticide is made with the algae.
- Liquid applications will not sink through the water column as readily as a granular application.
- When treating surface mats and blooms, it is possible that GreenClean Granular will not penetrate the water column below the infested area, and a second application is then required for treating any bottom growing algae.
- Apply more frequently during the summer months when water consumption and temperatures are high.

APPLICATION METHODS

In bodies of water where an aerator is available, and when treating the entire water volume, dose GreenClean Granular at the edges, or in the turbulence created while the aerator runs to facilitate rapid and adequate mixing.

SPREADING / BROADCASTING:

Broadcast GreenClean Granular with a mechanical spreader or by hand, directly on the water surface, from shore or from a properly equipped boat.

SPOT TREATMENT:

Apply GreenClean Granular directly over the infested area. Re-treatment is required when heavy growth occurs.

LIQUID:

Make a solution with GreenClean Granular (refer to liquid application rates). Spray this solution on the water surface from shore or a properly equipped boat. When using this method, the wind direction is important as well as the operation of the boat. If using a slurry, agitate constantly.

INJECTION:

Make a solution with GreenClean Granular (refer to liquid application rates). Inject this solution into the water via a piping system.

SUBSURFACE:

Place GreenClean Granular in burlap bags and drag through the water by means of a boat. Use granular application rates. Begin treatment along the shoreline, and proceed outward. The path of the boat shall insure an even distribution. Continue dragging until all GreenClean is dissolved.

SURFACE TREATMENT:

Use GreenClean Granular on all non-painted surfaces, to prevent and control algae, moss, liver worts, slime molds and their spores, and the odors and conditions that these organisms cause (such as the breeding grounds for pests such as shore flies and fungus gnats).

APPLICATION RATES

Ground/Surface Rates:

	HEAVY GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR:	2-3 pounds of GreenClean Granular per 1000 square feet of area. (1 lb. = 2 cups)	1-2 pounds of GreenClean Granular per 1000 square feet of area. (1 lb. = 2 cups)
	Make granular applications over a wet surface or activate with water immediately following application.	
LIQUID:	<u>Solution Preparation:</u> Due to solubility limitations, it is necessary to use at least 1 gallon of water to fully dissolve each 0.5 pounds of GreenClean Granular. Dissolution of GreenClean Granular in cold water takes approximately 5 minutes.	
	<u>Treatment Rates:</u> Use the same rates as the granular application given above. (For example: To treat a heavy algae infestation on a 1000 square foot area, dissolve 2 pounds of GreenClean Granular in 4 gallons of water – up to 3 pounds of GreenClean Granular in 6 gallons of water).	
FOAM:	<u>Solution Preparation:</u> Follow the Liquid solution preparation instructions above. Add 2.0 - 5.0 fluid ounces of an alkaline-based foam, such as BioSafe Systems "Alk-A-Foam", per gallon of finished solution.	
	<u>Treatment Rates:</u> Use the same rates as the granular/liquid application given above.	

GENERAL TREATMENT NOTES

- Control is most easily achieved when growth is not yet well established. Treat when growth first begins to appear.
- Apply in a manner that will insure even distribution of GreenClean Granular within the treatment area.
- GreenClean Granular is water activated. Watering before application is preferred over misting after application because it prevents over watering leading to a reduced effectiveness.
- Use GreenClean Granular in conjunction with ZeroTol® Broad Spectrum Algaecide/Fungicide and TerraCyte® as part of a comprehensive cleanliness/treatment program.
- When applying GreenClean Granular to soil, gravel or other similar media, incorporate the application of GreenClean Granular into the first inch of substrate for optimum effectiveness.
- To maintain clean surfaces, apply GreenClean Granular at maintenance rates every 5-7 days or as needed to control new or established conditions.
- After application, do not allow undiluted granules to remain in an area where humans or animals are exposed.

- Non-target plants will suffer contact burn if undiluted granules are accidentally spilled on them. Do not apply in such a way that the concentrated product comes in contact with grass, ornamentals and other foliage.
- Do not tank mix with aquatic herbicides or algaecides containing copper or bromides. Always apply GreenClean Granular at least one day prior to the application of these products.

APPLICATION METHODS

SPREADING / BROADCASTING:

Broadcast GreenClean Granular with a mechanical spreader or by hand. A lawn spreader or any other applicator that will insure uniform coverage is acceptable.

SPOT TREATMENT:

Apply GreenClean Granular directly over the infested area. Re-treatment is required when heavy growth occurs.

LIQUID:

Make a solution with GreenClean Granular (refer to liquid application rates). Spray this solution on the desired treatment surface.

FOAM:

Make a solution with GreenClean Granular (refer to foam application rates). Spray this solution on the desired treatment surface. Use a foamer, such as the BioSafe BioFoamer, to apply.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.**

GreenClean® Pro

Granular Algaecide

* For indoor or outdoor uses.

Active Ingredient:

Sodium Carbonate Peroxyhydrate* 85.00%
 Other Ingredients:..... 15.00%
 Total: 100.00%

*Contains 27.60% Hydrogen Dioxide by weight.

KEEP OUT OF REACH OF CHILDREN
DANGER – PELIGRO

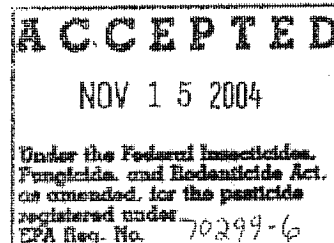
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • 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. You may also contact 1-800-222-1222 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Registration No. 70299-6
 EPA Establishment No. 68660-TX-001

Manufactured by:
 BioSafe Systems
 35 Commerce Street
 Glastonbury, CT 06033

Net Contents:



2005 DEC 20 A 9 21

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 USDA NATIONAL
 ORGANIC PROGRAM

GreenClean® Pro Granular Algaecide; EPA Reg. No. 70299-6
 Label amendment (fast track) to add new uses
 Label version (8) dated November 5, 2004
 Page 1 of 8

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS – DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE): When handling wear protective eyewear (goggles or face shield) and chemical resistant gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds. Do not contaminate water when disposing of equipment washwaters or rinsate. 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 area. Do not apply this product or allow it to drift to crops where beneficials are part of an integrated pest management strategy.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not bring in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Avoid use near shallow waterbody margins during amphibian breeding seasons

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted entry intervals (REI). The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

For enclosed environments:

There is a restricted entry of one (1) hour for this product when applied via spraying or foaming on hard surfaces in enclosed environments. PPE requirement for early entry to treated areas that is

permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, waterproof gloves and shoes plus socks.

There is a restricted entry of zero (0) hours for spreading, broadcasting, spot treatment, injection or other non-spraying or non-foaming application methods when used in enclosed environments.

For water treatment and applications in non-enclosed environments:

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

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

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

Apply GreenClean Pro Granular Algaecide to any listed water or surface sites.

* Application sites include:

Farms, Sod Farms, Aquaculture Production Facilities, Fisheries, Hatcheries, Greenhouses, Nurseries, Golf Courses, Amusement Parks, Water Parks, Aquariums, Zoos, Botanical Gardens, National Parks, Recreational Areas, Non-Chlorinated Swimming Areas, Raceways, Sports Facilities, Business Parks, Indoor/Interiors, Malls, Hotels, Kennels, Cemeteries, Carwashes, Marinas, Boats, Docks, Garden Centers, Power Washing, Water Gardens, Landscapes, Municipalities, Reservoirs, Waterways, Storm Waters, Drainage Systems, Impounded Waters, and Wastewater.

* Application surfaces include:

WATER SURFACES

Ponds, Lakes, Lagoons, Fish Ponds, Stock Tanks, Golf Course Ponds, Industrial/Commercial Ponds, Impounded Waters, Standing Water, Bilge Water, Reservoir Water, Waterways, Conveyance Ditches, Canals, Laterals, Drainage Systems, Irrigation Systems, Irrigation Ponds, Catch Basins, Flooded Areas, Sewage Systems, Drain Fields, Fire Ponds, Watering Tanks, Storage Tanks, Water Collectors and Domestic/Commercial Waters

NON-PAINTED SURFACES

Floors, Walkways, Storage Areas, Patios, Decks, Railings, Roofs, Asphalt Shingles, Siding, Fiberglass, Boats, Piers, Docks, Stairs, Ramps, Ground Cover Mats, Weed Control Mats, Concrete, Brick, Tile, Slate, Granite, Statues/Monuments, Outdoor Furniture, Tennis Courts (non-grass), Nursery Yards, Shorelines, Gravel, Dirt Floors, Under Benches, and Other Non-Painted Surfaces

WATER TREATMENT:

Use GreenClean Pro Granular Algaecide to treat, control, and prevent a broad spectrum of algae. Effects of treatment are immediately apparent (bubbling, bleaching/discoloration of algae, floating of dead organic matter). Waters treated with GreenClean Pro Granular Algaecide are permissible to be used without interruption.

DETERMINING WATER VOLUME

Measure length (L), width (W), and average depth (D) in feet (ft) or meters (m) and calculate volume using one of the following formulas:

Square/Rectangular:

$L(ft) \times W(ft) \times D(ft) \times 7.5 = \text{Gallons}$

$L(m) \times W(m) \times D(m) \times 1000 = \text{Liters}$

Circular/Elliptical:

$L(ft) \times W(ft) \times D(ft) \times 5.9 = \text{Gallons}$

$L(m) \times W(m) \times D(m) \times 786 = \text{Liters}$

1 acre-foot of water =

- water measuring 208.7 ft long x 208.7 ft wide x 1 ft deep
- 43,560 cubic feet
- 325,851 gallons
- 2,780,000 pounds

$\frac{\text{Avg. Length (ft)} \times \text{Avg. Width (ft)} \times \text{Avg. Depth (ft)}}{43,560} = \text{acre-feet of water}$

$\frac{\text{Avg. Length (ft)} \times \text{Avg. Width (ft)}}{43,560} = \text{acres}$

APPLICATION RATES

Full Water Volume Rates:

	HEAVY ALGAE GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR: Lg. Volume	50-250 pounds of GreenClean Pro Granular Algaecide per million gallons of water. - or - 20-90 pounds of GreenClean Pro Granular Algaecide per acre-foot of water.	5-25 pounds of GreenClean Pro Granular Algaecide per million gallons of water. - or - 2-9 pounds of GreenClean Pro Granular Algaecide per acre-foot of water.
For example: Lakes, ponds, lagoons		
GRANULAR: Sm. Volume	2-10 tablespoons of GreenClean Pro Granular Algaecide per 1000 gallons of water. (16 Tbs. = 1 Cup) (2 Cups = 1 lb.)	1-3 teaspoons of GreenClean Pro Granular Algaecide per 1000 gallons of water. (3 tsp. = 1 Tbs.)
For example: indoor or outdoor water gardens, fountains, ornamental waterfalls		

Surface Water Volume Only Rates:

Use a "surface only" treatment for suspended algae and free-floating algae mats.

	HEAVY ALGAE GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR:	20-90 pounds of GreenClean Pro Granular Algaecide per acre-foot of water.	2-9 pounds of GreenClean Pro Granular Algaecide per acre-foot of water.
LIQUID:	Solution Preparation: Due to solubility limitations, use at least 1 gallon of water to fully dissolve each 0.5 pounds of GreenClean Pro Granular Algaecide.	

	Dissolution of GreenClean Pro Granular Algaecide in cold water takes approximately 5 minutes.
	<u>Treatment Rates:</u>
	Use the same rates as the granular application given above.

GENERAL TREATMENT NOTES

- Control is most easily achieved when algae are not yet well established. Treat when growth first begins to appear. This is especially important in the prevention of clogged irrigation systems, pumps, filters etc.
- Apply early in the day under calm, sunny conditions, and when water temperatures are warm. Sunlight and higher temperatures both enhance GreenClean Pro Granular Algaecide activity.
- Apply in a manner that will insure even distribution of GreenClean Pro Granular Algaecide within the treatment area.
- Break up any heavy floating algae mats before or during application.
- Skim any dead algae and organic matter that rises to the water's surface after treatment. Allowing dead organics to sink and decay will provide a food source and additional nutrients that stimulate algae re-growth and further blooms.
- Use GreenClean Pro Granular Algaecide as an integral part of your water management system. If using in conjunction with other water additives (such as bacteria or enzymes), always apply GreenClean Pro Granular Algaecide first and wait several hours before adding any other products.
- Re-treat areas if re-growth begins to appear. Allow 48 hours between consecutive treatments.
- Maintain an algae free pond with GreenClean Pro Granular Algaecide maintenance rates at a frequency appropriate for your environmental conditions.
- In regions where water freezes in the winter, treatment with GreenClean Pro Granular Algaecide (including skimming) 6-8 weeks before expected freeze will help prevent masses of decaying algae under the ice cover.
- After application, do not allow undiluted granules to remain in an area where humans or animals are exposed.
- Non-target plants will suffer contact burn if undiluted granules are accidentally spilled on them. Do not apply in such a way that the concentrated product comes in contact with grass, ornamentals and other foliage.
- Do not tank mix with aquatic herbicides or algaecides containing copper or bromides. Always apply GreenClean Pro Granular Algaecide at least one day prior to the application of these products.
- 100 pounds of GreenClean Pro Granular Algaecide per million gallons of water = 4ppm of sodium.

EFFECTIVENESS FACTORS

- Effects of GreenClean Pro Granular Algaecide treatment are immediately apparent (bubbling, bleaching/discoloration of algae, floating dead organic matter).
- GreenClean Pro Granular Algaecide treatments are successful when contact of the pesticide is made with the algae.
- Liquid applications will not sink through the water column as readily as a granular application.
- When treating surface mats and blooms, it is possible that GreenClean Pro Granular Algaecide will not penetrate the water column below the infested area, and a second application is then required for treating any bottom growing algae.
- Apply more frequently during the summer months when water consumption and temperatures are high.

APPLICATION METHODS

In bodies of water where an aerator is available, and when treating the entire water volume, dose GreenClean Pro Granular Algaecide at the edges, or in the turbulence created while the aerator runs to facilitate rapid and adequate mixing.

SPREADING / BROADCASTING:

Broadcast GreenClean Pro Granular Algaecide with a mechanical spreader or by hand, directly on the water surface, from shore or from a properly equipped boat.

SPOT TREATMENT:

Apply GreenClean Pro Granular Algaecide directly over the infested area. Re-treatment is required when heavy growth occurs.

LIQUID:

Make a solution with GreenClean Pro Granular Algaecide (refer to liquid application rates). Spray this solution on the water surface from shore or a properly equipped boat. When using this method, the wind direction is important as well as the operation of the boat. If using a slurry, agitate constantly.

INJECTION:

Make a solution with GreenClean Pro Granular Algaecide (refer to liquid application rates). Inject this solution into the water via a piping system.

SUBSURFACE:

Place GreenClean Pro Granular Algaecide in burlap bags and drag through the water by means of a boat. Use granular application rates. Begin treatment along the shoreline, and proceed outward. The path of the boat shall insure an even distribution. Continue dragging until all GreenClean Pro Granular Algaecide is dissolved.

SURFACE TREATMENT:

Use GreenClean Pro Granular Algaecide on all listed non-painted surfaces, to prevent and control algae, moss, slime molds and their spores, and the odors and conditions that these organisms cause (such as the breeding grounds for pests such as shore flies and fungus gnats).

APPLICATION RATES

Ground/Surface Rates:

	HEAVY GROWTH	LOW ALGAE GROWTH / MAINTENANCE
GRANULAR:	1-2 pounds of GreenClean Pro Granular Algaecide per 1000 square feet of area.	0.5-1 pounds of GreenClean Pro Granular Algaecide per 1000 square feet of area.
	(1 lb. = 2 cups)	(1 lb. = 2 cups)
	Make granular applications over a wet surface or activate with water immediately following application.	
LIQUID:	<u>Solution Preparation:</u>	
	Due to solubility limitations, it is necessary to use at least 1 gallon of water to fully dissolve each 0.5 pounds of GreenClean Pro Granular Algaecide.	
	Dissolution of GreenClean Pro Granular Algaecide in cold water takes approximately 5 minutes.	
	<u>Treatment Rates:</u>	
	Use the same rates as the granular application given above.	

FOAM:	<u>Solution Preparation:</u>
	Follow the Liquid solution preparation instructions above.
	Add 2.0 - 5.0 fluid ounces of an alkaline-based foam, such as BioSafe Systems "Alk-A-Foam", per gallon of finished solution.
	<u>Treatment Rates:</u>
	Use the same rates as the granular/liquid application given above.

GENERAL TREATMENT NOTES

- Control is most easily achieved when growth is not yet well established. Treat when growth first begins to appear.
- Apply in a manner that will insure even distribution of GreenClean Pro Granular Algaecide within the treatment area.
- GreenClean Pro Granular Algaecide is water activated. Watering before application is preferred over misting after application because it prevents over watering leading to a reduced effectiveness.
- Use GreenClean Pro Granular Algaecide in conjunction with ZeroTol® Broad Spectrum Algaecide/Fungicide and TerraCyte® as part of a comprehensive cleanliness/treatment program.
- When applying GreenClean Pro Granular Algaecide to soil, gravel or other similar media, incorporate the application of GreenClean Pro Granular Algaecide into the first inch of substrate for optimum effectiveness.
- To maintain clean surfaces, apply GreenClean Pro Granular Algaecide at maintenance rates every 5-7 days or as needed to control new or established conditions.
- After application, do not allow undiluted granules to remain in an area where humans or animals are exposed.
- Non-target plants will suffer contact burn if undiluted granules are accidentally spilled on them. Do not apply in such a way that the concentrated product comes in contact with grass, ornamentals and other foliage.
- Do not tank mix with aquatic herbicides or algaecides containing copper or bromides. Always apply GreenClean Pro Granular Algaecide at least one day prior to the application of these products.

APPLICATION METHODS

SPREADING / BROADCASTING:

Broadcast GreenClean Pro Granular Algaecide with a mechanical spreader or by hand. A lawn spreader or any other applicator that will insure uniform coverage is acceptable.

SPOT TREATMENT:

Apply GreenClean Pro Granular Algaecide directly over the infested area. Re-treatment is required when heavy growth occurs.

LIQUID:

Make a solution with GreenClean Pro Granular Algaecide (refer to liquid application rates). Spray this solution on the desired treatment surface.

FOAM:

Make a solution with GreenClean Pro Granular Algaecide (refer to foam application rates). Spray this solution on the desired treatment surface. Use a foamer, such as the BioSafe BioFoamer, to apply.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

-10299-3

TerraCyte™

MASTER LABEL

Sublabel A:	Agriculture, Horticulture, and Commercial
Sublabel B:	Residential

Active Ingredient:

Sodium Carbonate Peroxyhydrate* 34.00%

Other Ingredients: 66.00%

Total: 100.00%

*Contains 27.60% Hydrogen Dioxide by weight.

EPA Registration No. 70299-3

EPA Establishment No. 68660-TX-001

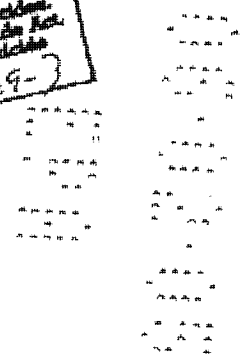
Manufactured by:

BioSafe Systems

36 Commerce Street

Glastonbury, CT 06033

ACCEPTED
 SEP 01 2005
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No. 70299-3



2005 DEC 20 A 9 22

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Sublabel A: Agriculture, Horticulture, and Commercial

TerraCyte™

- Algaeicide
- Granular Algaeicide/Fungicide (for Ornamental Plants and Turf).
- A treatment for the prevention and control of horticultural diseases in or around commercial greenhouses, garden centers, terrestrial landscapes, nurseries, interiorscapes and golf courses.
- For indoor and outdoor horticultural, agricultural and commercial uses.

Active Ingredient:

Sodium Carbonate Peroxyhydrate* 34.00%

Other Ingredients:..... 66.00%

Total: 100.00%

*Contains 27.60% Hydrogen Dioxide by weight.

**KEEP OUT OF REACH OF CHILDREN
DANGER – PELIGRO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • 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. You may also contact 1-800-222-1222 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Registration No. 70299-3
EPA Establishment No. 68660-TX-001

Manufactured by: BioSafe Systems
36 Commerce Street
Glastonbury, CT 06033

Net Contents:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS - DANGER: Corrosive: Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE): When handling wear protective eyewear (goggles or face shield) and chemical resistant gloves. Applicators and handlers must wear coveralls over long-sleeved shirt, long pants, and chemical resistant footwear plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply to treated, finished drinking water reservoirs or drinking water receptacles. 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 area. Do not apply this product or allow it to drift to crops where beneficials are part of an integrated pest management strategy.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. **Corrosive.** Do not bring in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted entry intervals (REI). The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE requirement for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, waterproof gloves and shoes plus socks.

Non-Agricultural Use Requirements

The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until dusts have settled and activating water sprays have dried.

Application Directions

Treats, controls and prevents algae, bacteria, fungi and moss on ornamental plants and turf. Organisms controlled include Algae, Moss, Liver Worts, Slime Molds and their spores.

For use in greenhouses, storage areas and nursery yards:

Spread TerraCyte on walkways, under benches, on gravel and dirt floors, weed control mats and hard surfaces to prevent and control algae, bacteria, fungi, moss, slime molds, and the odors and conditions that these organisms can cause.

TerraCyte is activated by moisture, so applications must either be made over wet surfaces or must be watered immediately after spreading. To treat areas that are already heavily contaminated with algae, slime molds and scum, apply 4 lbs. of TerraCyte per 1000 square feet. Make subsequent preventative treatments by applying 2 - 4 lbs. of TerraCyte per 1000 square feet. Repeat applications every 5 to 7 days to control new or established conditions. Optimum treatment time is early morning or late afternoon. If applied to a dry surface, activate TerraCyte with water immediately following application.

Apply TerraCyte using a lawn spreader or any other applicator that will ensure uniform coverage. Calibrate spreaders for accurate output. The following settings are approximations for calibration for specific makes of spreaders.

Make of Spreader	Rate per 1000 sq. ft.	Spreader Settings	Spreader Width
CYCLONE	2 lbs.	4	6 ½ feet
	4 lbs.	6	6 ½ feet
SCOTT'S	2 lbs.	4	20 inches
	4 lbs.	7	20 inches

For use on soil surfaces containing growing plants:

Apply TerraCyte to soil surfaces for the prevention and control Algae, Moss, Liver Worts; Slime Molds and their spores. Use on container, bench, and planters for ornamental plants.

- Plant beds and bench areas - TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For heavily contaminated beds or benches, distribute 15 lbs uniformly over 1000 square feet of bed or bench area.

For follow-up or preventative applications, apply 5 lbs of TerraCyte per 1000 square feet on a weekly to bi-weekly basis.

- Mature Potted plants - TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For curative applications, evenly distribute .08 oz or 1/3 teaspoon of TerraCyte over the surface of 8-inch pots; 0.13 oz or 1/2 teaspoon of TerraCyte over the surface of 10-inch pots.

For follow-up and preventative applications, evenly distribute 0.026 oz. or 1/8 teaspoon of TerraCyte over the surface of 8-inch pots; 0.04 oz. or 1/6 teaspoon of TerraCyte over the surface of 10-inch pots. Repeat on a bi-weekly basis.

Seedlings or recent transplants – First test the plants for sensitivity to TerraCyte. TerraCyte increases pH by 0.5 pH unit. TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For curative applications, evenly distribute 10 – 15 lbs TerraCyte over 1000 square feet (1/2 to 1 teaspoon per square foot). Rinse TerraCyte granules thoroughly from foliage.

For follow-up and preventative applications, evenly distribute 6 lbs of TerraCyte per 1000 square feet (1/8 teaspoon per square foot). Rinse TerraCyte granules thoroughly from foliage. Repeat on a weekly to bi-weekly basis.

For use on turf grasses:

Apply TerraCyte to **well-established** golf course fairways, greens and tees for the prevention and control of Algae, Moss, Slime Molds and their spores. TerraCyte is activated by moisture and must be watered in after application.

The best time to apply TerraCyte for curative applications is either the spring or fall when temperatures are 50°F or above. Apply TerraCyte to well-established golf course fairways, greens and tees at a rate of 8 pounds per 1,000 square feet. When using a drop spreader, uniform coverage is essential for best results (see Tables 2 and 3 for spreader settings). Take caution to avoid overlap. If applying on greens, always open up the spreader off of the green and on the collar.

Activate TerraCyte with water immediately following application (see Table 1). Water to recommended amount or for at least 10 minutes.

Make subsequent applications by applying 2 - 4 pounds of TerraCyte per 1,000 square feet. Repeat applications as needed. Apply TerraCyte on consecutive days. The optimum application time is early morning or late afternoon.

During summer months, use TerraCyte for spot treatments. Spoon-feed TerraCyte on infected areas.

Table 1 – Application Rate

Application Rate Lbs./1,000 ft ²	Amount of water (inches) applied by sprinkler Irrigation
2	1/10"
4	1/10"
6	1/10"
8	1/8"

Table 2 – Scotts and Prizelawn Drop Spreader Settings

Scotts and Prizelawn	
----------------------	--

Rate in Lbs. / 1,000 ft ²	Spreader Setting*
2	N/a
4	2
6	2 1/2
8	3

* Use of disbursement bars

Table 3 – Gandy Drop Spreader Settings

Gandy Rate in Lbs. / 1,000 ft ²	Spreader Setting* @ 4 mph	Spreader Setting @ 6 mph
2	12	14
4	16	19
6	19	22
8	21	24

* Use of disbursement bars

NOTICE: A broad spectrum of plant and turf species have been found to be tolerant to TerraCyte; however, due to the large number of species and varieties of ornamental plants and turf, it is impossible to test every one for tolerance to TerraCyte. Neither the manufacturer nor the seller has determined whether or not TerraCyte can be used on all known species of plants and turf. Therefore, test a small section at labeled rates for phytotoxicity prior to widespread use. Repeat applications can raise soil pH to levels that can adversely affect plant growth. TerraCyte is incompatible with metal-based fungicides and fertilizers. Do not apply TerraCyte within three days of metal-based fungicides or fertilizer applications.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original containers in dry conditions in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated (>50°C) in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur. Do not store near incompatible materials such as reducing agents, combustible materials, organic materials or acids.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinses (or equivalent). Then offer for recycling or dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions

given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR
MERCHANTIBILITY IS MADE.

Sublabel B: Residential

TerraCyte™

- * Algaecide
- * Granular Algaecide/Fungicide (for Ornamental Plants and Turf in or around the home and for residential lawns).
- * A treatment for the prevention and control of horticultural diseases around residential areas.
- * For residential use.

Active ingredient:
 Sodium Carbonate Peroxyhydrate* 34.00%
 Other Ingredients: 66.00%
Total: 100.00%

*Contains 27.60% Hydrogen Dioxide by weight.

**KEEP OUT OF REACH OF CHILDREN
 DANGER – PELIGRO**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 or doctor. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • 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. You may also contact 1-800-222-1222 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

EPA Registration No. 70299-3
 EPA Establishment No. 68860-TX-001

Manufactured by: **BioSafe Systems**
 36 Commerce Street
 Glastonbury, CT 06033

Net Contents:

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TerraCyte™; EPA Reg. No. 70299-3
 MASTER LABEL - Version (11) dated May 26, 2005
 Page 5 of 12

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMAN AND DOMESTIC ANIMALS - DANGER: Corrosive. Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) and waterproof gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. When prolonged or repeated contact may occur, use chemically resistant gloves and full body clothing.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate. Do not apply to treated, finished drinking water reservoirs or drinking water receptacles.

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. **Corrosive.** Mix only with water in accordance with label instructions. Do not bring in contact with other pesticides, cleaners or oxidative agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Application Directions

Treats, controls and prevents algae, bacteria, fungi and moss on ornamental plants and turf. Organisms controlled include Algae, Moss, Liver Worts, Slime Molds and their spores.

For use in home greenhouses, storage areas and yards:

Spread TerraCyte on walkways, under benches, on gravel and dirt floors, weed control mats and hard surfaces to prevent and control algae, bacteria, fungi, moss, slime molds, and the odors and conditions that these organisms can cause.

TerraCyte is activated by moisture, so applications must either be made over wet surfaces or must be watered immediately after spreading. To treat areas that are already heavily contaminated with algae, slime molds and scum, apply 4 lbs. of TerraCyte per 1000 square feet. Make subsequent preventative treatments by applying 2 - 4 lbs. of TerraCyte per 1000 square feet. Repeat applications every 5 to 7 days to control new or established conditions. Optimum treatment time is early morning or late afternoon. If applied to a dry surface, activate TerraCyte with water immediately following application.

Apply TerraCyte using a lawn spreader or any other applicator that will ensure uniform coverage. Calibrate spreaders for accurate output. The following settings are approximations for calibration for specific makes of spreaders.

Make of Spreader	Rate per 1000 sq. ft.	Spreader Settings	Spreader Width
CYCLONE	2 lbs.	4	6 ½ feet
	4 lbs.	6	6 ½ feet
SCOTT'S	2 lbs.	4	20 inches
	4 lbs.	7	20 inches

For use on soil surfaces containing growing plants:

Apply TerraCyte to soil surfaces for the prevention and control Algae, Moss, Liver Worts, Slime Molds and their spores. Use on container, bench, and planters for ornamental plants.

- **Plant beds and bench areas** - TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For heavily contaminated beds or benches, distribute 1 teaspoon uniformly per square foot of bed or bench area.

For follow-up or preventative applications, apply 1/8 teaspoon of TerraCyte per square foot on a weekly to bi-weekly basis.

- **Mature Potted plants** - TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For curative applications, evenly distribute .08 oz or 1/3 teaspoon of TerraCyte over the surface of 8-inch pots; 0.13 oz or 1/2 teaspoon of TerraCyte over the surface of 10-inch pots.

For follow-up and preventative applications, evenly distribute 0.026 oz. or 1/8 teaspoon of TerraCyte over the surface of 8-inch pots; 0.04 oz. or 1/6 teaspoon of TerraCyte over the surface of 10-inch pots. Repeat on a bi-weekly basis.

- **Seedlings or recent transplants** - First test the plants for sensitivity to TerraCyte. TerraCyte increases pH by 0.5 pH unit. TerraCyte is activated by moisture. Applications must be made over wet surfaces. Thoroughly water soil surface to be treated.

For curative applications, evenly distribute 1/2 to 1 teaspoon per square foot. Rinse TerraCyte granules thoroughly from foliage.

For follow-up and preventative applications, evenly distribute 1/8 teaspoon per square foot. Rinse TerraCyte granules thoroughly from foliage. Repeat on a weekly to bi-weekly basis.

For use on turf grasses:

Apply TerraCyte to well-established lawns for the prevention and control of Algae, Moss, Slime Molds and their spores. TerraCyte is activated by moisture and must be watered in after application.

The best time to apply TerraCyte for curative applications is either the spring or fall when temperatures are 50°F or above. Apply TerraCyte to well-established lawns a rate of 8 pounds per 1,000 square feet. When using a drop spreader, uniform coverage is essential for best results (see Tables 2 and 3 for spreader settings). Take caution to avoid overlap.

Activate TerraCyte with water immediately following application (see Table 1). Water to recommended amount or for at least 10 minutes.

Make subsequent applications by applying 2 - 4 pounds of TerraCyte per 1,000 square feet. Repeat applications as needed. Apply TerraCyte on consecutive days. The optimum application time is early morning or late afternoon. During summer months, use TerraCyte for spot treatments. Spoon-feed TerraCyte on infected areas.

Table 1 – Application Rate

Application Rate Lbs./1,000 ft ²	Amount of water (inches) applied by sprinkler irrigation
2	1/10"
4	1/10"
6	1/10"
8	1/8"

Table 2 – Scotts and Prizelawn Drop Spreader Settings

Scotts and Prizelawn Rate in Lbs. / 1,000 ft ²	Spreader Setting*
2	N/a
4	2
6	2 ½
8	3

* Use of disbursement bars

Table 3 – Gandy Drop Spreader Settings

Gandy Rate in Lbs. / 1,000 ft ²	Spreader Setting* @ 4 mph	Spreader Setting @ 6 mph
2	12	14
4	16	19
6	19	22
8	21	24

* Use of disbursement bars

NOTICE: A broad spectrum of plant and turf species have been found to be tolerant to TerraCyte; however, due to the large number of species and varieties of ornamental plants and turf, it is impossible to test every one for tolerance to TerraCyte. Neither the manufacturer nor the seller has determined whether or not TerraCyte can be used on all known species of plants and turf. Therefore, test a small section at labeled rates for phytotoxicity prior to widespread use. Repeat applications can raise soil pH to levels that can adversely affect plant growth. TerraCyte is incompatible with metal-based fungicides and fertilizers. Do not apply TerraCyte within three days of metal-based fungicides or fertilizer applications.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

STORAGE: Store in original containers in a cool, well-ventilated area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water.

DISPOSAL: If empty – Do not reuse this container. Place in trash or offer for recycling if available. If partly filled – Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

Sodium carbonate peroxyhydrate
Biopesticides Registration Action Document

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Sodium Carbonate Peroxyhydrate
(PC Code 128860)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
September 16, 2002

2005 DEC 20 A 9 22

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TABLE OF CONTENTS

Sodium Carbonate Peroxyhydrate BRAD
(PC Code 128860)

- I. EXECUTIVE SUMMARY
 - A. IDENTITY
 - B. USE
 - C. RISK ASSESSMENT
 - 1. Human Health Risk Assessment
 - 2. Ecological Risk Assessment
 - D. DATA GAPS/LABELING RESTRICTIONS

- II. OVERVIEW
 - A. ACTIVE INGREDIENT OVERVIEW
 - B. USE PROFILE
 - C. ESTIMATED USAGE
 - D. DATA REQUIREMENTS
 - E. REGULATORY HISTORY
 - F. CLASSIFICATION
 - G. FOOD CLEARANCES/TOLERANCES

- III. SCIENCE ASSESSMENT
 - A. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT
 - 1. Product Identity and Mode of Action
 - 2. Physical And Chemical Properties Assessment
 - B. HUMAN HEALTH ASSESSMENT
 - 1. Toxicology Assessment
 - 2. Dose Response Assessment
 - 3. Aggregate Exposure and Risk Characterization
 - 4. Occupational, Residential, School, and Day care Exposure and Risk Characterization
 - 5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children
 - 6. Aggregate Exposure from Multiple Routes Including Oral, Dermal, and Inhalation
 - 7. Cumulative Effects
 - 8. Risk Characterization
 - C. ENVIRONMENTAL ASSESSMENT
 - 1. Ecological Effects Hazard Assessment
 - 2. Environmental Fate and Ground Water Data
 - 3. Ecological Exposure and Risk Characterization

D. EFFICACY DATA

IV. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

B. REGULATORY POSITION

1. Unconditional Registration
2. Tolerances for food uses
3. CODEX Harmonization
4. Non-food Re/Registrations
5. Risk Mitigation
6. Endangered Species Statement

C. LABELING RATIONALE

1. Human Health Hazard
2. Environmental Hazards Labeling
3. Application Rate

D. LABELING

V. ACTIONS REQUIRED BY REGISTRANTS

VI. DATA GAPS

VII. APPENDIX A

VIII. REFERENCES

BIOPESTICIDE REGULATORY ACTION DOCUMENT TEAM

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Microbiologist, Team Leader
Entomologist
Chemist
Biologist
Biologist, Regulatory Action Leader

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 I ecological studies for 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: $2\text{Na}_2\text{CO}_3 \cdot 3\text{H}_2\text{O}_2$

CAS number: 15630-894

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

OPP Chemical Code: 128860

Basic Manufacturer: Solvay Interlox 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 Interlox, 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°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 Interlox, 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 ($2 \text{ Na}_2\text{CO}_3 \cdot 3\text{H}_2\text{O}_2$) 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

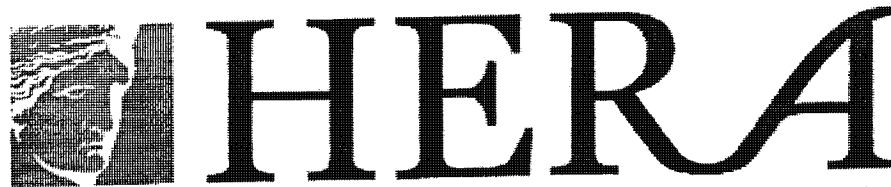
The active ingredient, sodium carbonate peroxyhydrate, is a free flowing, white crystalline powder having the chemical formula $2 \text{Na}_2 \text{CO}_3 \cdot 3 \text{H}_2 \text{O}_2$. Technical sodium carbonate peroxyhydrate consists of 85 % of the active ingredient, sodium carbonate peroxyhydrate. 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 TGA/MUP and the end-use product are summarized below in Table 1a, and their physical and chemical properties are shown in Table 1b.



Human & Environmental Risk Assessment
on ingredients of household cleaning products

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Hydrogen Peroxide
CAS No: 7722-84-1

2006 JUN 19 A 10:14

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Edition 1.0 April 2005

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The content of this document has been prepared and reviewed by experts on behalf of HERA with all possible care and from the available scientific information. It is provided for information only. Much of the original underlying data which has helped to develop the risk assessment is in the ownership of individual companies.

HERA cannot accept any responsibility or liability and does not provide a warranty for any use or interpretation of the material contained in this publication.

1. Abstract

Hydrogen peroxide (H_2O_2 , CAS No: 7722-84-1) is a high production volume (HPV) chemical, for which a European Union Risk Assessment has recently become available (European Commission, 2003). This EU risk assessment includes both an environmental risk assessment for the entire EU tonnage of hydrogen peroxide, and also human health risk assessments covering the use of several household cleaning products containing hydrogen peroxide which are within the scope of HERA.

HERA is determined to avoid any duplication of effort and to discourage effort for the sake of marginal improvements. However, HERA believes that HERA Risk Assessments should be carried out where significant additional risk information can be obtained, and where a refinement of the existing assessments would yield new or significantly different conclusions in particular for the detergent use scenario.

This document refers to the information in the EU Risk Assessment which covers hydrogen peroxide use in the household cleaning products which are within the scope of HERA. It also contains additional, recent exposure information which broadly supports the figures provided there.

Human Health

Products used in HERA applications may contain between 4% and 8% hydrogen peroxide. The main application of those products is the bleaching of textiles in the washing machine, but the use of hydrogen peroxide in surface- or toilet cleaners has also been reported. These uses give rise to a variety of possible consumer contacts.

The EU Risk Assessment concludes that there is no need for further information and/or testing for acute toxicity, sensitisation, repeated oral toxicity, repeated dermal toxicity, mutagenicity and carcinogenicity for all exposure scenarios concerning consumers.

The only relevant potential human health concern identified by the EU Risk Assessment is that of skin and eye irritation. Concentrated solutions of hydrogen peroxide are irritant to skin and eyes. The irritation potential of aqueous solutions of hydrogen peroxide depends on concentration. Local effects of hand wash solutions containing hydrogen peroxide do not cause concern given that it is not a contact sensitiser and that the concentrations of hydrogen peroxide in such solutions are well below those expected to be irritating to eye or skin. Laundry pre-treatment or surface cleaning tasks, which may translate into brief hand skin contact with higher concentrations of hydrogen peroxide, may occasionally result in mild irritation easily avoided by prompt rinsing of the hands in water. Accidental spillage of neat product into the eye is to be avoided as can be expected to result in likely irritation.

In the view of the extensive database on toxic effects and the low exposure values in the intended use patterns of the HERA applications, it can be concluded that the use of Hydrogen peroxide in household cleaning products raises no safety concern for consumers.

Environment

A quantitative risk assessment was performed for aquatic organisms and microorganisms. The assessment concludes that there is no need for further information and/or testing for any of the generic scenarios. The conclusion that no further information or testing was required also applies to the sediment, terrestrial, and atmospheric compartments. Also, the conclusion that no further information or testing is required was found for the other consumer exposure scenarios. Thus, the uses of hydrogen peroxide in products which are covered by HERA are not a subject of concern in the EU, with regard to the environment.

Table of Contents

1. Abstract.....	2
Table of Contents.....	4
2. Introduction.....	5
3. Substance information	5
Substance Identification.....	5
Physical-chemical Properties	5
Occurrence	5
Production and Use	6
4. Environmental Risk Assessment.....	7
Environmental fate.....	7
Environmental effects assessment	7
5. Human Health	9
Consumer exposure.....	9
Health hazard data.....	9
Risk Characterization for consumers	11
6. References.....	13
7. Contributors to the report.....	13

2. Introduction

Hydrogen peroxide (H₂O₂) is a high production volume (HPV) chemical, for which a European Union Risk Assessment has recently become available (European Commission, 2003). This HERA 'short version' report summarises the human and environmental risk assessment of the use of hydrogen peroxide in household cleaning applications, supplementing the EU risk assessment with current usage information (AISE, 2002).

3. Substance information

Substance Identification

This summary covers hydrogen peroxide (H₂O₂), CAS No: 7722-84-1, which has a structure H-O-O-H and a molecular weight of 34.02 g/mol (European Commission, 2003).

Physical-chemical Properties

The physical properties of hydrogen peroxide are given in Table 1 (European Commission, 2003). Hydrogen peroxide is normally handled as an aqueous solution. Commercial solutions must be stabilised with additives to prevent possible violent decomposition due to catalytic impurities or elevated temperatures and pressure. The danger of vapour phase explosion on storage of liquid hydrogen peroxide will be encountered only with concentrated H₂O₂ solutions above 74% at elevated temperatures. Solutions used in HERA applications are below the level of concern, as shown in Table 2.

Table 1. Physical and chemical properties of pure hydrogen peroxide (100%)¹

Property	Value
Melting point	-0.40 - 0.43°C
Boiling point	150-152°C decomposition
Density	1.4425 g/cm ³ (25°C)
Vapour pressure	3 hPa (25°C)
Water solubility	miscible in all proportions
Log Kow	-1.5 (calculated)
pKa	11.62 (25°C)
Henry's law constant	7.5.10 ⁻⁴ Pa m ³ /mol (20°C) measured

¹ pure hydrogen peroxide (100%) does not exist in practice

Occurrence

Hydrogen peroxide has both natural and anthropogenic sources. Environmental releases from anthropogenic sources may take place during production, formulation, processing and consumer use of products. Natural hydrogen peroxide may be formed by photochemical, chemical or biochemical process (European Commission, 2003).

Production and Use

Hydrogen Peroxide is mainly used for pulp bleaching (48%) and manufacture of other chemicals (38%) such as sodium perborate, percarbonate and peracetic acid. The remaining 15% of the total volume consumed in Europe is used for different applications including textile bleaching, environmental applications, metal etching, sanitisation of chemical instruments and surfaces, metal semiconductor chips manufacturing, disinfection of drinking water, disinfectant in aseptic packaging and bleaching of certain foodstuffs. Less than 1- 4% of the production volume is for personal and domestic use e.g. hair bleaching, dyeing or fixing of hair perm, household cleaning, tooth bleaching, food processing, disinfection of wounds and mouth and disinfection of eye contact lenses. Also cosmetics, toothpastes and deodorants contain or have contained hydrogen peroxide (European Commission, 2003).

Uses in household cleaning products, the scope of HERA, include use as a laundry additive (liquid bleach/gel), and in hand dishwashing detergents, hard surface cleaners and toilet cleaners. The ranges of hydrogen peroxide in these products are shown in table 2.

The total consumption of H₂O₂ in HERA applications in the 15 European Union Countries in 2002, plus Iceland, Switzerland and Norway, by formulating companies who contributed data to AISE in 2002 was 7696 tonnes per annum. As HERA formulators represent approximately 80% of the European market, it is estimated that less than 9700 tonnes per annum hydrogen peroxide was used in household applications in 2002 (AISE, 2002). This compares with the EU production tonnage of 750 000 tonnes per annum which was used in the EU risk assessment for hydrogen peroxide (European Commission, 2003). The tonnage estimated for use in applications covered by HERA is at the lower of the 1-4% of total hydrogen peroxide production volume which is estimated to be due to domestic and personal use in the EU Risk assessment (European Commission, 2003).

Table 2: Household applications and finished product concentrations of Hydrogen peroxide (AISE, unpublished data, 2002)

Product application	Range of H ₂ O ₂ level in finished product, % by weight
Regular laundry detergents	0
Compact laundry detergents	0
Fabric conditioners	0
Laundry additives - Liquid bleach/gel	0 - 8.5%
Machine dishwashing detergent	0
Surface cleaners	0 - 5 %
Toilet cleaner	4.6%

4. Environmental Risk Assessment

Environmental fate

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that the general characteristics of H₂O₂ that are relevant for the exposure assessment are:

Degradation

- **Abiotic degradation:** Abiotic degradation of H₂O₂ is due to either reaction with itself (disproportionation), or reaction with transition metals, organic compounds able to react with H₂O₂, reaction with free radicals, heat or light. Hydrogen peroxide is normally a short-lived substance in the environment but half-lives vary greatly depending on the circumstances. Thus, no abiotic half-life in water or soil has been determined. The estimated half-life in the atmosphere is ca. 24 hours.

- **Biodegradation:** Standard ready biodegradation tests are not applicable to inorganic substances like hydrogen peroxide. However, the data set available is regarded as sufficient to draw conclusions upon the degradation of H₂O₂. Enzymes produced by aerobic bacteria convert hydrogen peroxide to water and oxygen. Based on specific degradation data, a biodegradation rate constant of 21 h⁻¹ (half-life 2 min) in STP is used. In surface waters a realistic worst-case half-life of 5 days is used.

Distribution

A Henry's Law constant of 7.1x10⁻⁴ Pa·m³/mol at 20°C was measured. This indicates that volatilisation of H₂O₂ from surface waters and moist soil is expected to be very low. Using the measured log K_{ow} of -1.5, a K_{oc} of 0.2 can be estimated according to the Technical Guidance Document (TGD) (European Commission et al., 2003). Based on this value, hydrogen peroxide is expected to be highly mobile in soil.

Accumulation

There are no experimental results on bioaccumulation available. Hydrogen peroxide is reactive and a short-lived polar substance and no bioaccumulation is expected. This is supported by the calculated log K_{ow} of about -1.5. BCFs calculated according to the TGD for fish and earthworm are low, 1.4 and 3.3, respectively.

The EU risk assessment for hydrogen peroxide (European Commission, 2003) used the information above to determine that, for hydrogen peroxide in products covered by HERA, the local Predicted Environmental Concentration (PEC) values in various environmental compartments are as shown in Table 3.

Table 3: Local PEC values for hydrogen peroxide in products covered by HERA

	Local PEC in surface Water (mg/l)	PEC for microorganisms (mg/l)	Local PEC in soil (mg/kg)	Local PEC in air (mg/m ³)
Consumer use II: Household cleaning agents	0.00425	0.0125	1.09.10 ⁻⁴	2.25.10 ⁻⁶

Environmental effects assessment

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that, in the aquatic environment, there are short-term toxicity data for fish,

invertebrates and algae. In addition to algal studies, long-term data are available for zebra mussels. The lowest long-term aquatic toxicity test result is the NOEC of 0.1 mg/l for algae. According to the TGD an assessment factor of 50 should be used for deriving the Predicted No Effect Concentration (PNEC) in water. However, based on the data on natural background concentrations (typically <1 – 30 µg/l) it is obvious that this would overestimate the toxicity. Furthermore it is not probable that further long-term studies would show higher toxicity than the NOEC for the most sensitive group of organisms, i.e. algae. Therefore an assessment factor of 10 is considered to be appropriate. The extrapolation with the factor of 10 results in a **PNEC_{water} of 10 µg/l**.

The EU risk assessment for hydrogen peroxide (European Commission, 2003) extrapolated the PNEC for microorganisms from the EC₅₀ activated sludge respiration test (466 mg/l) using an assessment factor of 100. This results in a **PNEC_{microorganisms} of 4.66 mg/l**.

For the sediment compartment, The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that hydrogen peroxide does not adsorb to sediment and is rapidly degraded there. Thus the report concluded that **sediment dwelling organisms are adequately protected by the PNEC for water phase**.

The EU risk assessment for hydrogen peroxide (European Commission, 2003) calculated the PNEC for the terrestrial compartment based on the equilibrium partitioning method, as no suitable studies are available on the effects of hydrogen peroxide on soil-dwelling organisms. The results gave a **PNEC_{terrestrial} of 1.19.10⁻³ mg/kg wwt**.

Although some experiments are available on fumigation of plants with H₂O₂, no NOEC or EC₅₀ levels were determined in these tests. Thus the EU risk assessment for hydrogen peroxide (European Commission, 2003) found that a **quantitative assessment for the atmosphere cannot be performed**.

A quantitative risk assessment was performed for aquatic organisms and microorganisms. The EU risk assessment for hydrogen peroxide (European Commission, 2003) gives the PEC/PNEC ratios shown in Table 4 for hydrogen peroxide in the uses covered by HERA. The assessment concludes that "There is no

Table 4. PEC/PNEC ratios for hydrogen peroxide

Scenario	Aquatic organisms	Microorganisms
Consumer use II: Household cleaning agents	0.425	0.00267

need for further information and/or testing: **conclusion (ii) for this use**. The conclusion that no further information or testing was required also applies to the sediment, terrestrial, and atmospheric compartments. Thus **hydrogen peroxide use in products which are covered by HERA are not a subject of concern in the EU, with regard to the environment**.

5. Human Health

Consumer exposure

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that bleaching, disinfection and cleaning are the main uses of H₂O₂ in consumer products. Many consumer products, such as household cleaning and bleaching agents, hair dyeing and bleaching products, tooth bleaching agents, mouthwashes, disinfectants, contact lens disinfectants, and even food contain H₂O₂.

Table 5, taken from Table 4.2 of the summary report of the EU risk assessment for hydrogen peroxide (European Commission, 2003), gives data for the consumer exposure to H₂O₂ from the scenarios relevant for products covered by HERA. The duration and frequency of exposure and values for the external, route-specific doses/concentrations are given. Note that the concentrations given in table 5 are somewhat higher than the recent concentrations given in table 2 (AISE, 2002).

Table 5. Consumer exposure data used in the EU risk assessment for hydrogen peroxide (European Commission, 2003)

Scenario	Exposure time		Inhalation (mg/m ³)	Ingestion (mg/kg of bw/d)	Skin / Eye deposition	
	Duration of treatment	Frequency of treatments per year	Estimated	Estimated	Concn. of H ₂ O ₂ in the product	Estimated dose
Textile bleaching	5-10 min	25	0.02-0.13	na	<8 (35) %	0.6 mg/kg bw, on the skin ¹
Cleaning agents	10-20 min	25	<0.13	na	usually about 8%(0.2- 35%)	<0.6 mg/kg bw, on the skin ¹

1) 0.6 mg/kg of body weight per day is the potential dermal deposition (estimated by EUSES)

Health hazard data

Toxicokinetics, metabolism and distribution

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that H₂O₂ is an endogenous product of oxygen reduction in the aerobic cell and passes readily across biological membranes. At high-uptake rates H₂O₂ can pass the absorption surface entering the adjacent tissues and blood vessels where it is rapidly degraded by catalase liberating oxygen bubbles; consequently, mechanical pressure injury and oxygen embolism may be produced. In the view of the high degradation capacity for hydrogen peroxide in blood, it is unlikely that the substance is

systemically distributed, and therefore the endogenous steady state levels of the substance in tissues are unlikely to be affected.

Acute toxicity

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found oral LD₅₀ values or lethal doses in rats range between 800 mg/kg for 70% H₂O₂ to more than 5,000 mg/kg for 10% H₂O₂. There are also a number of reported human incidents by oral ingestion of H₂O₂ water solutions, but few reports have given data on the dose. The mechanism of systemic effect has been oxygen embolism. Thus, the substance proved to be harmful if swallowed by a physical mode of action. The dermal LD₅₀ values in animals range between 700-5,000 mg/kg for 90% H₂O₂. The test methods are mostly poorly described, but the studies indicate that H₂O₂ is not acutely toxic after skin application.

Acute inhalation toxicity studies have been performed with aerosols (mice) and vapours (rats and mice). Due to the corrosive nature of the substance after inhalation exposures to highly concentrated aerosols (70% H₂O₂ as "droplets"), lethality occurs at quite low air concentrations (0,92-2 mg/l). The lethal event can be attributed to the substance corrosivity rather than its systemic toxicity. Since exposure to significant concentrations of hydrogen peroxide was not observed in the risk assessment and the predominant human exposures were related to vapors only, vapour experiments were preferred in the hazard assessment. Based on vapour inhalation studies in mice and rats the substance was considered to be harmful by inhalation.

Irritation and corrosivity

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that in rabbits, H₂O₂ solutions of 10% were slightly irritating to the skin, 35% solutions proved to be moderately irritating and caused delayed epidermal necrosis and sloughing, while 50% solutions and more concentrated solutions were severely irritating and corrosive.

Eye irritation is reported in humans and animals. The effect of H₂O₂ in 5 and 10% solutions are known to cause adverse effects in humans. An 8% solution was highly irritating and caused irreversible effects in the rabbit eye.

Sensitisation

It was concluded in the EU risk assessment that the skin sensitisation potential of hydrogen peroxide is extremely low.

Repeated dose toxicity

A number of repeated dose toxicity studies in experimental animals via the oral and inhalation routes have been reviewed in the EU Risk assessment report (EU, 2003). The oral NOAEL of 26-37 mg/kg bw (100 ppm in drinking water) is based on local effects on the gastrointestinal tract and reductions in food and water consumption in a 90 day drinking water study in a catalase deficient mice strain. Based on irritation of the upper airways (nose) an NOAEL of 2.9 mg/m³ was derived in a 28-day rat study, while from human occupational data an approximate human NOAEL of 1.4 mg/m³ was derived.

Mutagenicity

Hydrogen peroxide was mutagenic and genotoxic in a variety of *in vitro* test systems without metabolic activation. The responses observed were modified by the presence of degrading enzymes (catalase), the extent of formation of hydroxyl radicals by the Fenton reaction, and the cells repair abilities. *In vivo* genotoxicity studies employing modern methodologies were all negative. The EU risk assessment concluded that the available studies are not in support of a significant genotoxicity or mutagenicity under *in vivo* conditions.

Carcinogenicity

The critical review of a number of publications on the carcinogenicity of hydrogen peroxide by EU, 2003 and consideration of the overall evidence available at this time led to the conclusion that the special nature of a local carcinogenic effect observed the duodenum of a sensitive mouse strain, that furthermore showed a marked tendency of regression and even disappearance after cessation of treatment was of no practical relevance for humans and should not trigger classification.

Toxicity to reproduction

Due to the rapid degradation of hydrogen peroxide in tissues of first contact and blood yielding oxygen and water no studies for reproductive endpoints were requested in the EU risk assessment, as hydrogen peroxide is unlikely to be systemically available to the developing embryo or fetus or the sex organs. Results from animal studies also suggest local toxicity at the point of contact and no systemic effect as the primary mode of action and consequently, although there were gaps in data, reproductive effects by hydrogen peroxide were not deemed to cause any concern.

Risk Characterization for consumers

The EU risk assessment concluded that the toxicokinetic evaluation of hydrogen peroxide suggests that only under conditions of very high exposure rates the substance might enter the systemic circulation. When accidental swallowing is excluded, it is unlikely that such high exposures could be reached in any realistic scenario of consumer exposure. It is especially unlikely that the substance deposited on the skin is systemically absorbed to a meaningful degree. Results from animal studies also suggest local toxicity at the point of contact and no systemic effect as the primary mode of action and consequently, although there were gaps in data, reproductive effects by hydrogen peroxide were not deemed to cause any concern.

The EU risk assessment for hydrogen peroxide (European Commission, 2003) found that local irritation and, in extreme and uncommon cases, corrosion of the skin, eye, gingivae or the teeth are the critical adverse effects caused by exposure to H₂O₂. Most of the effects reported are transient or are considered mild. However, even rather dilute solution of H₂O₂ (3%) may cause danger, if swallowed in large enough volume accidentally. Effects of splashes of strong solutions to the eye (> 5%) and skin (> 35%) represent scenarios that may be relevant in terms of consumer exposure.

The EU risk assessment for hydrogen peroxide (European Commission, 2003) concluded that all other endpoints, acute toxicity, sensitisation, repeated dose toxicity, mutagenicity and carcinogenicity were not considered to cause concern for human health of consumers. Thus, the conclusions regarding sensitisation, repeated dose toxicity, mutagenicity and carcinogenicity are **conclusions (ii) – There is at present**

no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Table 6, taken from Table 4.4 of the summary report of the EU risk assessment for hydrogen peroxide (European Commission, 2003), characterizes the risks to the consumer from exposure to H₂O₂ in the scenarios relevant for products covered by HERA. **Eye irritancy is shown to be of concern for products containing H₂O₂ in concentrations ≥5%. Thus for these products Conclusion iii - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account – is applicable.** The legislation supporting this recommendation can be found in the *Official Journal of the European Union, 2004.*

Table 6 – Risk characterization for consumers for product types included in HERA

Scenario	Irritation/corrosivity			Repeated dose toxicity, oral	Acute toxicity; sensitisation; mutagenicity; carcinogenicity others
	Eye	Skin	Airways		
Textile bleaching	iii ¹	ii	ii	ii	ii
Cleaning agents	iii ¹	ii	ii	ii	ii

1) Current data suggest that textile bleaching products and cleaning agents available for consumers normally contain less than 8% of H₂O₂ but in some unusual extreme cases may contain up to 35% of H₂O₂. Eye irritancy is of concern if the actual concentration of H₂O₂ in the substance used is ≥5%

Risks to Consumers from the physicochemical properties of hydrogen peroxide have also been identified in the EU risk assessment for hydrogen peroxide (European Commission, 2003). The risk assessment finds that an accident may occur if H₂O₂ (even diluted) is inappropriately stored in a glass bottle with a tight stopper. In the course of time, overpressure will be generated in the bottle due to slow decomposition of the peroxide and there is the possibility that the bottle may break, rupturing violently.

No risks were identified in the EU risk assessment for humans indirectly exposed via the environment and combined exposures for consumers.

In summary, the only relevant potential human health concern identified by the EU Risk Assessment is that of eye irritation. Concentrated solutions of hydrogen peroxide are irritant to skin and eyes. The irritation potential of aqueous solutions of hydrogen peroxide depends on concentration. Local effects of hand wash solutions containing hydrogen peroxide do not cause concern given that it is not a contact sensitizer and that the concentrations of hydrogen peroxide in such solutions are well below those expected to be irritating to eye or skin. Laundry pre-treatment or surface cleaning tasks, which may translate into brief hand skin contact with higher concentrations of hydrogen peroxide, may occasionally result in mild irritation easily avoided by prompt rinsing of the hands in water. Accidental spillage of neat product into the eye is to be avoided as can be expected to result in likely irritation.

Conclusion:

In the view of the extensive database on toxic effects and the low exposure values in the intended use patterns of the HERA applications, it can be concluded that the use of Hydrogen peroxide in household cleaning products raises no safety concern for consumers.

6. References

AISE (2002). Unpublished data gathered among the HERA Formulator Companies and aggregated by the Cefic Statistical Service department.

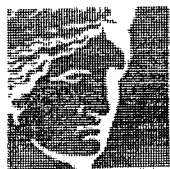
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7. Contributors to the report

This dossier has been prepared by the HERA Secretariat. Additional input was provided by experts of the HERA (Environment and Human Health) Task Forces. Volume and exposure information for the use of household detergents and cleaners was gathered among the HERA Formulator Companies and has been aggregated by the Cefic Statistical Service department.



HERA

Human & Environmental Risk Assessment on
ingredients of
European household cleaning products

Sodium percarbonate
(CAS No. 15630-89-4)

August, 2002

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Executive Summary

Sodium percarbonate is mainly used as a bleaching chemical in laundry detergents, laundry additives and machine dishwashing products. The pure product (100 %) is also available for consumers as a laundry additive. Sodium percarbonate may also be used in products for drain cleaning, multipurpose cleaning or for denture cleansing. The amount of sodium percarbonate, which is used in household cleaning products in Europe, was estimated to be 100,000 – 150,000 tonnes in 2001 but the amount is expected to increase the coming years.

Environment

Sodium percarbonate rapidly dissolves in water and dissociates into sodium, carbonate and hydrogen peroxide. Acute ecotoxicity tests with fish and water fleas revealed LC50 values of 71 and 4.9 mg/l. The available data show that the observed aquatic toxicity of sodium percarbonate can be explained by the formation of hydrogen peroxide. Because sodium percarbonate dissociates into sodium, carbonate and hydrogen peroxide, the environmental risk assessment is based on the risk assessment of the individual components.

After use of the household cleaning product, the spent washing liquor (containing the sodium percarbonate) will be disposed via the drain. Neither hydrogen peroxide nor carbonate will be discharged to aquatic ecosystems. Hydrogen peroxide will be degraded in the biological waste water treatment plant, while carbonate will be neutralised by the biological waste water treatment plant to bicarbonate. Sodium has a low toxicity and the emitted amount of sodium is relatively low compared to background concentrations and therefore the emitted amount of sodium will not have an effect on the aquatic organisms of the receiving water.

Based on the available data, the use of sodium percarbonate in household cleaning products has no adverse effect on the aquatic ecosystem.

Human health

Sodium percarbonate has a low acute toxicity via the oral and dermal route (LD50 > 1000 mg/kg bodyweight). The existing animal data on acute toxicity show that sodium percarbonate has a local effect. In animal tests a slight irritating effect on the skin was reported for solid sodium percarbonate and it was highly irritating to the rabbit eye (not rinsed). Sodium percarbonate did not have sensitising properties in a test with guinea pigs.

When consumers are exposed to sodium percarbonate, neither hydrogen peroxide nor sodium carbonate will be systemically available due to their effective detoxification (degradation or neutralisation) in the body. Consequently it is to be expected that the concentration of hydrogen peroxide and sodium in the blood and the pH of the blood will not be increased. Therefore, neither sodium percarbonate itself nor hydrogen peroxide or carbonate will reach the organs or the foetus and there is no risk for systemic, developmental or reproductive toxicity. With regard to genotoxicity and carcinogenicity the properties of sodium percarbonate also resemble those of hydrogen peroxide and it can be concluded that there is no concern for humans with regard to a possible genotoxicity or carcinogenicity of sodium percarbonate. The only critical endpoint for sodium percarbonate seems to be local irritation.

Consumers can be exposed to sodium percarbonate due to skin contact with solutions which contain sodium percarbonate, which can be laundry hand washing. However, the estimated concentrations of sodium percarbonate in these solutions are too low to cause skin irritation.

Accidental exposure of the eyes to dry products which contain sodium percarbonate or to solutions of household cleaning products which contain sodium percarbonate could result in eye irritation. Only if the sodium percarbonate concentration in the product or the solution is very high (> 25%) irreversible damage to the eye could occur if the product is not immediately washed out, which would normally be the case.

Acute cases of oral poisoning or effects on human eyes, due to accidental or intentional overexposure to sodium percarbonate, have not been found in the literature.

Based on the available data, the use of sodium percarbonate in household cleaning products has no adverse effect on consumers.

Contents

<i>Executive Summary</i>	2
<i>Contents</i>	4
<i>1. Introduction</i>	5
1.1 Identity and physical/chemical properties	5
1.2 Production	6
1.3 Use	6
<i>2. Environmental Assessment</i>	7
2.1 Environmental exposure assessment	7
2.1.1 Environmental Fate	8
2.1.2 Monitoring Data	9
2.1.3 Predicted Environmental Concentrations	9
2.2 Environmental effects assessment	11
2.2.1 Toxicity	11
2.2.2 Derivation of PNEC	12
2.3 Environmental Risk Characterisation	13
2.4 Discussion and Conclusions	14
<i>3. Human Health Assessment</i>	15
3.1 Consumer Exposure	15
3.1.1 Skin contact	15
3.1.2 Inhalation	16
3.1.3 Oral uptake	17
3.1.4 Accidental or intentional overexposure	17
3.2 Hazard Assessment	17
3.2.1 Toxicokinetics, metabolism and mechanism of action	17
3.2.2 Acute Toxicity	19
3.2.3 Skin Irritation	20
3.2.4 Eye Irritation	20
3.2.5 Sensitisation	22
3.2.6 Repeated Dose Toxicity	22
3.2.7 Genetic toxicity	24
3.2.8 Carcinogenicity	24
3.2.9 Toxicity to Reproduction	25
3.2.10 Developmental Toxicity / Teratogenicity	25
3.2.11 Experience with human exposure	26
3.2.12 Identification of critical endpoints	26
3.3 Consumer Risk Characterisation	27
3.3.1 Skin contact with sodium percarbonate via solutions	27
3.3.2 Accidental or intentional overexposure	27
3.4 Discussion and conclusions	28
<i>4. References</i>	30
<i>5. Contributors to the report</i>	33

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1. Introduction

1.1 Identity and physical/chemical properties

Sodium percarbonate is an addition compound of hydrogen peroxide and sodium carbonate. Based on the molecular formula, the pure substance sodium percarbonate contains 32.5 % hydrogen peroxide and 67.5 % sodium carbonate (based on weight). Sodium percarbonate is a white crystalline powder.

A melting and a boiling point can not be determined because sodium percarbonate decomposes when heated. The decomposition is exothermic and releases oxygen gas. Determination of log P_{ow} and vapour pressure are not applicable as sodium percarbonate is an ionisable, inorganic compound. The average particle size diameter of sodium percarbonate is in the range of 300 – 900 μm . Sodium percarbonate is readily soluble in water, producing a moderately alkaline solution. The pH is about 10.5 at 1 % concentration. The identity and several physical/chemical properties are summarized in Table 1.

Table 1: Identity and physical/chemical properties of sodium percarbonate

Property	Results / Remarks	Reference
Molecular formula	$2\text{Na}_2\text{CO}_3 \cdot 3\text{H}_2\text{O}_2$	
Molecular Weight	314.06	
CAS number	15630-89-4	
EINECS number	239-707-6	
Average particle size	300 – 900 μm	
Melting Point	Not applicable. Decomposition when heated.	
Density	2.14 g/cm^3	
Bulk density	900 – 1100 kg/m^3 ^A	Bertsch-Frank et al (1995)
Water Solubility	140 g/l	Bertsch-Frank et al (1995)
Vapour Pressure	Negligible	

^A Data from sodium percarbonate producers show that the bulk density ranges between 900-1200 kg/m^3 .

Based on the active oxygen content, the commercialised product sodium percarbonate has a purity of more than 85 %. The product sodium percarbonate can contain up to 15 % inorganic salts e.g. sodium carbonate, sodium chloride, sodium silicates, sodium sulfate, magnesium sulfate, sodium hexametaphosphate and borates. These inorganic salts are present as

impurities or are used as coatings. These coatings have been developed to maintain the stability of sodium percarbonate in household cleaning products.

1.2 Production

Globally sodium percarbonate is produced at 10 – 15 production sites and about half of them are located in Europe.

Sodium percarbonate is produced by the reaction of sodium carbonate with hydrogen peroxide, which can be done via dry, spray and wet processes. In the dry process aqueous hydrogen peroxide solution is sprayed on solid sodium carbonate; a solid-liquid reaction yields sodium percarbonate. In the spray process sodium percarbonate is produced by a fluid bed process. Solutions of sodium carbonate and hydrogen peroxide are sprayed into a drying chamber where the water is evaporated. In the wet process sodium percarbonate is usually prepared by crystallisation possibly in combination with salting out.

1.3 Use

The main user of sodium percarbonate is the household cleaning products industry, which is expected to use more than 95 % of the European sodium percarbonate demand.

Sodium percarbonate is mainly used as a bleaching chemical in laundry detergents (tablets, compact or regular powders), laundry additives and machine dishwashing products. The concentrations of sodium percarbonate in the different household cleaning products are presented in Table 2. However, higher concentrations are used also. Bleach booster products with a sodium percarbonate concentration between 65 and 85 % are placed on the market. Furthermore the pure product (100 %) is available for consumers as a laundry additive. Minor amounts of sodium percarbonate may be used in products for drain cleaning, multipurpose cleaning or for denture cleansing.

The amount of sodium percarbonate, which is used in household cleaning products in Europe, was estimated to be 100,000 –150,000 tonnes in 2001 but the amount is expected to increase the coming years. The amount of 150,000 tonnes will be used as a worst case scenario for the environmental assessment.

Table 2: Sodium percarbonate content in household cleaning products (AISE, 2002a)

Product	Content sodium percarbonate (%)	Typical content (%)
Laundry regular, powder	7-16	8-16
Laundry compact, powder	12-21	12-21
Laundry compact, tablet	12-24	12-20
Laundry additive, powder bleach	20-40	23-31
Laundry additive, tablet	25-56	28-56
Machine dishwashing, powder	3-21	21
Machine dishwashing, tablet	8.5	8.5

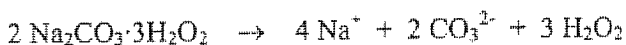
2. Environmental Assessment

2.1 Environmental exposure assessment

In most cases the household cleaning products, which contain sodium percarbonate, are added to tap water during use. For example laundry detergents are dissolved in water during the laundry washing process, while machine dishwashing products are also added to water. After use, the spent washing liquor will be disposed via the drain and finally it will be discharged to aquatic ecosystems (e.g. rivers, lakes, estuaries, sea) after a treatment.

2.1.1 Environmental Fate

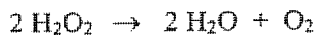
Sodium percarbonate rapidly dissolves in water and dissociates into sodium, carbonate and hydrogen peroxide.



Sodium, carbonate and hydrogen peroxide do not adsorb to sediment. Furthermore there is no distribution or transport to the atmosphere and therefore the environmental risk assessment can be focussed on the aquatic compartment. The environmental fate of hydrogen peroxide and sodium carbonate will be discussed below.

Hydrogen peroxide

Hydrogen peroxide is a reactive substance in the presence of other substances, elements, radiation, materials or cells. Both biotic and abiotic degradation processes are important routes in removal of hydrogen peroxide in the environment:



All organisms contain catalase and other enzymes to degrade hydrogen peroxide. The stability of hydrogen peroxide has been studied extensively (ECETOC, 1993; European Commission, 2001). It's half-life in both surface water and sediment can be significantly less than 1 day but in some cases it can be up to 5 days.

Hydrogen peroxide is rapidly degraded in a biological waste water treatment plant. An activated sludge, respiration inhibition test was conducted according to OECD Guideline 209 (Groeneveld et al., 1999). The test was conducted at concentrations of 0, 1.0, 3.0, 10, 30, 100, 300 and 1000 mg/l. In all test solutions the half-life was less than 2 minutes and therefore it can be concluded that hydrogen peroxide is degraded completely in biological waste water treatment plants. Not only a biological waste water treatment plant but also other domestic clarifiers are able to degrade hydrogen peroxide (Guhl et al., 2001).

Sodium carbonate

The environmental fate of sodium carbonate is presented already in the HERA Sodium carbonate report (HERA, 2002) and for this reason only a short summary of the aquatic fate will be presented here.

An emission of sodium carbonate to water will result in an increase in alkalinity and a tendency to raise the pH value:



However, the increase in pH depends on the buffer capacity of water which in most cases is determined by the natural background concentration of bicarbonate. To underline the importance of the buffer capacity, a table is included with the concentration of sodium carbonate needed to increase the pH to a value of 9.0, 10.0 and 11.0 at different bicarbonate concentrations. The data of Table 3 were based on calculations (De Groot et al., 2002).

Table 3: Concentration of sodium carbonate (mg/l) needed to increase the pH to values of 9.0, 10.0 and 11.0 (De Groot et al., 2002).

Buffer capacity ^A	Final pH ^B		
	9.0	10.0	11.0
0 mg/l HCO ₃ ⁻ (distilled water)	1.1 (0.6)	16 (6.1)	603 (61)
15 mg/l HCO ₃ ⁻ (10 th percentile of 21 European rivers)	2.3 (16)	28 (21)	725 (76)
128 mg/l HCO ₃ ⁻ (mean value of 21 European rivers)	12 (129)	120 (134)	1646 (189)
233 mg/l HCO ₃ ⁻ (90 th percentile of 21 European rivers)	20 (234)	206 (239)	2502 (294)

^A The initial pH of a bicarbonate solution with a concentration of 15 – 233 mg/l is 8.3 (calculated).

^B Between brackets the final concentration of bicarbonate is given.

2.1.2 Monitoring Data

Hydrogen peroxide, inorganic carbon and sodium are naturally present in the environment.

In natural water hydrogen peroxide occurs naturally as a result of dry and wet deposition, photochemical and biological formation or through the oxidation of metals (ECETOC, 1993; European Commission, 2001). Both field and laboratory studies indicate that the major pathway for production of hydrogen peroxide in natural waters is photochemical formation, although it is also introduced to water bodies through rain and biological processes. Natural background concentrations are normally less than 10 µg/l but concentrations significantly higher than 10 µg/l have been reported.

Normally the pH in aquatic ecosystems is significantly less than 10.3 and therefore carbonate is present in very low concentrations in aquatic ecosystems, which explains why monitoring data are not available for carbonate. However, for bicarbonate many monitoring data are available. An overview of the bicarbonate concentration in world river basins has been published by UNEP (1995). The concentration was measured in a total number of 21 rivers in Europe. The 10th-percentile, mean and 90th-percentile were 15, 128 and 233 mg/l,

respectively. The concentrations of the bicarbonate ion were strongly related to Ca^{2+} concentrations which reflect the weathering of rocks. The distribution of bicarbonate followed therefore the same pattern as that of the Ca^{2+} ion.

The sodium ion is ubiquitously present in the environment and it has been measured extensively in aquatic ecosystems. Sodium and chloride concentrations in water are tightly linked. They both originate from natural weathering of rock and from atmospheric transport of oceanic inputs and from a wide variety of anthropogenic sources. The anthropogenic sources of sodium are so pervasive that the concentrations of sodium in water have risen by a factor of 10 to 20 in many rivers in the 20th century. The sodium concentration was reported for a total number of 21 rivers in Europe, with a 10th percentile of 1.9 mg/l, mean of 56 mg/l and 90th percentile of 92 mg/l (UNEP, 1995).

2.1.3 Predicted Environmental Concentrations

To evaluate the potential effect of sodium percarbonate on the aquatic organisms, the concentration of sodium percarbonate in the receiving water (an aquatic ecosystem) must be determined. In other words, the Predicted Environmental Concentration (PEC) must be determined to know the exposure of the aquatic organisms to sodium percarbonate.

To estimate the PEC, computer models can be used. In the European Union the model EUSES has been used to calculate the PEC of organic compounds (Vermeire et al., 1994). In some cases it can also be used for inorganic compounds to obtain a preliminary idea about the order of magnitude of the PEC. Within HERA the EUSES model has been adapted to develop a specific scenario for detergents (HERA, 2001). The HERA detergents scenario assigns a value of 7% of the EU tonnage to the standard EU region, while the Technical Guidance Document (TGD) of the European Commission (1996) uses a default of 10%. Furthermore the HERA detergents scenario increases the emissions at local level by a factor of 1.5, instead of the TGD default factor of 4. These changes introduced by HERA more realistically represent the regional emissions and the local input of substances used in household detergents, as experimentally demonstrated (Fox, 2001).

The $\text{PEC}_{\text{added}}$ has been calculated using a tonnage of 150,000 t/y and assuming that the compound is inert. There is no distribution to air or sludge and degradation in the waste water treatment plant does not occur. The HERA detergent scenario revealed a $\text{PEC}_{\text{regional,added}}$ and a $\text{PEC}_{\text{local,added}}$ of 0.5 and 1.6 mg sodium percarbonate per liter, respectively.

The previous calculations were reported to obtain a preliminary idea about the order of magnitude of the $\text{PEC}_{\text{added}}$ when the substance would be discharged to aquatic ecosystems, without considering the fate of the compound, effluent treatments and other emission sources. Because sodium percarbonate rapidly dissociates into sodium, carbonate and hydrogen peroxide in water an individual exposure assessment (and risk characterisation) will be performed for these substances.

Hydrogen peroxide

Based on the HERA detergent scenario the $\text{PEC}_{\text{regional,added}}$ and the $\text{PEC}_{\text{local,added}}$ of hydrogen peroxide are 0.2 and 0.5 mg/l, respectively. However, hydrogen peroxide is unstable and will be degraded already for a significant extent during use. After disposal the degradation of hydrogen peroxide will continue and hydrogen peroxide will be completely degraded in a biological waste water treatment plant (see section 2.1.1). Not only a biological waste water

treatment plant but also other domestic clarifiers are able to degrade hydrogen peroxide (Guhl et al., 2001). For this reason it can be concluded that the emission of hydrogen peroxide to aquatic ecosystems is negligible.

Carbonate

Based on the HERA detergent scenario the $PEC_{\text{regional,added}}$ and the $PEC_{\text{local,added}}$ of the carbonate anion are 0.2 and 0.6 mg/l, respectively. However, in reality the total domestic discharge of carbonate to aquatic ecosystems will be completely different because :

- The final discharge of carbonate/bicarbonate will depend very significantly on the domestic waste water treatment method. Normally the pH of the untreated waste water is measured and adapted when necessary (to neutral pH) to optimise the conditions for the domestic waste water treatment plant (WWTP). This means that carbonate is already neutralised to bicarbonate before the domestic WWTP.
- The discharge of organic and inorganic carbon via faeces and urine is much higher than the discharge via household cleaning products. Based on a total amount of 150 million kg of sodium percarbonate used per year and based on 370 million inhabitants in the European Union, the daily use of inorganic carbon is 0.085 g per inhabitant per day. According to Directive 91/271/EEC the biodegradable organic load is 60 g oxygen per inhabitant per day in the EU. If this amount of oxygen is used for the formation of carbon dioxide then the discharge of organic carbon would be equal to 22.5 g per inhabitant per day. This shows that the amount of carbon, emitted via faeces/urine is much higher than the amount emitted via the use of sodium percarbonate in household cleaning products. Due to the biodegradation of organic carbon to inorganic carbon in the waste water treatment plant, it is unlikely that the sodium percarbonate of the household cleaning products has an effect on the final concentration of inorganic carbon in the effluent.

These 2 factors show that the use sodium percarbonate in household cleaning products has a negligible effect on the carbon chemistry of the aquatic ecosystems. The domestic effluent treatment method and the discharges of organic carbon are more important for the carbon chemistry of the receiving water. Even the effect of these 2 factors is questionable. Eutrofication, acidification, deforestation and agricultural practices are known to have an important effect on the carbon chemistry of aquatic ecosystems (Kempe, 1984).

Sodium

It is evident that effluent treatments do not affect the discharge of sodium. Therefore it can be assumed that the total quantity of sodium is emitted to the aquatic ecosystems. Based on the HERA detergents scenario this would result in a $PEC_{\text{regional,added}}$ and a $PEC_{\text{local,added}}$ for sodium of 0.1 and 0.5 mg/l, respectively.

Although the use of sodium percarbonate in household cleaning products results in an emission of sodium to aquatic ecosystems it is clear that other anthropogenic activities, e.g. mining and use of road salt, result also in an emission of sodium to aquatic ecosystems. According to UNEP (1995) the sodium and chloride concentrations in water are tightly linked for the major rivers of the world. Furthermore it should be realised that sodium is taken up via food, excreted and emitted to aquatic ecosystems. A normal uptake of sodium via food is 3.1-6.0 g per inhabitant per day according to Fodor et al. (1999) and a similar amount will be emitted to aquatic ecosystems. The daily discharge of sodium, via sodium percarbonate containing household cleaning products, is only 0.3 g per inhabitant per day.

Overview of PEC_{added} values

An overview of the PEC_{added} values is presented in Table 4. Hydrogen peroxide is degraded before discharge to the aquatic ecosystem, while carbonate is neutralised to bicarbonate before emission and therefore the realistic PEC_{added} of these components is 0.

Table 4: Overview of Predicted Environmental Concentrations added (PEC_{added}) to the aquatic ecosystem

Component	HERA Detergents scenario	HERA Detergents scenario	Realistic scenario
	$PEC_{regional,added}$ (mg/l)	$PEC_{local,added}$ (mg/l)	$PEC_{local,added}$ (mg/l)
Sodium percarbonate	0.5	1.6	Not applicable
Hydrogen peroxide	0.2	0.5	Negligible
Carbonate	0.2	0.6	Negligible
Sodium	0.1	0.5	0.5

2.2 Environmental effects assessment

2.2.1 Toxicity

Effects on fish

A semi-static acute toxicity study with fathead minnow (*Pimephales promelas*) and sodium percarbonate has been conducted according to GLP (Good Laboratory Practice) and EPA (Environmental Protection Agency) test guidelines (Shurtleff, 1989a). The fathead minnow is a saltwater fish species. Test solutions were renewed daily and the hydrogen peroxide concentration was determined before and after renewal using a titration with potassium permanganate. The measured hydrogen peroxide concentration was used to calculate mean measured sodium percarbonate concentrations. Fish were exposed for 96 hours to mean measured sodium percarbonate concentrations of 0; 1.1; 7.4; 34; 81; 465 and 937 mg/l and observations were made after 24, 48, 72 and 96 hours. The LC50 and NOEC (No Observed Effect Concentration) of sodium percarbonate were 71 and 7.4 mg/l, respectively. No control mortality was observed.

Another fish toxicity test without any quality assessment was reported (Japanese Patent Office, 1989). The original reference was not available but the study was reported in the IUCLID published by the ECB (2000). The test was performed on fish infested with skin parasites. Fish were treated twice a week for 3 minutes and the NOEC was ≥ 500 mg/l.

Effects on invertebrates

The effects of sodium percarbonate on the water flea *Daphnia pulex* have been studied by Shurtleff (1989b) according to GLP and EPA guidelines. Daphnids were exposed for 48 hours and they were transferred to fresh test solutions daily. The hydrogen peroxide concentrations were measured before and after each renewal using a titration with potassium permanganate.

The measured hydrogen peroxide concentration was used to derive mean measured sodium percarbonate concentrations. Mean measured test concentrations were 0; 2.0; 12; 46; 89; 416 and 835 mg/l. The EC50 and NOEC of sodium percarbonate were 4.9 and 2.0 mg/l, respectively. No control mortality was observed.

Effects in aquatic plants/algae

Algal studies have been reported by Clarke (1991) but these studies were not performed according to GLP or standard guidelines. In these studies three green algae, *Chlamydomonas eugametos*, *Chlorella emersonii* and *Scenedesmus quadricauda* and three cyanobacteria, *Anabaena variabilis*, *Anabaena A₄* and *Synechococcus leopliensis* were used. The algae were incubated in microtitre plates (300 µl). Analytical measurements were not available. Reported EC50 values ranged between 8-160 mg/l but these high values are not reliable. Probably hydrogen peroxide degraded during the test period, because the duration was too long for algal tests (140-240 hours). A significant recovery of the algal growth was seen in most cases during the test, which indicates a lack of exposure at the end of the test.

An algal study with *Chlorella vulgaris* has been conducted with hydrogen peroxide under standard test conditions (Degussa, 1991). The EC50 and NOEC of this study were 2.5 and 0.1 mg/l, respectively. Based on the study of Degussa (1991) predicted EC50 and NOEC values for a study with *C. vulgaris* and sodium percarbonate are 7.7 and 0.3 mg/l, respectively.

2.2.2 Derivation of PNEC

The results of ecotoxicity tests with sodium percarbonate, hydrogen peroxide and sodium carbonate are compared in Table 5. The results are expressed as sodium percarbonate, hydrogen peroxide and sodium carbonate concentrations, if applicable. The data of Table 5 show that the amount of hydrogen peroxide, which is released at EC50 concentrations of the fish and invertebrates tests with sodium percarbonate, is sufficient to explain the acute toxicity of sodium percarbonate. However, the amount of sodium carbonate, which is released at EC50 concentrations of the fish and invertebrates tests with sodium percarbonate, is not sufficient to explain the acute toxicity of sodium percarbonate.

Table 5: Comparison of acute toxicity of sodium percarbonate, hydrogen peroxide and sodium carbonate

Test substance	Species	EC50 (mg/l)			Reference
		SPC [^]	H ₂ O ₂ [^]	SC [^]	
Sodium percarbonate	Fathead minnow	50-100	16-33	34-68	Shurtleff (1989a)
Hydrogen peroxide	Fathead minnow		13-21		Shurtleff (1989a)
Sodium carbonate	Freshwater fish			300-740	HERA (2002)
Sodium percarbonate	<i>Daphnia pulex</i>	2-12	0.7-3.8	1.4-8.0	Shurtleff (1989b)
Hydrogen peroxide	<i>Daphnia pulex</i>		1.0-5.5		Shurtleff (1989b)
Sodium carbonate	<i>Ceriodaphnia dubia</i>			200-227	HERA (2002)

[^] LC₅₀ values are expressed as 95 % confidence intervals.

SPC = sodium percarbonate, H₂O₂ = hydrogen peroxide and SC = sodium carbonate.

Based on the results of Table 5, the acute toxicity of sodium percarbonate can be explained by the formation of hydrogen peroxide. The PNEC of hydrogen peroxide is equal to 10 µg/l and algae are the most sensitive species for hydrogen peroxide (European Commission, 2001).

A PNEC or a PNEC_{added} has not been derived for sodium carbonate because (HERA, 2002):

- The natural alkalinity/pH of aquatic ecosystems can vary significantly between aquatic ecosystems and
- Also the sensitivity of the aquatic ecosystems to a change of the alkalinity/pH can vary significantly between aquatic ecosystems.

The increase in pH of the receiving water was used to obtain an idea of the acceptable amount of sodium carbonate which can be added to aquatic ecosystems. Depending on the buffer capacity of the aquatic ecosystem, an estimate of the acceptable amount ranges between 2 and 20 mg/l (see also Table 3). The PNEC of hydrogen peroxide is much lower (10 µg/l) and this confirms that hydrogen peroxide is the component which is responsible for the toxicity of sodium percarbonate.

There is no need to derive a PNEC of sodium percarbonate for risk characterisation because the risk characterisation should be based on the separate risk characterisations of hydrogen peroxide and sodium carbonate. However, to describe the general hazard of sodium percarbonate for aquatic ecosystems in a quantitative way it could be useful to calculate a PNEC. Because sodium percarbonate contains 32.5 % hydrogen peroxide, the PNEC of sodium percarbonate would be equal to $10/0.325 = 31$ µg/l.

2.3 Environmental Risk Characterisation

To characterize the risk of sodium percarbonate, the exposure data (section 2.1.3) will be compared with the results of the effects assessment (section 2.2). The risk characterisation will be based on the risk characterisation for hydrogen peroxide, carbonate and sodium.

Hydrogen peroxide

Based on the HERA detergent scenario the PEC_{regional,added} and the PEC_{local,added} of hydrogen peroxide are 0.2 and 0.5 mg/l, respectively. However, hydrogen peroxide will be degraded during use, in the biological waste water treatment plant and even in domestic clarifiers and therefore the emission of hydrogen peroxide is considered negligible (Guhl et al., 2001). The concentration of hydrogen peroxide in the effluent will be similar to natural background concentrations of hydrogen peroxide and therefore there is no risk for the aquatic ecosystem. The PNEC of hydrogen peroxide is equal to 10 µg/l (European Commission, 2001).

Carbonate

Based on the HERA detergent scenario the PEC_{regional,added} and the PEC_{local,added} of the carbonate anion are 0.2 and 0.6 mg/l, respectively. However, the use of sodium percarbonate in household cleaning products will not result in an emission of carbonate to aquatic ecosystems because the domestic effluents are neutralised and because the organic carbon from faeces and urine have a more important effect on the carbon chemistry of the aquatic ecosystems (see section 2.1.3). Eutrofication, acidification, deforestation and agricultural practices are also known to have an important effect on the carbon chemistry of aquatic

ecosystems (Kempe, 1984). For this reason it can be concluded that the use of sodium percarbonate in household cleaning products has a negligible effect on the carbon chemistry of aquatic ecosystems.

The previous paragraph indicated that the acceptable amount of sodium carbonate which can be discharged to an ecosystem would be 2.3 to 20 mg/l (order of magnitude). This was based on the increase of the pH.

Sodium

Based on the HERA detergents scenario the $PEC_{\text{regional,added}}$ and the $PEC_{\text{local,added}}$ for sodium were 0.1 and 0.5 mg/l, respectively. It is evident that effluent treatments do not affect the discharge of sodium. Therefore it can be assumed that the total quantity of sodium is emitted to the aquatic ecosystems.

Concentrations of 0.1-0.5 mg/l are not expected to have an effect on aquatic organisms because reconstituted water for acute and chronic toxicity tests contain sodium concentrations which range between 3.3 and 105 mg/l (ASTM, 1996). These PEC_{added} values of sodium are also relatively low compared to measured concentrations of sodium in aquatic ecosystems. The sodium concentration was reported for a total number of 21 rivers in Europe, with a 10th percentile of 1.9 mg/l, mean of 56 mg/l and 90th percentile of 92 mg/l (UNEP, 1995). Other anthropogenic activities have most likely a more important effect on the sodium content of aquatic ecosystems. For this reason it can be concluded that the sodium, which originates from the use of sodium percarbonate in household cleaning products, has a negligible effect on the aquatic ecosystems.

2.4 Discussion and Conclusions

Sodium percarbonate rapidly dissolves in water and dissociates into sodium, carbonate and hydrogen peroxide. Acute ecotoxicity tests with fish and water fleas revealed LC50 values of 71 and 4.9 mg/l. The available data show that the observed aquatic toxicity of sodium percarbonate can be explained by the formation of hydrogen peroxide. Because sodium percarbonate dissociates into sodium, carbonate and hydrogen peroxide, the environmental risk assessment is based on the risk assessment of the individual components.

After use of the household cleaning product, the spent washing liquor (containing the sodium percarbonate) will be disposed via the drain. Neither hydrogen peroxide nor carbonate will be discharged to aquatic ecosystems. Hydrogen peroxide will be degraded in the biological waste water treatment plant, while carbonate will be neutralised by the biological waste water treatment plant to bicarbonate. Sodium has a low toxicity and the emitted amount of sodium is relatively low compared to background concentrations and therefore the emitted amount of sodium will not have an effect on the aquatic organisms of the receiving water.

Based on the available data, the use of sodium percarbonate in household cleaning products has no adverse effect on the aquatic ecosystem.

3. Human Health Assessment

3.1 Consumer Exposure

Based on information from AISE (2002a) the concentrations of sodium percarbonate in laundry detergents, laundry additives and machine dishwashing products are 7-24, 20-56 and 3-21 %, respectively. However, higher concentrations are used also. A bleach booster tablet with 85 % sodium percarbonate is commercialised also in Europe. The pure product (100 %) is also available for consumers as a laundry additive.

As relevant consumer contact scenarios, skin contact, inhalation, oral uptake and accidental or intentional overexposure of sodium percarbonate were identified and assessed.

3.1.1 Skin contact

Consumers may be exposed to sodium percarbonate via skin contact with solutions which contain sodium percarbonate. A common exposure scenario seems to be laundry hand washing with a detergent and therefore this scenario will be discussed below. Other applications, resulting in exposure to solutions of sodium percarbonate, do exist but they are probably less common or the exposure will be lower.

Laundry hand washing

There is a consolidated overview concerning habits and uses of detergents and surface cleaners in Western Europe issued by AISE (2002b). This list reflects the consumer's use of detergents in g/cup, tasks/week, duration of task and other uses of products. This overview of AISE (2002b) has been used to calculate the exposure.

The concentration of laundry detergent in the hand washing solution is approximately 1 % (10 g/l). The highest concentration of sodium percarbonates in laundry detergents amounts to 24 % (see Table 2). For this reason the hands and forearms of the consumer are exposed to an estimated sodium percarbonate concentration of 2.4 g/l (= mg/ml). However, a quantity of 15 gram of pure sodium percarbonate can be added as a laundry bleaching additive according to label information from a pure sodium percarbonate product available for consumers in Europe. Based on a volume of 10 liter this would result in an additional concentration of 1.5 g/l. For this reason, in a worst case assumption, the hands and forearms of the consumer are exposed to an estimated sodium percarbonate concentration of 3.9 g/l (= mg/ml).

Using the equations of the HERA guidance document (2001) the following exposure can be derived:

$C_{\text{sodium percarbonate}}$ = Maximum concentration of sodium percarbonate : 3.9 g/l (= mg/ml)

T_{der} = Thickness of layer on skin: 0.01 cm (HERA 2001; European Commission, 1996)

S_{der} = Exposed area of hands and forearms of adult male: 1980 cm² (EPA, 1997)

F = Fraction absorbed in 24 h exposure period: 0.001 (Schaefer et al., 1996).

$$\begin{aligned} \text{EXP}_{\text{sys}} &= C_{\text{sodium percarbonate}} \times T_{\text{der}} \times S_{\text{der}} \times F \\ \text{EXP}_{\text{sys}} &= 3.9 \text{ mg/ml (cm}^3\text{)} \times 0.01 \text{ cm} \times 1980 \text{ cm}^2 \times 0.001 = \\ &\quad \mathbf{0.077 \text{ mg sodium percarbonate absorbed in 24 hours}} \end{aligned}$$

As this is calculated for a 24 h exposure and the exposure time is normally 10 minutes (AISE, 2002b) this has to be corrected by a factor of (24x60/10) yielding an assumed absorption of 5.4×10^{-4} mg per event.

Based on a body weight of 60 kg the estimated systemic dose of sodium percarbonate would be equal to $5.4 \times 10^{-4} / 60 = 8.9 \times 10^{-6}$ mg/kg body weight per event.

Contact with solid product

Another scenario would be dermal contact to a fraction of the solid (0.1%) when filling the washing machine. In this case it can be assumed that the contact lasts less than 1 minute (AISE, 2002b) and only affects a fraction of the hand surface (palms of the hands). According to EPA (1997) the surface of the hands would constitute ca. 840 cm², the palms would then be one half, 420 cm². Only a fraction of the amount would be soluble and available for absorption. The maximum amount of detergent powder used per event was 150 g. With a maximum amount of 24% sodium percarbonate this would contain 36 g sodium percarbonate. If about 0.1% comes into contact with the skin, this would constitute 36 mg. It can be assumed that only a fraction of this will be soluble and available on the skin for absorption.

Given the very short duration of exposure and the very low levels of material expected to be available for skin absorption, this exposure scenario can be expected to be negligible. In the case of the use of tablets the exposure would be even lower as only the thumb and the index finger of one hand (approximately 2 cm²) are in contact with the products.

Pure sodium percarbonate is also available as a laundry additive and therefore there could be some skin contact with pure sodium percarbonate. Given the very short duration of exposure and the very low levels of material expected to be available for skin absorption, also this exposure scenario can be expected to be negligible.

3.1.2 Inhalation

The dust formation from products containing sodium percarbonate, is so small that the amount is considered negligible for consumers. The negligible inhalation has been confirmed for the laundry washing scenario. According to Van de Plassche et al. (1998) studies indicate an average exposure of about 0.27 µg dust per cup of product used for machine laundering, of which up to 24 % or 0.06 µg is sodium percarbonate. Based on the large particle size of the pure sodium percarbonate, which is available as a laundry additive, the inhalation exposure is considered negligible.

3.1.3 Oral uptake

Oral uptake of sodium percarbonate by consumers via the use of household cleaning products is considered negligible under normal handling and use conditions.

3.1.4 Accidental or intentional overexposure

Accidental or intentional overexposure to sodium percarbonates may potentially occur via:

- oral exposure to products which contain sodium percarbonate,
- oral exposure to solutions of these products in water,
- exposure of the eyes to products which contain sodium percarbonate,
- exposure of the eyes to solutions of these products in water (e.g. due to splashing) and
- inhalation exposure to products which contain sodium percarbonate.

No fatal cases arising from oral uptake of sodium percarbonate (solutions) have been found in the literature. Furthermore case reports related with high exposure to sodium percarbonate (solutions) have not been reported in the medical literature. The German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV, 1999) published recently a report on products involved in poisoning cases. No fatal case of poisoning with detergents was reported in this report. Detergent products were not mentioned as dangerous products with a high incidence of poisoning.

Accidental spillage may cause eye contact of sodium percarbonate. Cases of eye irritation, which were caused by sodium percarbonate (solutions), have not been found in the literature.

Cases of accidental inhalation exposure to the product sodium percarbonate have not been found in the literature but inhalation of laundry detergent powder by children has been reported in the United States (Einhorn et al., 1989). The predominant symptoms were stridor, drooling and respiratory distress. It is unknown if similar cases of accidental inhalation exposure have occurred in Europe.

3.2 Hazard Assessment

3.2.1 Toxicokinetics, metabolism and mechanism of action

Sodium percarbonate is an inorganic, water soluble solid of relatively low molecular weight. Dermal absorption is assumed to be low due to the hydrophilic character and the ionic structure of the substance.

When sodium percarbonate is getting into contact with body fluids it will dissociate into hydrogen peroxide, carbonate and sodium. All three substances are naturally present in the human body. The substances will be discussed separately below.

Hydrogen peroxide

The toxicokinetics, metabolism and distribution of hydrogen peroxide has been described in detail by the European Commission (2001). Hydrogen peroxide is a normal metabolite in the aerobic cell, but there is uncertainty about the true levels of the substance in biological media due to analytical difficulties. The steady state level appears to depend on the balance between its generation and degradation. There are two main hydrogen peroxide metabolizing enzymes,

catalase and glutathione peroxidase, which control the hydrogen peroxide concentration at different levels and in different parts of the cell as well as in the blood. At the site of contact hydrogen peroxide will in part be decomposed by the cells of the tissue of first contact. Remaining hydrogen peroxide diffusing into the capillaries will be immediately decomposed in the blood. Red blood cells remove hydrogen peroxide efficiently from the blood due to a very high catalase activity whereas in the serum catalase activity is low. In view of the high degradation capacity for hydrogen peroxide in tissues and blood it is unlikely that the endogenous steady state level of the substance is affected. In other words, hydrogen peroxide is not expected to be systemically available in the body.

Carbonate

The toxicokinetics, metabolism and distribution of carbonate has been described by the HERA report on sodium carbonate (HERA, 2002) but it will be summarized below. The carbonate could potentially increase the pH of the blood.



The major extracellular buffer in the blood and the interstitial fluid of vertebrates is the bicarbonate buffer system, described by the following equation:



The blood plasma of man normally has a pH of 7.4. Should the pH fall below 7.0 or rise above 7.8, irreversible damage may occur. Compensatory mechanisms for acid-base disturbances function to alter the ratio of HCO_3^- to PCO_2 , returning the pH of the blood to normal. Thus, metabolic acidosis may be compensated for by hyperventilation (increased excretion of carbon dioxide) and increased renal absorption of HCO_3^- . Metabolic alkalosis may be compensated for by hypoventilation (decreased excretion of carbon dioxide) and the increased excretion of HCO_3^- in the urine (Johnson and Swanson, 1987). Therefore, if carbonate is absorbed its concentration will be regulated by these physiological mechanisms and therefore elevated amounts of carbonate are not expected to be available in the body. In other words, carbonate is not expected to be systemically available in the body.

Furthermore it should be realised that an oral uptake of sodium percarbonate results in a neutralisation of carbonate in the stomach by the gastric acid. Significant amounts of gastric acids are present in the stomach (pH about 2) which will result in a formation of bicarbonate and/or carbon dioxide. Therefore it is very unlikely that an oral uptake of sodium percarbonate will result in a pH increase of the blood.

Sodium

Sodium is an essential element in the diet but a high intake of sodium has been associated with cardio-vascular diseases (Fodor et al., 1999). Sodium is readily absorbed throughout the small intestine and is subject to rapid exchange by the large majority of cells in the body. The main regulation of the body concentrations of sodium takes place in the kidney. The consumer exposure to household cleaning products results in a relatively low exposure to sodium (compared to dietary uptake) and therefore elevated amounts of sodium are not expected to be available in the body. In other words, sodium is not expected to be systemically available in the body.

Conclusion

Under normal handling and use conditions hydrogen peroxide, carbonate and sodium are not expected to be systemically available in the body. Hydrogen peroxide is rapidly degraded in the tissues of first contact and the blood by catalase, carbonate will be neutralised in the blood to bicarbonate. The sodium uptake, due to sodium percarbonate exposure, is relatively small to dietary uptake and the body concentration of sodium will be regulated mainly by the kidney.

3.2.2 Acute Toxicity

Oral toxicity

An acute oral study has been conducted with rats according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990a). Sodium percarbonate was mixed with deionised water and the resulting suspension was administered. The study was conducted at sodium percarbonate dose levels of 700, 1000 and 1500 mg/kg bw (body weight). A total number of 30 rats was used for this study. The LD₅₀ was 1034 mg/kg bw. Mortality occurred within 3 days of test material administration. Coloration changes in the glandular portion of the stomach were observed at necropsy and the walls of these stomachs were occasionally thickened as well.

Rats were dosed with sodium percarbonate, as a 10 % suspension in maize oil, at dose levels of 1000, 1700, 2900 and 5000 mg/kg bw (Chater, 1978). This study was not performed according to GLP or standard test guidelines. A total number of 24 rats was used in this study. The LD₅₀ was 2000 mg/kg bw. Necropsy findings indicated that an effect was present in the stomach. Inflammation and necrosis were observed. Death was always found to be associated with the stomach and intestine being enlarged and filled with gas.

Another acute oral study has been conducted with mice and sodium percarbonate (Momma et al., 1986). This study was not performed according to GLP or standard test guidelines. A total number of 130 female and male mice were dosed with a solution of sodium percarbonate in water at dose levels of 1500 – 3040 mg/kg bw. The LD₅₀ value was 2050 mg/kg for the males and 2200 mg/kg for the females. At necropsy, dead animals presented a slight degree of congestion or blood spots in the stomach mucosa, and blood was mixed with the stomach contents. Furthermore distension of the gastro-intestinal tract was observed.

Dermal toxicity

A single dose of 2000 mg/kg bw sodium percarbonate was administered to the intact skin of 10 New Zealand White rabbits according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990b). The rabbits were exposed to the test substance for 24 hours. No mortality or test material related clinical signs were observed during the study. The level of dermal irritation was severe. Dermal irritation consisted of slight to severe erythema and oedema and slight to marked atonia, desquamation, corioceousness and fissuring. No other macroscopic findings were observed at necropsy.

Inhalation toxicity

The following data was reported without any quality assessment: LC₀ rat > 4.58 mg/l at an exposure time of 1 hour (ICI, 1977). The original reference was not available but the study was reported in the IUCLID published by the ECB (2000).

Conclusion

Standard acute oral and dermal toxicity studies with a high reliability are available. Acute oral LD50 values in rats and mice were 1034 and 2000 mg/kg body weight, while the acute dermal LD50 in rabbits was > 2000 mg/kg bw respectively. The acute oral toxicity is dependent on the concentration of the administered solution and the vehicle and is due to the local irritating/corrosive effects of the substance. The existing animal data on acute toxicity show that sodium percarbonate has a local effect and that systemic effects are not to be expected.

3.2.3 Skin Irritation

A skin irritation study was conducted with 6 New Zealand White rabbits according to EPA test guidelines and EPA GLP guidelines (Glaza, 1990c). Application of sodium percarbonate to rabbits under 4-hour semi-occluded conditions resulted in reversible slight erythema (mean grade 0.8) and oedema (mean grade 0.1) reactions.

Another skin irritation study was conducted with rats exposed to repeated applications (12 days) of sodium percarbonate, either as solid or as a 1 % aqueous solution (Chater, 1978). This study was not performed according to GLP or standard test guidelines. The powder caused slight to mild irritation to rat skin. Slight erythema and desquamation developed by the 4th application but this did not progress during the remainder of the test period. The 1 % aqueous solution appeared to be non-irritant to rat skin, slight erythema and desquamation only becoming apparent during the last 2 days of the test.

The irritant effect of sodium percarbonate can be explained by the presence and formation of hydrogen peroxide. The available irritation and corrosivity studies of hydrogen peroxide have been reviewed by the European Commission (2001). Furthermore the evaluation of hydrogen peroxide by the EU Commission Working Group on the Classification and Labelling of Dangerous Substances has been finalised in 2001. Based on this evaluation a hydrogen peroxide concentration of 50 % and higher is corrosive, while concentrations of 35-50 % are irritant to the skin. Sodium carbonate (solid) and sodium carbonate solutions are essentially non-irritant for the skin (HERA, 2002). Sodium percarbonate itself is only slightly irritant to the skin, which is consistent with the hydrogen peroxide content being just below the irritation limit of hydrogen peroxide.

3.2.4 Eye Irritation

The eye irritation studies conducted with sodium percarbonate (solutions) are summarized in Table 6.

An eye irritation study was performed with New Zealand White rabbits (Chater, 1978). Ocular irritancy was tested by introducing sodium percarbonate into the rabbit eye, either in powder form, or as 1 % aqueous solution. Initial pain and irritancy were recorded over a period of 7 days. The 1 % aqueous solution was considered not irritant while the powder was considered a severe irritant.

An eye irritation study was conducted which was comprised of three groups of three rabbits (Momma et al., 1986). This study was not performed according to GLP or standard test guidelines. Quantities of 100 mg of the solid test substance were instilled in the rabbit left eyes and the eyes were submitted to three different treatments. One group's eye was left unrinsed, one group's left eye was rinsed after 4 seconds and the third group's eye was rinsed

Table 6: *In vivo* eye irritation tests with sodium percarbonate

Species	Protocol	Test material and concentrations	Result	Reference / CoR ^A
Rabbit	Sodium percarbonate was tested Either As 1 % Aqueous Solution Or In Powder Form	1 % Solution and powder	1 %: Slight irritation Powder: severe irritation	Chater (1978) CoR = 2
Rabbit	Dose of 100 mg , rinsed (after 4 and 30 s) and unrinsed eyes OECD Guideline 405	White granules. test material contained several percent of non-ionic surfactant	Without rinse: severe irritation Rinsed after 4 s: no irritation Rinsed after 30 s: mild irritation	Momna et al. (1986) CoR = 1
Rabbit	Dose of 100 mg, exposure for 96 hours, not rinsed EPA OPP 81-4	White granules	Highly irritating	Glaza (1990d) CoR = 1
Rabbit	Dose of 100 mg, exposure for 24 hours, not rinsed OECD Guideline 405	White granular solid, ground to a fine powder before use	Highly irritating	Driscoll (1985a) CoR = 1
Rabbit	Dose of 100 mg, exposure for 24 hours, not rinsed OECD Guideline 405	White granular solid, ground to a fine powder before use	Highly irritating	Driscoll (1985b) CoR = 1
Rabbit	Dose of 10 and 50 mg, exposure for 21 days and 48 hours, respectively, not rinsed OECD Guideline 405	White granular solid, ground before use	Corrosive (10 mg), irreversible effect in one treated eye (three eyes were treated)	Driscoll (1985c) CoR = 1

^A CoR = Code of Reliability (Klimisch et al., 1997)

Reliability : 1 = valid without restrictions, 2 = valid with restrictions, 3 = invalid and 4 = not assignable.

after 30 seconds. Severe irritation was observed in the eye of the group of animals which had not been rinsed. When the eyes had been rinsed after 4 seconds no lesion in the cornea and iris was observed. Redness, oedema of conjunctiva disappeared after 7 days. When the eyes had been rinsed after 30 seconds no effect on the iris was observed. Redness, oedema of conjunctiva persisted up to day 7.

Rabbit eyes were exposed to 100 mg sodium percarbonate in powder form according to EPA test guidelines (Glaza, 1990d). The eyes were exposed for 96 hours and not rinsed. Necrosis of the conjunctivae was seen in one animal at 48 hours and in six animals at 72 and 96 hours. Sodium percarbonate was considered highly irritating.

A dose of 100 mg sodium percarbonate was instilled in the eye of a female rabbit (Driscoll, 1985a). The eye was exposed for 24 hours without washing. The eye was examined after 1 and 24 hours. A similar study was conducted in which 100 mg sodium carbonate was instilled in the eye of a male rabbit without washing (Driscoll, 1985b). The study was stopped after 5 hours and the eye was examined after 1 and 5 hours. In both studies translucent corneal

opacity, iridial inflammation, moderate to severe conjunctival irritation was observed and sodium percarbonate was considered to be highly irritating.

Amounts of 10 and 50 mg sodium percarbonate were instilled into the eyes of rabbits (Driscoll, 1985c). At the 10 mg dose level observations were made 1, 24, 48 and 72 hours following treatment. Additional observations were made on day 7, 14 and 21 to assess the reversibility of the ocular effects. At the 50 mg dose level observations were made 1, 24 and 48 hours following treatment and this study was stopped after 48 hours. A single 10 mg application of the test material to the non-irrigated eye of three rabbits produced translucent corneal opacity, iridial inflammation, moderate conjunctival irritation and vascularisation of the cornea. Two treated eyes appeared normal 7 days after treatment. Corneal opacity and vascularisation persisted in one treated eye at the 21-day observation and these effects were considered to be irreversible. A single 50 mg application of sodium percarbonate to the non-irrigated eye of one rabbit produced translucent corneal opacity, iridial inflammation and moderate to severe conjunctival irritation. Sodium percarbonate (10 mg) was considered to be corrosive to the eye due to irreversible effects noted in one treated eye.

Conclusion

Results in this section show that the powder sodium percarbonate is highly irritating to corrosive to the eye (not rinsed). The irreversible effect on one rabbit eye was observed when the granular solid was ground before use.

The irritant/corrosive effect of sodium percarbonate can be explained by the presence and formation of hydrogen peroxide. The evaluation of hydrogen peroxide by the EU Commission Working Group on the Classification and Labelling of Dangerous Substances has been finalised in 2001. Based on this evaluation a hydrogen peroxide concentration of 5-8 % will be labelled with "irritating to eyes" (R36), a concentration of 8-50 % will be labelled with "risk of serious damage to eyes" and concentrations higher than 50 % will be "corrosive". Sodium carbonate (solid) is also irritating for the eye (HERA, 2002).

3.2.5 Sensitisation

A skin sensitisation test was conducted on 24 guinea pigs according to EPA test guidelines and EPA GLP guidelines (Buehler method) (Glaza, 1990e). A naive control group of 10 animals was included. The animals received one application (0.4 ml of a 75 % w/v mixture) per week for 3 weeks for a total of three applications, the naive control animals were not treated during this phase. Two weeks following the third induction dose, a challenge dose (0.4 ml of a 25 % w/v mixture) was administered to the test animals and the naive control animals. Application sites were examined and scored for erythema and oedema at 24 and 48 hours following the induction and challenge applications. Very faint to faint dermal reactions were elicited from all test animals during the induction phase. None of the test or naive control animals reacted to the challenge application of the test. Sodium percarbonate was classified as not-sensitising.

3.2.6 Repeated Dose Toxicity

No animal data are available on repeated dose toxicity studies by oral, dermal or inhalation exposure routes for sodium percarbonate. However, repeated dose toxicity data are available for hydrogen peroxide, carbonate and sodium. The data for hydrogen peroxide have been reviewed by the European Commission (2001).

In a 90-day study with hydrogen peroxide mild duodenal mucosal hyperplasia was seen in catalase deficient mice given hydrogen peroxide in drinking water in concentrations between 100 and 3000 ppm resulting in doses between 78 and 260 mg/kg (Freeman et al, 1997). Both males and females receiving 3000 ppm exhibited significant reductions in body weight and food and water consumption. Animals receiving 300 and 1000 ppm displayed intermittent reductions in food and water consumption. No biologically significant differences in haematology parameters were noted among treated animals relative to controls. Males receiving 3000 ppm displayed significant reductions in total protein and globulin levels (clinical chemistry parameters) in the blood possibly attributed to reduced food consumption or reduced protein absorption caused by mucosal hyperplasia observed in the duodenum of these animals. No treatment-related significant differences in absolute or relative organ weights were noted.

Necropsy revealed no treatment-related gross lesions. Macroscopic evaluation of tissue slides indicated an increase in the cross sectional diameter and wall thickness of the duodenum. Subsequent microscopic evaluation of the duodenum revealed minimal to mild mucosal hyperplasia in eight of nine males receiving 3000 ppm and in seven of ten males receiving 1000 ppm. Minimal mucosal hyperplasia was noted in one of ten males receiving 300 ppm. Minimal to mild mucosal hyperplasia was also noted in ten of ten females receiving 3000 ppm and in eight of ten females receiving 1000 ppm. No duodenal mucosal hyperplasia was noted neither among females receiving 300 ppm nor among males or females receiving 100 ppm. Duodenal mucosal hyperplasia is defined as an increase in mucosal area and an increase of villi size. No other areas of the gastrointestinal tract were affected. Microscopically, no evidence of cellular atypia or architectural disruptions nor any other indications of neoplastic changes were observed; therefore, the treatment-related mucosal hyperplasia noted in this study is not considered to be a pre-neoplastic lesion.

After a 6-week recovery period no significant differences in haematology, clinical chemistry or organ weight parameters were noted among recovery animals. No treatment-related gross lesions were noted during necropsy of animals following the recovery period. No histopathological findings were noted that were attributed to previous treatment among any recovery animals following the recovery period. No mucosal hyperplasia was noted among recovery animals.

Based on dose-related reductions in food and water consumption, and the observation of duodenal mucosal hyperplasia for hydrogen peroxide, the Lowest Observed Adverse Effect Level (LOAEL) was 300 ppm and the No Observed Adverse Effect Level (NOAEL) was 100 ppm (26 and 37 mg/kg/day for males and females, respectively). The food and water consumption decreases among animals receiving 300 and 1000 ppm were intermittent and reversible. Histopathological effects were not present in any organ other than the duodenum. Microscopically, neither evidence of cellular atypia or architectural disruptions nor any other indications of preneoplastic lesions were observed.

All effects noted during the treatment period of the study were reversible. Animals sacrificed following the recovery period were considered biologically normal. No clinical signs of toxicity or morphological effects on any organ systems other than the local effects on the gastrointestinal tract were noted during the study.

In another study on hydrogen peroxide, rats were given by gavage solutions of 0.1 to 1.1 % (v/w), 56-506 mg/kg bw, in water 6 days per week for 12 weeks. At the high dose group of

506 mg/kg bw lesions of the gastric mucosa were reported while the NOAEL was 169 mg/kg bw (0.34 %) (Ito et al., 1976).

If the lowest NOAEL of the study in catalase deficient mice, a very sensitive animal model is considered, the dose of 37 mg/kg/day of hydrogen peroxide is equivalent to a sodium percarbonate dose of 114 mg/kg/day. As the local effect is more dependent on the concentration than on the administered dose the no effect concentration of 100 ppm of hydrogen peroxide would be equivalent to a concentration of 308 ppm of sodium percarbonate.

An oral uptake of carbonate will result in a neutralisation in the stomach by the low pH of the gastric juice and therefore neither local nor systemic effects are expected after oral exposure. Also via other exposure routes (inhalation, dermal exposure) carbonate is not expected to be systemically available in the body due to the limited uptake compared to the neutralisation capacity of the blood.

The effect of repeated exposure of humans to sodium has been studied extensively and has mainly focussed on the effects of sodium on the prevention and control of hypertension. Recommendations on daily dietary sodium intake were reported to be 2.0-3.0 g for a moderately restricted intake and 3.1-6.0 g was considered to be a normal intake (Fodor et al., 1999).

Although a repeated dose study is not available for sodium percarbonate, an additional repeated dose toxicity study in rats with sodium percarbonate is not necessary because the effects can be predicted based on the release of hydrogen peroxide, carbonate and sodium.

3.2.7 Genetic toxicity

Studies with sodium percarbonate are not available but the mutagenicity of hydrogen peroxide has been tested extensively. A review has been presented for example by ECETOC (1996) and the European Commission (2001). A genotoxic potential was found for *in vitro* tests but there was no evidence for *in vivo* mutagenicity. Due to the rapid degradation in the whole body, hydrogen peroxide has no systemic genotoxic potential. Also for sodium carbonate there was no concern with regard to a possible genotoxicity. In contact with body fluids sodium percarbonate dissociates into hydrogen peroxide and sodium carbonate and for this reason sodium percarbonate is considered non-mutagenic under *in vivo* conditions.

3.2.8 Carcinogenicity

Carcinogenicity studies with animals and sodium percarbonate are not available. The only component that could give rise to some concerns with regard to this endpoint is hydrogen peroxide that has been intensively studied for possible carcinogenic effects.

For hydrogen peroxide several studies show that long-term oral administration of 0.1-0.4 % hydrogen peroxide causes an inflammatory response in gastroduodenal tissue of mice. The response is limited to the glandular stomach and, to a lesser extent, to the peri-pyloric and proximal portion of the duodenum. No inflammatory response was observed in the oral cavity, forestomach or distal intestinal tract. The incidence was higher in strains of mice with a low catalase activity. Studies by Ito et al (1982) revealed that cessation of hydrogen peroxide administration causes a regression of lesions induced by prolonged (up to 180d) administration of hydrogen peroxide in drinking water.

The investigations by Ito et al (1981a,b) suggest that this inflammatory response may progress to carcinogenic changes in mice that are catalase deficient. In rats, hydrogen peroxide induced only papillomas; no malignant tumours of the forestomach were seen, even at nearly lethal concentrations (1-1.5% hydrogen peroxide in drinking water). Initiation-promotion studies suggest that hydrogen peroxide is not an initiator in skin, but may be a weak promoter of tumours in the rat at high (>15%) concentrations on the skin, or nearly lethal concentrations (1.5%) in drinking water.

In the 90-d study performed on catalase-deficient, C57BL/6NCrIBR mice that received constant concentrations of 0, 100, 300, 1000, or 3000 ppm of hydrogen peroxide in distilled drinking water for approximately 90 days, microscopically, no evidence of cellular atypia or architectural disruptions nor any other indications of neoplastic changes were observed. Therefore, the treatment-related mucosal hyperplasia noted in this study is not considered to be a neoplastic lesion. This reinforces the conclusion from the data of Ito suggesting that only inflammatory changes seen at nearly lethal concentrations in particularly catalase-deficient species or individuals could possibly lead to local tumours.

In vivo genotoxicity data currently point strongly to the fact that hydrogen peroxide is not an *in vivo* genotoxin. The induction of carcinogenicity by a non-genotoxic mechanism has been proposed (Troll and Wiesner, 1985). The fact that tumours were induced only at the sites where high concentrations of H₂O₂ came directly into contact with the tissues and that the tumours were associated with persistent local inflammation supports a non-genotoxic mechanism for the gastrointestinal tract tumours. It can be underlined also here that three recent studies demonstrated the lack of genotoxicity of hydrogen peroxide when administered *in vivo* at the maximally tolerated dose by different routes (intra-peritoneal, oral (2-wk via drinking water), i.v.). Consequently it can be concluded that hydrogen peroxide is unlikely to be carcinogenic under relevant human exposure conditions.

All recent evaluations have concluded that hydrogen peroxide is of no concern with regard to a possible carcinogenicity in humans (ACGIH, 1995; US FDA, 1991; European Commission, 2001; EPA, 2002).

3.2.9 Toxicity to Reproduction

An animal reproduction study with sodium percarbonate is not available. However, under normal handling and use conditions (non-irritating), sodium percarbonate will not reach the male and female reproductive organs when exposed orally, dermally or by inhalation, as it does not become available systemically (see section 3.2.1). For this reason the substance is not considered toxic to reproduction and it is considered not useful to perform a reproduction study with animals.

An animal reproduction study is not available for hydrogen peroxide. However, a reproduction toxicity study was not required because it is not systemically available in the body (European Commission, 2001).

3.2.10 Developmental Toxicity / Teratogenicity

An animal developmental/teratogenicity study with sodium percarbonate is not available. However, under normal handling and use conditions (non-irritating), sodium percarbonate does not become systemically available (see section 3.2.1). For this reason the substance is not considered toxic to the foetus and it is considered not useful to perform further studies with animals.

An animal developmental toxicity study is not available for hydrogen peroxide. However, a developmental toxicity study was not required because it is not systemically available in the body (European Commission, 2001).

3.2.11 Experience with human exposure

A poison centre report under the UK home accidents surveillance scheme has been prepared by DTI (1998). It summarises an analysis of accidents with household products for the year 1998, which were the most recent data available. However, the report included a survey from 1991 to 1998, which showed that the numbers were relatively constant. Of a total number of accident records of 145,361 only 59 accidents were related to laundry and dishwashing agents. Of these 59 accidents 30 were related with detergents/wash powder, 21 to dishwasher products and 8 to clothes wash liquid.

The accidents with laundry detergents and dishwashing agents mainly involved small children in the age group of 0-4 years. In this age group 5 accidents occurred with wash liquid, 17 with wash powder and 15 with dishwasher products. In the age group 5-14 years only 1 accident each with laundry detergents and dishwashing liquids occurred. For the age group of 15-64 years 2 accidents with washing liquids, 10 with laundry detergents and 5 with dishwashing agents were reported. In the age group of >65 years only 3 accidents were observed.

Poisoning, ingestion and skin contact (referred to as chemical injury) were the main causes of these accidents. Foreign body/eye injuries were reported in 4 cases for washing or dishwasher detergents, thereof 3 in children aged 0-4 years and one in the age group of 15-64 years.

The severity of the accidents seems rather low. No fatalities were reported and 59% of the accidents involving laundry and dishwashing agents could be treated at home. Further 46% could be treated ambulant by a doctor. None of the patients involved in laundry detergent/dishwashing agent accidents was treated in a hospital. The majority of the accidents in the household with products that could contain sodium percarbonate consist of accidental ingestion or skin contact in particular of small children with seemingly slight effects only. No firm conclusions on the involvement of percarbonate can be drawn, but it is noteworthy that only very few cases of eye irritation were observed.

3.2.12 Identification of critical endpoints

The existing animal data on acute toxicity show that sodium percarbonate has a local effect. In animal tests a slight irritating effect on the skin was reported for solid sodium percarbonate and it was highly irritating to the rabbit eye (not rinsed). The local effect of sodium percarbonate in the eyes can be explained by the presence of hydrogen peroxide because hydrogen peroxide causes irreversible damage to the eye in experimental animals at concentrations of 8 % and higher. A skin sensitisation study was negative.

When sodium percarbonate is getting into contact with body fluids it dissociates into hydrogen peroxide, carbonate and sodium. All three substances are naturally present in the human body. Under normal handling and use conditions (non-irritating) hydrogen peroxide, carbonate and sodium are not expected to be systemically available in the body. For this reason there are no concerns with regard to possible mutagenic, reproductive, teratogenic or

other systemic effects. The only critical endpoint for sodium percarbonate seems to be local irritation.

3.3 Consumer Risk Characterisation

Based on normal habits and uses, the consumer exposure to sodium percarbonate by inhalation, oral uptake and skin contact to solid sodium percarbonate is negligible and therefore the associated risk is also negligible. However, two relevant exposure scenario's were identified and the potential risks will be characterized for both scenario's.

3.3.1 Skin contact with sodium percarbonate via solutions

The estimated exposure to sodium percarbonate due to laundry hand washing was 5.4×10^{-4} mg per event. This is equal to an exposure of 0.54 μ g sodium percarbonate, which is equivalent with 0.18 μ g hydrogen peroxide, 0.21 μ g carbonate and 0.16 μ g sodium. Due to the rapid degradation the amount of 0.18 μ g will not increase the concentration of hydrogen peroxide in the blood. The amount of 0.21 μ g carbonate will not affect the pH of the blood, while the amount of 0.16 μ g sodium is negligible compared to the normal daily dietary uptake of sodium of 3.1- 6.0 g (Fodor et al., 1999). For this reason it can be concluded that the exposure to sodium percarbonate via solutions has no systemic effect on the consumers.

Data about the relationship between sodium percarbonate concentration and skin irritation potential are not available. However, to predict the skin irritation potential of sodium percarbonate solutions the hydrogen peroxide concentration could be used. Based on the evaluation of the EU Commission Working Group on the Classification and Labelling of Dangerous Substances a hydrogen peroxide concentration of 50 % and higher is corrosive, while concentrations of 35-50 % are irritant to the skin.

Because sodium percarbonate contains 32.5 % hydrogen peroxide, irritant levels of hydrogen peroxide can not be achieved in solutions. Based on the laundry hand washing scenario (with sodium percarbonate as extra laundry additive) the sodium percarbonate concentration in the solution would be 0.4 %, which is equivalent with a hydrogen peroxide concentration of 0.13 %. When humans are exposed to such a solution the hydrogen peroxide content in the solution is still about 250 times lower than the lower irritation limit of hydrogen peroxide (32.5 %). Therefore it can be concluded that local effects on the skin are not expected when consumers are exposed to sodium percarbonate via solutions (e.g. laundry hand washing).

3.3.2 Accidental or intentional overexposure

Accidental or intentional overexposure to sodium percarbonate may occur via the oral route, via exposure of the eyes (e.g. due to splashing) or via inhalation.

Acute oral LD50 values were 1034 and 2000 mg/kg body weight, while the acute dermal LD50 was > 2000 mg/kg body weight. Based on these LD50 values the uptake of sodium percarbonate by humans must be very high (> 50 g) to reach acute lethal effects. The amount of the household cleaning product which must be ingested is even higher and for this reason it is very unlikely that accidental overexposure results in lethal or severe effects. Typically one would estimate that not more than 5 g of detergent or 1.25 g of sodium percarbonate could be swallowed. For a 10 kg child this would result in a dose of 125 mg/kg bw. Lethal effects in animals occur from 1034 to 2000 mg/kg bw in rodents. However, it is likely that due to the

liberation of hydrogen peroxide in the stomach humans will vomit and not be able to take up lethal amounts of detergents. The poison centre records that have not registered any fatal poisonings due to the swallowing of detergents, and normally only immediately reversible irritation reactions of relatively benign nature corroborate this. Furthermore acute cases of oral poisoning, due to sodium percarbonate ingestion, were not found in the literature.

In vivo eye irritation tests show that the powder sodium percarbonate is highly irritating to corrosive to the eye (not rinsed). Therefore solid sodium percarbonate or household cleaning products which contain sodium percarbonate (e.g. detergents) could potentially result in eye irritation. However, the eye irritation potential of products which contain sodium percarbonate depends on many factors e.g. the sodium percarbonate content, the other components and also the particle size distribution.

An evaluation of hydrogen peroxide by the EU Commission Working Group on the Classification and Labelling of Dangerous Substances revealed that concentrations of 5-8 % will be labelled as "irritating to eyes" (R36), concentrations of 8-50 % will be labelled with "risk of serious damage to eyes" and concentrations higher than 50 % will be "corrosive". Based on these data "risk of serious damage to eyes" would only occur if the sodium percarbonate concentration is higher than 25 % in a solution.

A solution used for laundry hand washing contains only 0.39 % sodium percarbonate (= 0.13 % of hydrogen peroxide) and for this reason there is no risk for eye irritation if eyes were accidentally exposed to such a solution (e.g. due to splashing). Effects on human eyes, due to exposure to sodium percarbonate as such, were not found in the literature. However, a few cases of relatively mild eye irritation have been reported after exposure to detergents (DTI, 1998).

Although accidental oral, eye or inhalation exposure to the product sodium percarbonate has not been found in the literature, ingestion and inhalation of laundry detergent powder by children has been reported in the United States (Einhorn et al., 1989). The predominant symptoms were stridor, drooling and respiratory distress. It is unknown if similar cases of accidental inhalation exposure have occurred in Europe.

3.4 Discussion and conclusions

Sodium percarbonate has a low acute toxicity via the oral and dermal route (LD50 > 1000 mg/kg bodyweight). The existing animal data on acute toxicity show that sodium percarbonate has a local effect. In animal tests a slight irritating effect on the skin was reported for solid sodium percarbonate and it was highly irritating to the rabbit eye (not rinsed). Sodium percarbonate did not have sensitising properties in a test with guinea pigs.

When consumers are exposed to sodium percarbonate, neither hydrogen peroxide nor sodium carbonate will be systemically available due to their effective detoxification (degradation or neutralisation) in the body. Consequently it is to be expected that the concentration of hydrogen peroxide and sodium in the blood and the pH of the blood will not be increased. Therefore, neither sodium percarbonate itself nor hydrogen peroxide or carbonate will reach the organs or the foetus and there is no risk for systemic, developmental or reproductive toxicity. With regard to genotoxicity and carcinogenicity the properties of sodium percarbonate also resemble those of hydrogen peroxide and it can be concluded that there is

no concern for humans with regard to a possible genotoxicity or carcinogenicity of sodium percarbonate. The only critical endpoint for sodium percarbonate seems to be local irritation.

Consumers can be exposed to sodium percarbonate due to skin contact with solutions which contain sodium percarbonate, which can be laundry hand washing. However, the estimated concentrations of sodium percarbonate in these solutions are too low to cause skin irritation.

Accidental exposure of the eyes to dry products which contain sodium percarbonate or to solutions of household cleaning products which contain sodium percarbonate could result in eye irritation. Only if the sodium percarbonate concentration in the product or the solution is very high (> 25%) irreversible damage to the eye could occur if the product is not immediately washed out, which would normally be the case.

Acute cases of oral poisoning or effects on human eyes, due to accidental or intentional overexposure to sodium percarbonate, have not been found in the literature.

Based on the available data, the use of sodium percarbonate in household cleaning products has no adverse effect on consumers.

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5. Contributors to the report

- Leading company: Solvay S.A.
- Other contributors: Degussa A.G., members of HERA Environment Task Force.



Food and Agriculture
Organization
of the United Nations

World Health
Organization



JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Sixty-third meeting
Geneva, 8-17 June 2004

SUMMARY AND CONCLUSIONS

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 8 to 17 June 2004. The purpose of the meeting was to evaluate certain food additives and ingredients, flavouring agents, and a natural constituent of food.

Dr John Larsen, Division of Toxicology and Risk Assessment, Danish Institute of Food and Veterinary Research, Søborg, Denmark, served as Chairman and Mrs Inge Meyland, Danish Institute of Food and Veterinary Research, Søborg, Denmark, served as Vice-Chairman.

Dr Manfred Luetzow, Food Quality and Standards Service, Food and Nutrition Division, Food and Agriculture Organization of the United Nations, and Dr Angelika Tritscher, International Programme on Chemical Safety, World Health Organization, served as joint secretaries.

The present meeting was the sixty-third in a series of similar meetings. The tasks before the Committee were (a) to elaborate further principles for evaluating the safety of food additives; (b) to evaluate certain food additives, ingredients, and flavouring agents; (c) to review and prepare specifications for selected food additives and flavouring agents; (d) to evaluate a natural constituent of food.

The report of the meeting will appear in the WHO Technical Report Series. Its presentation will be similar to that of previous reports, namely, general considerations, comments on specific substances, and recommendations for future work. An annex will include detailed tables (similar to the tables in this report) summarizing the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological recommendations. Information on specifications for the identity and purity of certain food additives examined by the Committee will also be included.

The participants in the meeting are listed in Annex 1. Further information required or desired is listed in Annex 2. General considerations, that contain information that the Committee would like to disseminate quickly are included in Annex 3.

Toxicological monographs or monograph addenda on most of the substances that were considered will be published in WHO Food Additives Series No. 54.

New and revised specifications for the identity and purity of the compounds will be published in FAO Food and Nutrition Paper Series 52, Addendum 12.

More information on the work of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is available at:

www.fao.org/es/esn/jecfa/index_en.stm

www.who.int/pcs/jecfa/jecfa.htm

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Toxicological recommendations and information on specifications

1. Food additives and ingredients evaluated toxicologically

Food additive	Specifi- cations ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Benzoyl peroxide	R	Treatment of whey with benzoyl peroxide at a maximum concentration of 100 mg/kg does not pose a safety concern.
α -Cyclodextrin	-	α -Cyclodextrin does not pose a safety concern at the proposed use levels and resulting predicted consumption as food ingredient and food additive. The previously established ADI "not specified" for use as a carrier and stabilizer for flavours, colours, and sweeteners, as a water-solubilizer for fatty acids and certain vitamins, as a flavour modifier in soya milk, and as an absorbent in confectionery was maintained.
Hexose oxidase from <i>Chondrus crispus</i> expressed in <i>Hansenula polymorpha</i>	N	Not specified ^b
Lutein from <i>Tagetes erecta</i> L.	N	0-2 mg/kg bw (group ADI for lutein and zeaxanthin) ^c
Peroxyacid antimicrobial solutions containing 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) Containing HEDP and three or more of the following components: peroxyacetic acid, acetic acid, hydrogen peroxide, octanoic acid and peroxyoctanoic acid.	N	The peroxy compounds in these solutions (hydrogen peroxide, peroxyacetic acid and peroxyoctanoic acid) would break down into acetic acid and octanoic acid, and small residual quantities of these acids on foods at the time of consumption would not pose a safety concern. HEDP does not pose a safety concern at the levels of residue that are expected to remain on foods at the time consumption.
Acetic acid	R	
1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)	N	
Hydrogen peroxide	R	
Octanoic acid (as food additive)	N	
Steviol glycosides	N, T	0-2 mg/kg bw (temporary)
D-Tagatose	-	Not specified ^b
Xylanase from <i>Bacillus subtilis</i> expressed in <i>Bacillus subtilis</i>	N	Not specified ^b
Xylanase (resistant to xylanase inhibitor) from <i>Bacillus subtilis</i> containing a modified xylanase gene from <i>Bacillus subtilis</i>	N	Not specified ^b
Zeaxanthin	N	0-2 mg/kg bw (group ADI for lutein and zeaxanthin) ^c

^a N: new specifications prepared; R: existing specifications revised; T: tentative specifications.

^b ADI 'not specified' is used to refer to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of good manufacturing practice, i.e. it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal food of inferior quality or adulterated food, and it should not create a nutritional imbalance.

^c This group ADI does not apply to other xanthophyll-containing extracts with a lutein or zeaxanthin content lower than that cited in the specifications.

2. Food additives considered for specifications only

Food Additive	Specifications ^a
Aluminium lakes of colouring matters — General specifications	R
Aluminium powder	R
Hydroxypropyl cellulose	R
Hydroxypropylmethyl cellulose	R
Iron oxides	N, T
Magnesium sulfate ^b	R
Polyvinyl alcohol	R
Titanium dioxide	N, T
Zeaxanthin-rich extract from <i>Tagetes erecta</i> L.	

^a R: existing specifications revised; R: existing specifications revised; T: tentative specifications.

^b Magnesium sulfate was not evaluated at the present meeting because the intended use and use levels were not identified.

3. Revision of heavy metals limits for food additives

At its fifty-fifth meeting, the Committee began its implementation of a systematic five-year programme to replace the outdated test for heavy metals (as lead) in all existing food additive specifications with appropriate limits for individual metals of concern. At the present meeting, the heavy metals and arsenic limits of 84 additives with various technological functions were reviewed.

Comments on the Committee's new proposed limits are invited. If alternative values and supporting data are not received by the deadline for submission of data for the sixty-fifth meeting (30 November 2004), the proposed metal limits will be adopted and supersede the existing limits, replacing those published in FAO Food and Nutrition Paper 52 and its addenda 1 to 11.

Additive name	INS	Limits (mg/kg)			
		As	Pb	Cd	Hg
Aluminium	523	-	3	-	-
ammonium sulfate					
Ammonium chloride	510	-	2	-	-
Ammonium hydrogencarbonate	503 (ii)	-	2	-	-
Azodicarbonamide	927 a	-	2	-	-
Bees wax	901	-	2	-	-
Benzoic acid	210	-	2	-	-
Benzyl alcohol	-	-	2	-	-
Butan-1,3-diol	-	-	2	-	-
Butan-1-ol	-	-	2	-	-
Butan-2-ol	-	-	2	-	-
Butyl p-hydroxybenzoate	-	-	2	-	-
Calcium acetate	263	-	2	-	-
Calcium benzoate	213	-	2	-	-
Calcium carbonate	170	3	3	-	-
Calcium chloride	509	-	2	-	-
Calcium cyclamate	952	-	1	-	-
Calcium hydrogen phosphate	341 (ii)	3	4	-	-
Calcium sulfate	516	-	2	-	-
Candelilla wax	902	-	2	-	-
Castor oil	1503	-	2	-	-
Chlorine	925	-	2	-	1
Citranaxanthin	-	-	2	-	-
Cyclodextrin, beta-	459	-	1	-	-
Cyclohexane	-	-	2	-	-
Dammar gum	-	-	2	-	-
Diethyl tartrate	-	-	2	-	-

Additive name	INS	Limits (mg/kg)			
		As	Pb	Cd	Hg
Diethylene glycol monoethyl ether	-	-	2	-	-
Dimethyl dicarbonate	242	-	2	-	-
Diphenyl	-	-	2	-	-
Edible gelatin	-	1	1.5	0.5	0.15
Ferric ammonium citrate	-	-	2	-	-
Glycerol	422	-	2	-	-
Glycerol diacetate	-	-	2	-	-
Heptanes	-	-	2	-	-
Hexamethylene tetramine	239	-	2	-	-
Hydrogen peroxide	-	-	2	-	-
Isoamyl acetate	-	-	2	-	-
Isobutanol	-	-	2	-	-
Isopropyl acetate	-	-	2	-	-
Lactic acid	270	-	2	-	-
Light petroleum	-	-	2	-	-
Lysozyme	1105	-	2	-	-
hydrochloride					
Magnesium carbonate	504 (i)	-	2	-	-
Magnesium chloride	511	-	2	-	-
Magnesium hydrogen phosphate	343 (ii)	3	4	-	-
Magnesium lactate	329	-	2	-	-
Methanol	-	-	2	-	-
Mineral oil (high viscosity)	905	-	1	-	-

Additive name	INS	Limits (mg/kg)			
		As	Pb	Cd	Hg
Monoglyceride citrate	-	-	2	-	-
Nisin	234	-	1	-	-
Norhydroguaiaretic acid	-	-	2	-	-
Pentapotassium triphosphate	451 (ii)	3	4	-	-
Phenyl phenol, <i>o</i> -	231	-	2	-	-
Polyvinylpyrrolidone, Insoluble	1202	-	2	-	-
Polyvinylpyrrolidone	1201	-	2	-	-
Potassium acetate	261	-	2	-	-
Potassium benzoate	212	-	2	-	-
Potassium bromate	924 a	-	2	-	-
Potassium chloride	508	-	2	-	-
Potassium dihydrogen phosphate	501 (ii)	3	4	-	-
Potassium iodate	917	-	2	-	-
Potassium nitrate	252	-	2	-	-
Potassium nitrite	249	-	2	-	-
Potassium sodium L(+)-tartrate	337	-	2	-	-

Additive name	INS	Limits (mg/kg)			
		As	Pb	Cd	Hg
Potassium sulfate	515 (i)	-	2	-	-
Propan-1-ol	-	-	2	-	-
Propylene glycol	1520	-	2	-	-
Sodium benzoate	211	-	2	-	-
Sodium carboxymethyl cellulose	466	-	2	-	-
Sodium cyclamate	952	-	1	-	-
Sodium diacetate	262 (ii)	-	2	-	-
Sodium nitrate	251	-	2	-	-
Sodium nitrite	250	-	2	-	-
Sodium <i>o</i> -phenyl phenol	232	-	2	-	-
Sodium percarbonate	-	-	2	-	-
Sodium thiocyanate	-	-	2	-	-
Sorbic acid	200	-	2	-	-
Sucralose	955	-	1	-	-
Tannic acid	181	-	2	-	-
Tartaric acid, DL-	-	-	2	-	-
Toluene	-	-	2	-	-
Triacetin	1518	-	2	-	-
Trichlorotrifluoroethane, 1,1,2-	-	-	2	-	-
Urea	927 b	-	2	-	-

4. Flavouring agents evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

A. Pyridine, pyrrole and quinoline derivatives

Flavouring agent	No.	Specifications	Conclusions based on current intake
Indole	1301	N	No safety concern
6-Methylquinoline	1302	N	No safety concern
Isoquinoline	1303	N	No safety concern
Skatole	1304	N	No safety concern
1-Ethyl-2-acetylpyrrole	1305	N	No safety concern
1-Methyl-2-acetylpyrrole	1306	N	No safety concern
Methyl 2-pyrrolyl ketone	1307	N	No safety concern
2-Pyridinemethanethiol	1308	N	No safety concern
2-Acetylpyridine	1309	N	No safety concern
N-Furfurylpyrrole	1310	N	No safety concern
2-(2-Methylpropyl)pyridine	1311	N	No safety concern
3-(2-Methylpropyl)pyridine	1312	N	No safety concern
2-Pentylpyridine	1313	N	No safety concern
Pyrrole	1314	N	No safety concern
3-Ethylpyridine	1315	N	No safety concern
3-Acetylpyridine	1316	N	No safety concern
2,6-Dimethylpyridine	1317	N	No safety concern
5-Ethyl-2-methylpyridine	1318	N	No safety concern
2-Propionylpyrrole	1319	N	No safety concern
Methyl nicotinate	1320	N	No safety concern
2-(3-Phenylpropyl)pyridine	1321	N	No safety concern
2-Propylpyridine	1322	N	No safety concern

^aN: new specifications prepared.

B. Aliphatic and alicyclic hydrocarbons

Flavouring agent	No.	Specifi- cations	Conclusions based on current intake
Camphene	1323	N	No safety concern
beta-Caryophyllene	1324	N	No safety concern
d-Limonene	1326	N, T	ADI not specified ^b
Myrcene	1327	N	No safety concern
alpha-Phellandrene	1328	N	No safety concern
alpha-Pinene	1329	N	No safety concern
beta-Pinene	1330	N	No safety concern
Terpinolene	1331	N	No safety concern
Bisabolene	1336	N	No safety concern
Valencene	1337	N	No safety concern
3,7-Dimethyl-1,3,6-octatriene	1338	N	No safety concern
p-Mentha-1,3-diene	1339	N	No safety concern
p-Mentha-1,4-diene	1340	N	No safety concern
1,3,5-Undecatriene	1341	N	No safety concern
d-3-Carene	1342	N	No safety concern
Farnesene (alpha and beta)	1343	N	No safety concern
1-Methyl-1,3-cyclohexadiene	1344	N	No safety concern
beta-Bourbonene	1345	N	No safety concern
Cadinene (mixture of isomers)	1346	N	No safety concern
Guaiane	1347	N	No safety concern

^aN: New specifications prepared.

^bAn ADI "not specified" was established for *d*-limonene by the Committee at its forty-first meeting (Annex 1, reference 107), which was maintained at the present meeting.

C. Aromatic hydrocarbons

Flavouring agent	No.	Specifi- cations	Conclusions based on current intake
p-Cymene	1325	N	No safety concern
Biphenyl	1332	N	No safety concern
p,alpha-Dimethylstyrene	1333	N	No safety concern
4-Methylbiphenyl	1334	N	No safety concern
1-Methylnaphthalene	1335	N	No safety concern

^aN: new specifications prepared.

D. Aliphatic, linear α,β -unsaturated aldehydes, acids and related alcohols, acetals and esters

Flavouring agent	No.	Specifi- cations	Conclusions based on current intake
Butyl 2-decenoate	1348	N	No safety concern
2-Decenal	1349	N	No safety concern
2-Dodecenal	1350	N	No safety concern
Ethyl acrylate	1351	N	No safety concern
Ethyl 2-nonynoate	1352	N	No safety concern
2-Hexenal	1353	N	No safety concern
2-Hexen-1-ol	1354	N	No safety concern
2-(E)Hexen-1-yl acetate	1355	N	No safety concern
Methyl 2-nonynoate	1356	N	No safety concern
Methyl 2-octynoate	1357	N	No safety concern
Methyl 2-undecynoate	1358	N	No safety concern
2-Tridecenal	1359	N	No safety concern
trans-2-Heptenal	1360	N	No safety concern
trans-2-Hexenoic acid	1361	N	No safety concern
2-Nonenal	1362	N	No safety concern
2-Octenal	1363	N	No safety concern
2-Pentenal	1364	N	No safety concern
trans-2-Nonen-1-ol	1365	N	No safety concern
2-Undecenal	1366	N	No safety concern
trans-2-Octen-1-yl acetate	1367	N	No safety concern

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
trans-2-Octen-1-yl butanoate	1368	N	No safety concern
cis-2-Nonen-1-ol	1369	N	No safety concern
(E)-2-Octen-1-ol	1370	N	No safety concern
(E)-2-Butenoic acid	1371	N	No safety concern
(E)-2-Decenoic acid	1372	N	No safety concern
(E)-2-Heptenoic acid	1373	N	No safety concern
(Z)-2-Hexen-1-ol	1374	N	No safety concern
trans-2-Hexenyl butyrate	1375	N	No safety concern
(E)-2-Hexenyl formate	1376	N	No safety concern
trans-2-Hexenyl isovalerate	1377	N	No safety concern
trans-2-Hexenyl propionate	1378	N	No safety concern
trans-2-Hexenyl pentanoate	1379	N	No safety concern
(E)-2-Nonenoic acid	1380	N	No safety concern
(E)-2-Hexenyl hexanoate	1381	N	No safety concern
(Z)-3- & (E)-2-Hexenyl propionate	1382	N	No safety concern
(E)-2-Hexenal diethyl acetal	1383	N	No safety concern
2-Undecen-1-ol	1384	N	No safety concern

^aN: new specifications prepared.

E. Monocyclic and bicyclic secondary alcohols, ketones and related esters

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
Borneol	1385	N	No safety concern
Isoborneol	1386	N	No safety concern
Bornyl acetate	1387	N	No safety concern
Isobornyl acetate	1388	N	No safety concern
Bornyl formate	1389	N	No safety concern
Isobornyl formate	1390	N	No safety concern
Isobornyl propionate	1391	N	No safety concern
Bornyl valerate	1392	N	No safety concern
Bornyl isovalerate (endo-)	1393	N	No safety concern
Isobornyl isovalerate	1394	N	No safety concern
d-Camphor	1395	N	No safety concern
d-Fenchone	1396	N	No safety concern
Fenchyl alcohol	1397	N	No safety concern
Nootkatone	1398	N	No safety concern
1,3,3-Trimethyl-2-norbornanyl acetate	1399	N	No safety concern
Methyl jasmonate	1400	N	No safety concern
Cycloheptadeca-9-en-1-one	1401	N	No safety concern
3-Methyl-1-cyclopentadecanone	1402	N	No safety concern
2(10)-Pinen-3-ol	1403	N	No safety concern
Verbenol	1404	N	No safety concern
7-Methyl-4,4a,5,6-tetrahydro-2(3H)-naphthalenone	1405	N	No safety concern
3-Methyl-2-(n-pentanyl)-2-cyclopenten-1-one	1406	N	No safety concern
Dihydronootkatone	1407	N	No safety concern
3-L-Menthoxyp propane-1,2-diol	1408	N	No safety concern
beta-Ionyl acetate	1409	N	No safety concern
alpha-Isomethylionyl acetate	1410	N	No safety concern
3-(1-Menthoxy)-2-methylpropane-1,2-diol	1411	N	No safety concern
Bornyl butyrate	1412	N	No safety concern
D,L-Menthol(+/-)-propylene glycol carbonate	1413	N	No safety concern
L-Monomenthyl glutarate	1414	N	No safety concern
L-Menthyl methyl ether	1415	N	No safety concern
p-Menthane-3,8-diol	1416	N	No safety concern

^aN: new specifications prepared.

F. *Amino acids and related substances*

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
beta-Alanine	1418	N	No safety concern
L-Cysteine	1419	N	No safety concern ^b
L-Glutamic acid	1420	N	No safety concern ^{b,c}
Glycine	1421	N	No safety concern ^b
DL-Isoleucine	1422	N	No safety concern
L-Leucine	1423	N	No safety concern ^b
DL-Methionine	1424	N	No safety concern
L-Proline	1425	N	No safety concern ^b
DL-Valine	1426	N	No safety concern
DL-(3-Amino-3-carboxypropyl)dimethylsulfonium chloride	1427	N	No safety concern
L-Phenylalanine	1428	N	No safety concern ^b
L-Aspartic acid	1429	N	No safety concern ^b
L-Glutamine	1430	N	No safety concern ^{b,c}
L-Histidine	1431	N	No safety concern ^b
DL-Phenylalanine	1432	N	No safety concern
L-Tyrosine	1433	N	No safety concern ^b
Taurine	1434	N	No safety concern
DL-Alanine	1435	N	No safety concern
L-Arginine	1436	N	No safety concern ^b
L-Lysine	1437	N	No safety concern ^b

^a N: new specifications prepared. ^b Not evaluated using the Procedure for the Safety Evaluation of Flavouring Agents. The substance is a macronutrient and normal component of protein and, as such, human exposure through food is orders of magnitude higher than the anticipated level of exposure from use as flavouring agent. ^c The group ADI 'not specified' established at the thirty-first meeting for L-glutamic acid and its ammonium, calcium, magnesium, monosodium and potassium salts was maintained.

G. *Tetrahydrofuran and furanone derivatives*

Flavouring agent	No.	Specifications ^a	Conclusions based on current intake
2-Hexyl-4-acetoxytetrahydrofuran	1440	N	No safety concern
2-(3-Phenylpropyl)tetrahydrofuran	1441	N	No safety concern
Tetrahydrofurfuryl acetate	1442	N	No safety concern
Tetrahydrofurfuryl alcohol	1443	N	No safety concern
Tetrahydrofurfuryl butyrate	1444	N	No safety concern
Tetrahydrofurfuryl propionate	1445	N	No safety concern
4-Hydroxy-2,5-dimethyl-3(2H)-furanone	1446	N	No safety concern
Tetrahydrofurfuryl cinnamate	1447	N	No safety concern
2-Methyltetrahydrofuran-3-one	1448	N	No safety concern
2-Ethyl-4-hydroxy-5-methyl-3(2H)-furanone	1449	N	No safety concern
4-Hydroxy-5-methyl-3(2H)-furanone	1450	N	No safety concern
2,5-Dimethyl-4-methoxy-3(2H)-furanone	1451	N	No safety concern
2,2-Dimethyl-5-(1-methylpropen-1-yl)tetrahydrofuran	1452	N	No safety concern
2,5-Diethyltetrahydrofuran	1453	N	No safety concern
cis,trans-2-Methyl-2-vinyl-5-(2-hydroxy-2-propyl)tetrahydrofuran (Linalool oxide)	1454	N	No safety concern
5-Isopropenyl-2-methyl-2-vinyltetrahydrofuran (cis and trans mixture)	1455	N	No safety concern
4-Acetoxy-2,5-dimethyl-3(2H)furanone	1456	N	No safety concern
(+/-)-2-(5-Methyl-5-vinyl-tetrahydrofuran-2-yl)propionaldehyde	1457	N	No safety concern

^a N: new specifications prepared.

H. phenyl-substituted aliphatic alcohols and related aldehydes and esters

Flavouring agent	No.	Specifications*	Conclusions based on current intake
Ethyl 4-phenylbutyrate	1458	N	No safety concern
beta-Methylphenethyl alcohol	1459	N	No safety concern
2-Methyl-4-phenyl-2-butyl acetate	1460	N	No safety concern
2-Methyl-4-phenyl-2-butyl isobutyrate	1461	N	No safety concern
2-Methyl-4-phenylbutyraldehyde	1462	N	No safety concern
3-Methyl-2-phenylbutyraldehyde	1463	N	No safety concern
Methyl 4-Phenylbutyrate	1464	N	No safety concern
2-Methyl-3-(p-isopropylphenyl)propionaldehyde	1465	N	No safety concern
2-Methyl-3-tolylpropionaldehyde (mixed o-, m-, p-)	1466	N	No safety concern
2-Phenylpropionaldehyde	1467	N	No safety concern
2-Phenylpropionaldehyde dimethyl acetal	1468	N	No safety concern
2-Phenylpropyl butyrate	1469	N	No safety concern
2-Phenylpropyl isobutyrate	1470	N	No safety concern
2-(p-Tolyl)propionaldehyde	1471	N	No safety concern
5-Methyl-2-phenyl-2-hexenal	1472	N	No safety concern
4-Methyl-2-phenyl-2-pentenal	1473	N	No safety concern
2-Phenyl-2-butenal	1474	N	No safety concern
Ethyl 2-ethyl-3-phenylpropanoate	1475	N	No safety concern
2-Phenyl-4-pentenal	1476	N	No safety concern
2-Methyl-4-phenyl-2-butanol	1477	N	No safety concern
2-Oxo-3-phenylpropionic acid	1478	N	No safety concern
Sodium 2-oxo-3-phenylpropionate	1479	N, T	No safety concern

* N: new specifications prepared; T: tentative specifications.

5. Flavouring agents considered for specifications only

No.	Flavouring agent	Specifications*
53	Citronellyl formate	63rd/R
55	Neryl formate	63rd/R
68	Rhodinyll butyrate	63rd/R
399	Methyl-beta-ionone	63rd/R
471	2,8-Dithianon-4-ene-4-carboxaldehyde	63rd/R
504	S-Methyl benzothioate	63rd/R
557	1-Mercapto-2-propanone	63rd/R
570	Propenyl propyl disulfide	63rd/R
605	1,3-Nonanediol acetate (mixed esters)	63rd/R
615	Butyl ethyl malonate	63rd/R
628	Ethyl aconitate (mixed esters)	63rd/R
631.2	Sodium salt of 3-methyl-2-oxobutanoic acid	63rd/S ^b

No.	Flavouring agent	Specifications*
632.2	Sodium salt of 3-methyl-2-oxopentanoic acid	63rd/S ^b
633.2	Sodium salt of 4-methyl-2-oxopentanoic acid	63rd/S ^b
919	Glycerol monooleate	63rd/R
1203	Ammonium isovalerate	63rd/R
1218	4-Ethyl octanoic acid	63rd/R
1263	Isoeugenyl phenylacetate	63rd/R
1273	Ethyl 5-hexenoate	63rd/R
1291	3-Mercapto-2-methylpentan-1-ol (racemic)	63rd/R
1296	spiro[2,4-Dithia-1-methyl-8-oxabicyclo(3.3.0)octane-3,3'-(1'-oxa-2'-methyl)-cyclopentane]	63rd/R

* R, existing specifications revised; S, existing specifications were maintained; T, the existing, new, or revised specifications are tentative and new information is required.

^b Specifications will be withdrawn at the next meeting at which flavouring agents are discussed if no information becomes available by that time.

6. Evaluation of a natural constituent of food

Constituent	Toxicological recommendations
Glycyrrhizinic acid	Available data suggest that an intake of 100 mg per day would be unlikely to cause adverse effects in the majority of adults. In certain highly susceptible individuals, physiological effects could occur at exposure levels somewhat below this figure. The intake data indicate that consumers with a high intake of liquorice confectionery or herbal tea containing liquorice may be exposed to glycyrrhizinic acid at more than 100 mg/day.

Annex 1

Sixty-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Geneva, 8-17 June 2004

Members

- Prof. John R. Bend, Faculty of Medicine and Dentistry, University of Western Ontario, London, Ontario, Canada
- Dr David G. Hattan, Food and Drug Administration, College Park, MD, USA
- Dr Yoko Kawamura, National Institute of Health Sciences, Tokyo
- Dr Ada Knaap, National Institute of Public Health and the Environment, Bilthoven, The Netherlands
- Dr Paul M. Kuznesof, Food and Drug Administration, College Park, MD, USA
- Dr John Chr. Larsen, Danish Institute of Food and Veterinary Research, Søborg, Denmark (*Chairman*)
- Mrs Inge Meyland, Danish Institute of Food and Veterinary Research, Søborg, Denmark (*Vice-Chairman*)
- Dr Madduri V. Rao, Central Laboratories Unit, U.A.E. University, Al Ain, United Arab Emirates
- Dr Josef Schlatter, Food Toxicology Section, Swiss Federal Office of Public Health, Zürich, Switzerland
- Dr Maria Cecilia de Figueiredo Toledo, Faculty of Food Engineering, State University of Campinas, Campinas, Brazil
- Ms Elizabeth Vavasour, Food Directorate, Health Canada, Ottawa, Ontario, Canada
- Dr Philippe Verger, National Institute for Agricultural Research, Paris, France
- Prof Ronald Walker, School of Biomedical and Life Sciences, University of Surrey, Guildford, Surrey, United Kingdom
- Dr Harriet Wallin, National Food Agency, Helsinki, Finland
- Dr Donald Brian Whitehouse, Bowdon, Cheshire, United Kingdom

Secretariat

- Dr Peter J. Abbott, Food Standards Australia New Zealand (FSANZ), Canberra, Australia (*WHO Temporary Adviser*)
- Prof Michael C. Archer, Faculty of Medicine, University of Toronto, Toronto, Canada (*WHO Temporary Adviser*)
- Dr Ma. Patricia V. Azanza, Department of Food Science and Nutrition, College of Home Economics, Quezon City, Philippines (*FAO Consultant*)
- Dr Diane Benford, Food Standards Agency, London, United Kingdom (*WHO Temporary Adviser*)
- Dr Richard C. Cantrill, AOCS, Champaign IL, USA (*FAO Consultant*)
- Mrs Maria de Lourdes Costarrica, Food and Nutrition Division, Food and Agriculture Organization of the UN, Rome, Italy (*FAO Staff*)
- Dr Mukul Das, Industrial Toxicology Research Centre, Lucknow, India (*WHO Temporary Adviser*)
- Dr Michael DiNovi, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Prof Yehia El-Samragy, Food Science Department, Ain Shams University, Cairo, Egypt (*FAO Consultant*)
- Prof Hajimu Ishiwata, Seitoku University, Chiba, Japan (*FAO Consultant*)
- Prof Fujio Kayama, Division of Environmental Immunology & Toxicology, Department of Health Science, Jichi Medical School, Tochigi, Japan (*WHO Temporary Adviser*)
- Prof Robert Kroes, Institute for Risk Assessment Sciences, Utrecht University, Soest, The Netherlands (*WHO Temporary Adviser*)
- Dr Charles A. Lawrie, Food Standards Agency, London (*FAO Consultant*)
- Dr Catherine Leclereq, National Research Institute for Food and Nutrition, Rome, Italy (*FAO Consultant*)
- Dr Manfred Luetzow, Food and Nutrition Division, Food and Agriculture Organization of the United Nations (FAO), Rome, Italy (*FAO Joint Secretary*)

- Dr Antonia Mattia, Center for Food Safety and Applied Nutrition, US Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Dr Heidi Mattock, St Jean d'Ardières, France (*Editor*)
- Dr Gerald Moy, Food Safety Department, World Health Organization, Geneva, Switzerland (*WHO Staff Member*)
- Dr Ian C. Munro, CanTox Health Sciences International, Mississauga, Ontario, Canada (*WHO Temporary Adviser*)
- Dr Akiyoshi Nishikawa, Division of Pathology, National Institute of Health Sciences, Tokyo, Japan (*WHO Temporary Adviser*)
- Dr Zofia Olempska-Beer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, U.S.A. (*FAO Consultant*)
- Dr Sam Page, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland (*WHO Staff Member*)
- Mrs Ir Marja E.J. Pronk, Center for Substances and Integrated Risk Assessment, National Institute for Public Health and the Environment, Bilthoven, The Netherlands (*WHO Temporary Adviser*)
- Prof Andrew G. Renwick, Clinical Pharmacology Group, University of Southampton, Southampton, United Kingdom (*WHO Temporary Adviser*)
- Dr Sushil Kumar Saxena, Delhi, India (*FAO Consultant*)
- Prof I. Glenn Sipes, Department of Pharmacology, College of Medicine, University of Arizona, Tucson, AZ, USA (*WHO Temporary Adviser*)
- Dr James Smith, Prince Edward Island Food Technology Centre, Charlottetown, PE, Canada (*FAO Consultant*)
- Dr Ivan Stankovic, Institute of Bromatology, Faculty of Pharmacy, Belgrade, Serbia and Montenegro (*FAO Consultant*)
- Dr Angelika Tritscher, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland (*WHO Joint Secretary*)
- Mrs Annie de Veer, Department of Food and Veterinary Affairs, Ministry of Agriculture, The Hague, Netherlands (*WHO Temporary Adviser*)
- Professor Gary Williams, Environmental Pathology and Toxicology, New York Medical College, Valhalla, NY, USA (*WHO Temporary Adviser*)

Annex 2

Further information required or desired

Magnesium sulfate

Further information is required by the end of 2006 on functional uses of magnesium sulfate, including their use levels, and on the commercial use of anhydrous magnesium sulfate.

Steviol glycosides

The Committee required additional information by 2007, on the pharmacological effects of steviol glycosides in humans. These studies should involve repeated exposure to dietary and therapeutic doses, in normotensive and hypotensive individuals and in insulin-dependent and insulin-independent diabetics. In order to be able to remove the tentative designation from the specifications, further information for commercially available products is required on:

- Analytical data on distribution and concentrations of all component steviol glycosides, including those that are not identified in these tentative specifications.
- Method of analysis for the determination of all component steviol glycosides, including those that are not identified in these tentative specifications;
- The nature and concentration of the fractions that do not contain steviol glycosides.
- The quantities of residual solvents from isolation and purification steps of the manufacturing process.
- The hydrolytic stability of the steviol glycosides in acidic foods and beverages.

Zeaxanthin-rich extract from Tagetes erecta L

Information is required on the non-zeaxanthin components in total carotenoids and on the composition of the non-carotenoid components.

Annex 3

An edited version of this section will appear in the report of the sixty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It is reproduced here so that the information is disseminated quickly. This draft is subject to extensive editing.

General considerations**1. Estimating intake of flavouring agents**

At its fifty-fifth meeting, the Committee considered the use of the *per capita* x 10 method for estimating the intake of flavouring agents according to the Procedure for the Safety Evaluation of Flavouring Agents, as well as alternative procedures. While the Committee concluded that its use of the method was appropriate, it acknowledged that it may, in some cases, result in an underestimate of the intake of persons with high levels of consumption of specific foods. The Committee also recognised at the forty-ninth meeting that further consideration may be required in certain cases where there is conflicting information on intake. At the present meeting, the Committee reaffirmed these conclusions.

The Committee recognised that the estimates of current intake that it uses in evaluating the safety of flavouring agents, according to the Procedure, are difficult to reconcile with reported maximum use levels for some flavouring agents in different food groups. To help understand the basis for the apparent discrepancy in the information available to the Committee, the Committee requested that industry provide precise data on the use levels of flavouring agents that may be used in food products that are not widely distributed and that may be eaten on a regular basis by specific population groups in specific regions of the world.

The Committee anticipates that estimating the intake of flavouring agents, especially those with particularly low or particularly high production volumes, will be considered at the forthcoming joint FAO/WHO workshop on exposure assessment to be held in 2004.

Combined exposure

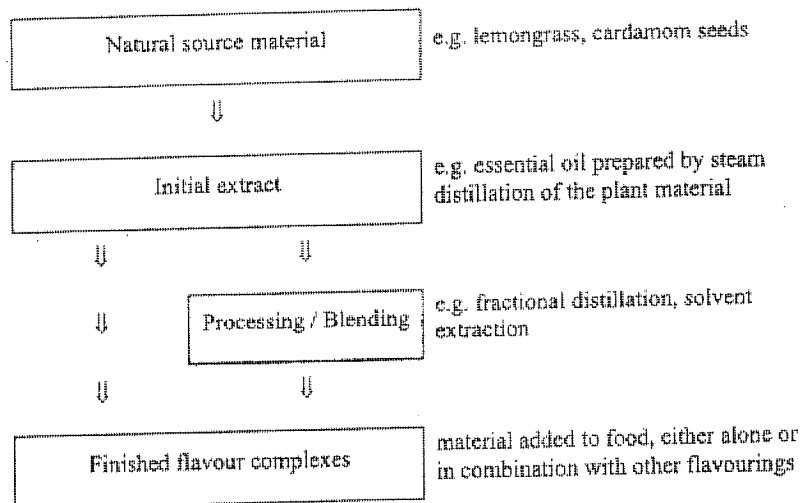
The Committee also recognised that the current procedure to estimate the combined intake for all congeners of one congeneric group of flavouring substances reflects an unlikely situation where the same individuals are consumers of all the substances. Nevertheless, this results in conservative estimates that allow evaluations to be completed. The Committee therefore recommends the establishment of a working group to develop a more adequate approach to be discussed during the next JECFA meeting that will include flavouring agents on the agenda.

2. Flavour complexes derived from natural sources

At this meeting, the Committee further considered a possible approach to the safety assessment of complex flavours derived from natural sources (usually from plant material) such as essential oils, oleoresins and solvent extracts. After considering the available data on three of the five flavour complexes originally included on the agenda – derived from essential oils of lemongrass, cardamom seed and bois de rose – the Committee defined the information that would be required in order to test the application of the revised Procedure for the Safety Evaluation of Flavouring Agents (Annex 1 Ref 131) which it had previously adopted for the safety evaluation of chemically-defined flavourings.

Background

Although these flavourings are typically named after the initial extract prepared from the source material, it is common practice for the initial extracts to be processed and refined in a variety of ways, to produce a range of flavour complexes with the specific properties desired for particular food applications. These processes might include distillation, concentration, solvent extraction and blending of extracts from different batches. Processing is generally carried out by flavour companies or, in certain cases, possibly by food manufacturers who use the finished flavours. The progression from source material to finished flavour is illustrated below:



The initial extracts are typically prepared from the plant material close to the point of production. Their composition may vary considerably at this level due to a variety of factors such as climate, geography, genotype and maturity of the source material. The flavour producer aims to supply flavour complexes with consistent technical and olfactory properties. This is primarily achieved by processing and blending to meet a target composition which is monitored by chemical analysis.

Although the finished flavour complexes are entirely derived from the original extract, using only physical processes such as those described above, their composition is likely to differ quantitatively from the initial extracts prepared directly from the source material.

The evaluation of finished flavour complexes is dependent upon:

- (a) information on the composition of the material that is added to food (and hence on the elaboration of a reliable specification that covers the range of finished flavour complexes that may be derived from the initial extracts);
- (b) safety evaluations of the individual components and congeneric groups
- (c) estimates of intake of the finished flavour complexes and, hence of the individual components.

Compositional data necessary to support the safety evaluation of a finished flavour complex

i. General considerations

The safety evaluations of finished flavour complexes derived from natural sources would be based on the revised Procedure, with particular consideration of the major components and of congeneric groups. The analytical data should be adequate to apply the revised Procedure.

Intake should be taken into account in determining the extent to which chemical characterisation and identification of individual components is necessary, beyond those necessary to define their flavour characteristics. In applying the Revised Procedure for the Safety Evaluation of Flavouring Agents the estimated intake of the individual agent is compared with appropriate thresholds of toxicological concern to determine whether or not the intake represents a safety concern. The same numerical thresholds can be applied to the intakes of individual identified components and combinations of components, such as occur in congeneric groups, which are present in finished flavour complexes derived from natural sources. The same intake thresholds can also be used as a basis for establishing analytical requirements as described below.

The human intake thresholds of toxicological concern are of two types: thresholds of 1800, 540 and 90 µg/person per day which are applied for structural classes I, II and III, respectively, and a general threshold of 1.5 µg/person per day applicable to all structural classes. The thresholds for classes I, II and III are based on the lower 5th percentile NOEL for the structural class, from toxicological studies in animals, divided by the usual 100-fold safety (uncertainty) factor. The general threshold (step B5 of the Procedure) is a pragmatic value based on an estimate of the human intake associated with a lifetime risk of cancer of less than 1 in a million calculated by linear-extrapolation from animal studies (Report of 46th Meeting). Because of the assumptions used in the derivation of this threshold, it is considered to be sufficiently conservative to cover all types of toxicity. The Committee considered that these thresholds can provide the basis for a pragmatic approach to the development of limits of sensitivity for analytical methods, when linked to reliable and validated estimates of intake, which should be derived from long-term average poundage.

*ii. Consideration of individual components**Identified components*

Based on step B5 of the Procedure, the Committee concluded there would be no significant safety concern if the intake for an identified component in a finished flavour complex derived from natural sources were less than 1.5 µg/person per day. This threshold can be used to establish a general limit for analytical characterization for components in a finished flavour complex under (b) below, based on the estimated intake of the complex. For example, if the estimated daily intake of the finished flavour complex is 150 µg/person per day, then there would be no safety concern for any component present at <1%. Similarly, if the estimated daily intake of the finished flavour complex is 15 µg/person per day, then there would be no safety concern for any component present at <10%. For high volume finished flavour complexes the limit for analytical characterisation would be set at 0.1-0.5% (see (b) below). Because the threshold is based on lifetime carcinogenicity data, the % should be the average value of the analyses, and not the highest single value.

Unidentified components

The chromatographic analysis of a finished flavour complex is likely to reveal the presence of a large number of unidentified minor components. Previously the Committee has not considered the general threshold of 1.5 µg/person per day for unidentified components. The Committee recognised that application of the general threshold to an unidentified component could not provide the same reassurance of safety as for structurally defined compounds, but considered that it could be incorporated into a pragmatic approach for establishing analytical requirements for finished flavour complexes derived from natural sources. This threshold combined with the estimated intake of the complex can be used to define a limit for the percentage of a chromatographic peak above which structural characterization would be necessary. For example, if the estimated daily intake of the finished flavour complex is 150 µg/person per day, then chemical characterization would be required for any component present >1%, so that safety evaluation of the component could be undertaken.

Product descriptions and specifications

A key part of the safety assessment will be the preparation of appropriate specifications covering the relevant finished flavour complexes. As with all food additive evaluations, the purpose of specifications for flavour complexes is to identify the material, to ensure that it meets the criteria for safe use, and to encourage good manufacturing practice. Specifications should reflect the materials used throughout the world and should take account of existing specifications drawn up at national or international level.

The Committee noted the existence of internationally agreed specifications prepared by the International Organization for Standardization (ISO) for over 100 essential oils obtained by steam distillation of plant materials. Essential oils and derived products are numerically the largest group of flavour complexes. ISO standards describe the oils and define the acceptable ranges for various parameters, including the methods for measuring these values. Many of these standards include ranges for the key chemical components, accompanied by typical gas chromatograms that can be used to confirm the identity of the oils. The Committee concluded that these standards need to be taken into account when setting specifications for food flavourings, particularly when selecting the parameters to be included and the associated analytical methods.

In order to develop specifications for flavour complexes added to food, and to provide the data necessary for the safety evaluation to proceed, the Committee requires a full description of the range of source materials and processing conditions. Manufacturers should also provide the results of appropriate analyses carried out on samples of representative flavour complexes, accompanied by details of the analytical methods (including validation of the methods) and a full description of each sample, including the source materials and production processes. Manufacturers should also address the possible presence of undesirable compounds associated with the source material (or species with which it might be confused) and should provide sufficient information to differentiate the flavour complexes from other products with similar properties.

Standard information in the specifications for finished flavour complexes will include: descriptions of the source material(s), the derivation of the initial extract, and any subsequent processing stages; a physical description of the flavour complexes; information on solubility; and (for liquid products) specific gravity, refractive index and optical rotation.

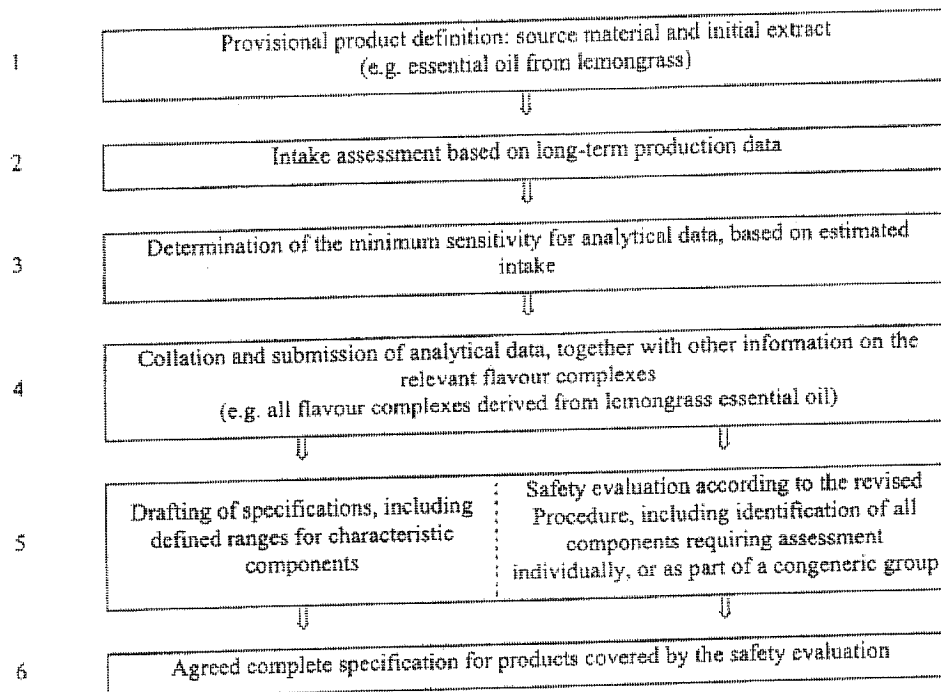
Specifications developed by the Committee will include the following information on composition, which is essential for the safety evaluation to proceed (see below).

(a) upper and lower concentrations of major characterising components, including all key constituents identified in relevant ISO standards and any other components considered to be critical for the organoleptic properties of the flavouring.

(b) a list of other components that may be present at or above a given level; the level will depend on the intake and the relevant threshold of toxicological concern (see above) in the revised Procedure for the Safety Evaluation of Flavouring Agents. Components present in the flavour complex at levels above 0.1-0.5% should be characterized if their estimated intake exceeds 1.5 µg/person per day. The need for more detailed characterization would be determined on a case-by-case basis depending on the nature of the starting material.

(c) upper limits for any other relevant components, including likely impurities and contaminants or potentially toxic components such as inherent toxins associated with any part of the source species or with related species with which it might be confused.

The overall scheme for evaluating finished flavour complexes is summarised in the following diagram:



The Committee requested data, in line with the above proposals, on examples of flavour complexes with a range of different constituents and representing different estimated intake levels in order to develop appropriate specifications and to evaluate the application of the revised Procedure to this type of flavouring agent. In particular, in the first detailed consideration of finished flavour complexes, quantitative data should be provided on the composition of representative samples of the selected flavour complexes, which allows the identification of all components present in the flavour complexes at levels above 0.1% and with an estimated intake of 1.5µg/day or more.

3. Evaluation of dietary nutrients and other ingredients

The Committee evaluated the safety of several substances that were claimed to have nutritional or health benefits. It was noted that there was increased interest in having the Committee evaluate such substances. The Committee noted that whether such products meet appropriate definitions as nutrients or are worthy of health, nutrient, or other claims was outside its remit. Therefore, the Committee only evaluated the safety of these ingredients. Moreover, the Committee expressed the view that the evaluation of the safety of these ingredients should not be interpreted to mean that the Committee endorses the use of these substances for their claimed nutritional or health benefits.

4. Determination of carotenoids

The Committee recognized that there is an increasing number of specifications for the analysis of members of the family of carotenoid compounds. Each specification prescribes the use of a different instrumental method of analysis. The Committee decided that it would be advantageous to consolidate and minimize the number of methods for the analysis of members of the carotenoid family and to publish them in FAO Food and Nutrition Paper, No. 5.

5. Revision of heavy metals and arsenic specifications

At its fifty-third meeting, the Committee agreed to implement the decision taken at its forty-ninth and fifty-first meetings, namely, to review and replace the limit test for heavy metals (as lead) and arsenic with, as appropriate, limits for the individual elements of concern in all existing specifications established by the Committee. In order to accomplish this, the Committee decided to review the existing specifications on the basis of functional use (e.g. antioxidant, preservative), and set a target of 5 years for completion of the task.

At its fifty-fifth and subsequent four meetings, the Committee reviewed all the specifications that had not been modified during previous meetings.

The principles adopted by the Committee in its reviews were as follows:

After removing the 'heavy metals (as lead)' specification, a maximum concentration of 2 mg/kg for lead and 1 mg/kg for cadmium and mercury would be established, except where there were data to support higher or lower maximum concentrations, or there were issues related to consumer exposure.

A limit for arsenic would only be included when the source from which the additive was prepared or the nature of the manufacturing method for the additive indicated that arsenic was likely to be a contaminant.

6. Core Standing Committee for JECFA

According to current procedure, JECFA is not a standing Committee. Members are selected for each meeting based on their expertise and according to the substances scheduled for evaluation. The Committee as such exists only during the actual time of the meeting which concludes with the adoption of the report.

In order to improve current working procedures and to facilitate the work of the Committee as well as of the Secretariats, the Joint Secretaries propose the establishment of a core JECFA Committee as a standing Committee for a period of three years. Chairs (one FAO and one WHO expert), rapporteurs (one FAO and WHO each) and four Members (two from FAO and WHO each) will be appointed by the secretariats according to WHO and FAO rules established for Expert Committees. The appointment of the Core JECFA Committee will be published on the JECFA websites.

The role of this standing committee is to ensure the continuity of the work of the Committee. Further responsibilities are to assist the secretariats in the following tasks: finalization of the agenda and formulation of appropriate call for data, identification of appropriate experts, and assignment of experts to specific substances for each meeting.

In addition, in agreement with the Secretariats, the Core Members may represent JECFA at specific meetings.

For each meeting additional Members will be appointed to the Committee according to existing procedures to cover all necessary expertise and to work with the Core Standing Committee in the evaluation of scheduled substances. All members of the Committee at the meeting have the same rights and responsibilities.

7. Provision of scientific advice by FAO and WHO

The Committee was informed about the advances on the consultative process carried out by FAO and WHO to enhance the procedures followed by both organizations for the provision of scientific advice to the Codex Alimentarius Commission and Member countries. In particular reference was made to the Joint FAO/WHO Workshop on the Provision of Scientific Advice to Codex and Member Countries held from 27 to 29 January 2004 which resulted in a set of recommendations on 1) essential principles, definitions and scope governing the provision of scientific advice, 2) management issues and 3) procedures and mechanism to be improved. The report of the Workshop is available on the websites of FAO (<http://www.fao.org/es/ESN/proscad/index.en.stm>) and WHO (<http://www.who.int/foodsafety/en/>).

The Committee noted that implementation of the recommendations will directly impact its work and that increased participation of experts from developing countries will require specific actions, for example, training on the operation of the Committee.

The Committee was informed that comments on the workshop recommendations received by FAO and WHO from their Member countries and international non-governmental organizations with observer status in Codex will be presented at the 27th session of the Codex Alimentarius Commission and that procedural guidelines on provision of scientific advice will be prepared and made public to increase transparency of the overall system. FAO/WHO will complete the consultative process and continue the implementation of the workshop recommendations depending on availability of resources.

8. IPCS Project on Dose-Response Modelling

The Committee was informed of the development of the project on dose-response modelling organized by the International Programme on Chemical Safety. The goal of this project is a state-of-the art review of dose-response modelling and its application in risk assessment, also harmonizing environmental and human health risk assessment. The outcome will be published in the Environmental Health Criteria document series. The Committee recognized the importance of this project with regard to chemical contaminants in food and endorsed the effort and urged its continuing support.

Material Safety Data Sheet

1. IDENTIFICATION

Product Name: TerraCyte®
Product Type:
 Granular Algaecide/Fungicide
Manufacturer:
 BioSafe Systems
 36 Commerce Street
 Glastonbury, CT 06033
Creation Date: 08/05

NOTE: Not valid two years after creation date.

2. COMPONENTS

Sodium Carbonate Peroxhydrate:
 CAS15630-89-4
 Calcium Carbonate

3. HEALTH HAZARDS DATA

Skin: May cause slight irritation.
Eyes: May cause severe eye irritation.
If swallowed: Severe irritation of the mouth, throat, esophagus and stomach.
If inhaled: Slight nose and throat irritation.

4. FIRST AID

Eyes: Immediately flush with plenty of cool running water. Remove contact lenses. Continue flushing for at least 15 minutes, holding eyelids apart to ensure rinsing of the entire eye. Call a physician immediately.
Skin: Immediately flush skin with plenty of cool, running water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before

reuse.

If swallowed: Rinse mouth at once; then drink 1 or 2 large glasses of water or milk. DO NOT induce vomiting. NEVER give anything by mouth to an unconscious person.

If inhaled: Immediately move a person to fresh air and let the person blow their nose.

5. FIRE AND EXPLOSION DATA

Special fire hazards: Oxidizing substance that causes exothermic reactions with organic materials.

Fire fighting methods: Product is not flammable and can be quickly diluted with clean water.

6. SPILL OR LEAK PROCEDURES

Cleanup: Collect the product with suitable means, shovel, sweep, avoiding dust formation.

Waste Disposal: Do not return spilled or contaminated material to inventory. Clean the area with large quantities of clean, cold water.

7. HANDLING AND STORAGE

- Never return product back to the original container
- Keep concentrate away from reactive substances
- Prevent contact with organic materials
- Keep product in original container
- Store in cool, dry area
- Keep out of direct sunlight

8. EXPOSURE CONTROLS/PERSONAL

PROTECTION

Respiratory: For most conditions, no respiratory protection should be needed.

Eyes: Use dust proof chemical goggles.

Skins: Rubber gloves – For brief contact, no precautions needed. Prolonged contact, use chemical gloves.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White, granular, solid

Odor: None

Bulk Density: 0.35 – 0.65 g/cm³

Solubility: 140 g/L @ 24°C (75°F)

pH: 1% solution: 10.4 – 10.6

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions

Materials to avoid:

- Acids
- Bases
- Reducing Agents
- Organic Materials

11. TOXICOLOGICAL INFORMATION

Acute toxicity:

- Dermal = LD rabbit > 2000 mg/kg
- Inhalation = LC 0 1 hour rat > 2290 mg /m
- Oral = LD 50 rat 517 mg /kg

12. ECOLOGICAL INFORMATION

toxic to simple cell organisms. Danger to the environment limited; due to product properties.

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- No bioaccumulation
- Soil degradation = 99% in 20 minutes
- Considerable abiotic and biotic degradability
- Sediments = Non-significant adsorption
- Weak persistence of degradation products
- Degradation products = sodium carbonate, carbon dioxide, bicarbonate carbonate, hydrogen dioxide

13. DISPOSAL CONSIDERATIONS

Packing Treatment: Rinse empty containers with clean water. Clean and empty containers are to be recycled or disposed in accordance with local regulations.

14. TRANSPORT INFORMATION

D.O.T. Shipping Name: Not regulated

UN Number: None

Hazard Class: None

Primary Hazard Label: None

Subsidiary Risk Label: None

Packing Group: None

WHMIS Classification: C – Oxidizing

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BiSafe Systems LLC
Glastonbury, CT 06033

Form #9004 08/05

1. IDENTIFICATION

Product Name: GreenCleanPRO
Granular Algaecide
Product Type: Algaecide
Manufacturer: BioSafe Systems L.L.C.
36 Commerce Street
Glastonbury, CT 06033

Creation Date: 11/05

NOTE: NOT VALID TWO YEARS AFTER
CREATION DATE.

2. COMPONENTS

Sodium Carbonate
Peroxyhydrate:CAS 15630-89-4

3. HEALTH HAZARDS DATA

Inhalation: Slight nose and throat irritation.

Eye contact: Severe eye irritation, risk
of serious eye lesions.

Skin contact: Slight irritation.

Ingestion: Severe irritation of the mouth,
throat, esophagus and stomach.

4. FIRST AID

If inhaled: Immediately move a person to
fresh air. Consult with a physician in case
of respiratory symptoms.

Eyes: Immediately flush with plenty of cool
running water. Remove contact lenses.
Continue flushing for at least 15 minutes,
holding eyelids apart to ensure rinsing of the
entire eye. Call a physician immediately.

Skin: Remove contaminated shoes, socks,
and clothing. Wash the affected skin with
running water. Wash clothing before
reuse.

If swallowed: Consult a physician in all cases.
If the subject is completely conscious, rinse
mouth and administer fresh water. Do NOT
induce vomiting. NEVER give anything by
mouth to an unconscious person.

5. FIRE AND EXPLOSION DATA

Special fire hazards: Oxidizing substance
that causes exothermic reactions with
organic materials.

Fire fighting methods: Product is not
flammable and can be quickly diluted with
clean water.

Specific Hazards: Reacts with strong
reducing agents – decomposition may
support combustion.

6. SPILL OR LEAK PROCEDURES

Cleanup: Collect the product with suitable
means, shovel, and sweep, avoiding dust
formation.

Waste Disposal: Do not return spilled or
contaminated material to inventory.
Clean the area with large quantities of
clean, cold water.

7. HANDLING AND STORAGE

- Never return unused product to the
original container.
- Keep concentrate away from reactive
substances.
- Prevent contact with organic materials.
- Keep product in original container.
- Store in cool, dry area.
- Keep out of direct sunlight and away
from heat sources.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory: For most conditions, no
respiratory protection should be needed.

Eyes: Use dust proof chemical goggles.

Hands: Protective gloves – chemical
resistant.

Skin: Body-covering clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White, granular, solid

Odor: None

Bulk Density: 1.0 – 1.2 g/cm³

Solubility: 140 g/L @ 24°C (75°F)

pH: 1% solution: 10.4 – 10.6

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions

Avoid:

- Heat/Sources of Heat
- Water/Moisture
- Acids
- Bases
- Reducing Agents
- Organic Materials

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

- Dermal = LD Lo rabbit > 2000 mg/kg
- Inhalation = LC 0.1 hour, rat
> 4580 mg /m

- Oral = LD 50 rat 1034 mg/kg

12. ECOLOGICAL INFORMATION

Toxic to simple cell organisms. Danger to
the environment is limited - due to
product properties.

- No bioaccumulation
- Soil degradation = 99% in 20 minutes
- Considerable abiotic and biotic
degradability
- Sediments = Non-significant adsorption
- Weak persistence of degradation prod-
ucts
- Degradation products = sodium
carbonate, carbon dioxide, bicarbonate
carbonate, hydrogen dioxide.

13. DISPOSAL CONSIDERATIONS

Packing Treatment: Rinse empty
containers with clean water. Clean and
empty containers are to be recycled or
disposed on accordance with local
regulations.

14. TRANSPORT INFORMATION

D.O.T. Shipping Name: Oxidizing Solid
N.O.S.

UN Number: UN # 3378

Hazard Class: 5.1

Primary Hazard Label: Oxidizer

Subsidiary Risk Label: None

Packing Group: III

WHMIS Classification: C – oxidizing
material

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