

FEB 10 2005

Kathleen Nese
Degussa Corporation
379 Interpace Parkway
Parsippany, NJ 07054

**Subject: Peraclean 15%: EPA Reg. No. 54289-4
Amendment Dated 11/12/04**

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised label which adds the "Me Too" use for treating process waters used for washing raw, unprocessed, post-harvest fruits and vegetables against non-public health spoilage/decay organisms, and which makes minor typographic corrections, is acceptable with the comment below, and providing you submit three final printed labels within 60 days from the date of this letter which makes the following changes.

Comment

When used to control non-public health spoilage/decay organisms in post-harvest fruits and vegetables, using the basic formula at the label dose produces ppm concentrations of the actives and inert ingredients at concentrations which do not exceed established tolerances listed in 40 CFR Part 180.940.

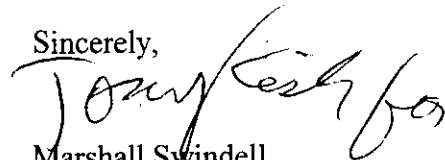
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In the continuous/intermittent section, correct the "20 ppm" to "7 ppm" in the fragment "...do not exceed 20 ppm...", and also correct "730 ppm" to "750 ppm" in the fragment "...do not exceed 730 ppm...".

Please include a copy of this letter with your re-submission.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

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Peraclean™ 15% (Peroxyacetic Acid Solution)

Peraclean™ 15% is a peroxyacetic acid-based sanitizer/disinfectant developed for the following uses:

Institutional/Industrial Sanitizing of Previously Cleaned Non-Porous Food Contact Surfaces in:

- ◆ Dairies
- ◆ Wineries
- ◆ Breweries
- ◆ Food and Beverage Plants
- ◆ Disinfecting Poultry Premises
- ◆ Poultry Hatcheries
- ◆ Animal Housing Facilities
- ◆ Reverse Osmosis Membranes and Ultra Filtration

Hard Surface Disinfection in:

- ◆ Hospitals
- ◆ Health Care Facilities
- ◆ Schools
- ◆ Colleges
- ◆ Veterinary Clinics
- ◆ Animal Life Science Laboratories
- ◆ Industrial Facilities
- ◆ Office Buildings
- ◆ Recreational Facilities
- ◆ Retail and Wholesale Establishments

Bacteria, Fungi, and Slime Control in:

- ◆ Pulp and Paper Mill Systems
- ◆ Dispersed Pigments
- ◆ Cooling Water Systems
- ◆ Coatings Preservation.

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Active Ingredients:

Hydrogen Peroxide	22.0%
Peroxyacetic Acid	15.0%

Inert Ingredients: 63.0%

Total: 100%

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

54289-4

EPA Reg. No. 54289-4

EPA Estab. No. 74130-DEU-001

Before Using This Product, Please Read This Entire Label Carefully.

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

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

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

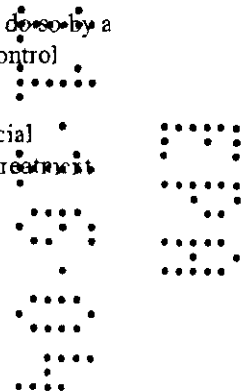
If swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call poison control center or doctor for treatment advice.

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

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured by:

Degussa Corporation
379 Interpace Parkway, P.O. Box 677
Passippany, New Jersey 07054-0677



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse

PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. Peraclean™ 15% is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the US Environmental Protection Agency.

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DIRECTIONS FOR USE

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

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SANITIZATION

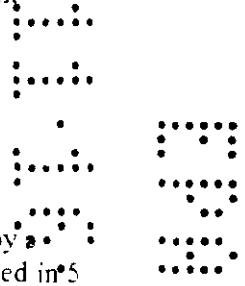
NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be used for subsequent sanitizing but may be reused for other purposes such as cleaning.
FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

Peraclean™ 15% peroxyacetic acid sanitizer is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, breweries, wineries, beverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. This product is effective as a sanitizer when solution is prepared in water of up to 400 ppm hardness as CaCO₃. This product has demonstrated greater than a 99.999% reduction of survivors after a 30 second exposure period in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study.

Sanitizing Food Contact Surfaces

Effective against Staphylococcus aureus and Escherichia coli.

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by potable water rinse. Sanitize with a concentration of 0.33 fluid ounce Peraclean™ 15% dissolved in 5 gallons of water (0.053% v/v concentration). This will provide 88 ppm of peroxyacetic acid. At this dilution Peraclean™ 15% is effective against Staphylococcus aureus and Escherichia coli. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of at least 60 seconds or more if specified by governing



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sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

Sanitizing, Eating, Drinking, And Food Prep Utensils

Remove gross food particles by a prescrape, a preflush and, when necessary, a presoak treatment.

Wash with a recommended detergent.

Rinse with clean water.

Sanitize in a solution of 0.33 fluid ounce Peraclean™ 15% dissolved in 5 gallons of water. Immerse all utensils for at least 60 seconds or contact time specified by governing sanitary code.

Drain and air dry.

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Sanitizing Tableware

For sanitizing tableware in low temperature warewashing machines, inject Peraclean™ 15% into the final rinse water at a concentration of 0.33 fluid ounce Peraclean™ 15% dissolved in 5 gallons of water. Do not exceed 0.053 % v/v. This will provide 88 ppm of peroxyacetic acid. Air dry.

To insure that the Peraclean™ 15% sanitizer concentration does not fall below 48 ppm peroxyacetic acid, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your technical service representative for assistance and further information on sanitizing tableware in warewashing machines.

Final Sanitizing Bottle Rinse

Peraclean™ 15% may be used as a final sanitizing rinse for returnable and non-returnable bottles at a 0.053% dilution (0.33 fluid ounce Peraclean™ 15% dissolved in 5 gallons of water). This will provide 88 ppm of peroxyacetic acid.

Batch Sanitization (NON-FOOD CONTACT SURFACES) of Ultra Filtration and Reverse Osmosis (RO) Membranes

Peraclean™ 15% can be used for the sanitization of ultra filtration, medical and non-medical institutional/industrial reverse osmosis (RO) membranes and their associated distribution systems.

This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. This product may not eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. Check with equipment manufacturer for membrane compatibility with Peraclean™ 15%.

Remove biological or organic fouling from the membrane or other parts of the system with an appropriate cleaner. Flush the system with RO permeate or similar quality water. Remove mineral deposits with suitable acidic cleaner prior to sanitizing the membranes with Peraclean™ 15%. Flush the system again with the RO permeate or similar quality water. Prepare an appropriate volume of 1% solution of the product (0.33 gallon of Peraclean™ 15% to 100 gallons of water). This will provide 568 ppm of peroxyacetic acid and 834 ppm hydrogen peroxide. Fill the entire water circuit to be sanitized with the dilute solution and allow the solution to reach a minimum of 20°C (68°F). Recirculate the dilute solution of Peraclean™ 15% for a minimum of 10 minutes. Allow membrane elements to soak in the solution for a minimum of 20 minutes. Rinse the RO system and test for residuals to ensure that there is less than 3 ppm per oxygen. Diverting product water to drain can reduce residuals.

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Batch Sanitization (NON-FOOD CONTACT SURFACES) of Piping Systems Associated with RO Membranes

Isolate incompatible equipment from piping system. This includes activated carbon filters and ion exchange equipment. Turn off power to ultraviolet light units. Estimate total volume of water contained in the system (tanks, rinse stations and piping). Prepare an appropriate volume of 0.33 to 0.5% Peraclean™ 15% by adding 0.33 to 0.5 gallons of the product for every 100 gallons of solution prepared. Use RO permeate or similar quality water for dilution. This will provide 554 to 840 ppm peroxyacetic acid and 813 to 1232 ppm hydrogen peroxide. Recirculate the dilute Peraclean™ 15% solution through the system for a minimum of 4 hours. Process usage valves should be opened and closed to expose internals to the Peraclean™ 15%. Completely drain the system of dilute Peraclean™ 15% solution. Thoroughly rinse the system by filling with RO permeate or similar quality water and recirculate before drainage. Repeat the process until test for residuals indicates there is less than 3 ppm peroxygen.

Continuous/Intermittent addition to minimize the Accumulation of Biological Matter Between Intermittent Sanitizing Episodes in Piping Systems Associated with RO Membranes for (NON-FOOD CONTACT SURFACES)

Peraclean™ 15%, as received or diluted, may be added continuously to the feed water system, between system sanitizing episodes, to aid in minimizing the regrowth/ accumulation of biological matter. The peroxygen residual in the system which will be effective will vary with the design and usage characteristics of the system. Adjust the addition rate of Peraclean™ 15% or the solution and periodically monitor residual peroxygen so that the desired effect is obtained. For continuous addition, do not exceed 20 ppm (0.33 fluid ounce of product per 440 gallons of water) Peraclean™ 15%. This will give 1 ppm peroxyacetic acid and 1.4 ppm hydrogen peroxide. For intermittent feed, do not exceed 730 ppm (8.5 fluid ounces of product per 100 gallons of water) Peraclean™ 15%. This will give 110 ppm peroxyacetic acid and 160 ppm hydrogen peroxide.

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HARD SURFACE DISINFECTION

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Peraclean™ 15% disinfects as it cleans in one operation. Peraclean™ 15% can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, non-porous porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

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Areas of use in hospitals: Peraclean™ 15% may be used for surgical and obstetrical suites; housekeeping services; physical therapy departments; nursing services; autopsy facilities. Also, use Peraclean™ 15% in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Combination Disinfection and Cleaning

Peraclean™ 15% is effective against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Trichophyton mentagrophytes, and Escherichia coli 0157:H7 at 0.08% (0.5 oz./5 gal.) in hard

water (400 ppm as CaCO₃) and 5% fetal bovine serum on hard nonporous surfaces. For heavily soiled areas a pre-cleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device, or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

Peraclean™ 15% is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, Peraclean™ 15% is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages, and feeding and watering equipment. In addition Peraclean™ 15% will deodorize those areas which are generally hard to keep smelling fresh such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.

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For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

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DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 54289-4

Poultry Hatchery Disinfection

Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.08% (0.5 oz./5 gal.) solution of Peraclean™ 15% for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse. See your technical representative for specific recommendations for all cleaning and rinsing requirements.

Disinfection And Deodorizing of Animal Housing Facilities (Barns, Kennels, Hutches, Etc.)

Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils). Remove animals and feed from premises, vehicles, and enclosures. Remove litter, waste matter, and gross soils from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering equipment. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.08% (0.5 oz./5 gal.) solution of Peraclean™ 15% for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

For Sanitizing of Hatching Eggs

Prepare a solution of Peraclean™ 15% by diluting 0.33 fluid ounce Peraclean™ 15% with 5 gallons of water. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces.

NOTE: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a

smaller test area to determine compatibility before proceeding with its use.

For Treatment of Raw, Unprocessed Fruit and Vegetable Surfaces

Peraclean 15% can be applied as a dip or spray to control the growth of non-public health microorganisms that may cause decay and/or spoilage on raw, post-harvest fruits and vegetables during the washing process. This product can be applied during physical cleaning processes, including at the roller spreader, washer manifold, dip tank, on the brushes or elsewhere in the washing process prior to, simultaneously with or after detergent wash.

1. Prepare treating solution by diluting 1 fluid ounce per 16 gallons of potable water. This will provide 85 ppm peroxyacetic acid and 125 ppm hydrogen peroxide.
2. Apply the diluted sanitizer solution using a coarse spray directed at the fruits or vegetables, or by soaking the fruits and vegetables in the solution. Allow a contact time of at least 45 seconds.
3. The treated produce can be drain dried without a potable water rinse.
4. Do not reuse solution after treatment.

BJOFOULING CONTROL IN PULP AND PAPER MILL SYSTEMS

For use in the manufacture of paper and paperboard intended for food-contact and non-food contact. Peraclean™ 15% can be used to control bacteria, fungi, and fresh water organisms in paper, paperboard, or nonwoven process water and influent water systems. Suitable dosing points include but are not limited to: stock chests, pulpers, the white water loop and white water storage systems and influent water streams.

Influent Water Systems:

Peraclean™ 15% should be fed continuously to incoming fresh water streams (nonpotable use only) at dosages ranging from 10-975 ppm peroxyacetic acid (65-6500 ppm Peraclean™ 15%).

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Mill Process Waters:

- Continuous Feed – Peraclean™ 15% should be fed continuously at dosages ranging from 10-975 ppm peroxyacetic acid (65-6500 ppm Peraclean™ 15%). This range is equivalent to 0.13 – 13 lbs. Peraclean™ 15% per ton (dry basis) of pulp or paper produced.
- Intermittent Feed – Peraclean™ 15% should be fed intermittently (6-8 times per day) at dosages ranging from 10-975 ppm peroxyacetic acid (65-6500 ppm Peraclean™ 15%). This range is equivalent to 0.13 – 13 lbs. Peraclean™ 15% per ton (dry basis) of pulp or paper produced.
- Shock Dose – Peraclean™ 15% should be shock dosed at dosages ranging from 98-2048 ppm peroxyacetic acid (648 – 13,638 ppm Peraclean™ 15%). This range is equivalent to 1.3 to 27.3 lbs. Peraclean™ 15% per ton (dry basis) of pulp or paper produced.

CONTROL OF BACTERIA AND FUNGI IN NON-FOOD CONTACT DISPERSED PIGMENTS

Peraclean™ 15% can be used in the control of bacteria and fungi in the manufacture and storage of dispersed pigments such as kaolin clay, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, magnesium silicate and diatomaceous earth used in paint and paper production.

Add 0.1 to 0.5 lbs. (1.4 to 6.85 fl. oz.) of Peraclean™ 15% to each 1000 lbs. of pigment slurry. This will provide 15 – 75 ppm peroxyacetic acid (100 to 500 ppm Peraclean™ 15%).

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CONTROL OF SLIME FORMING BACTERIA IN COOLING WATER SYSTEMS (COOLING TOWERS, EVAPORATIVE CONDENSERS).

- Severely fouled systems should be cleaned before adding the Peraclean™ 15% solution. Peraclean™ 15% should be added in the system directly and not mixed with any other chemicals or additives. Contamination with other chemicals could result in product decomposition.
- Add Peraclean™ 15% at a point in the system where uniform mixing and even distribution will occur.
- Use 0.1 to 0.5 lb. (1.4 to 6.85 fl. oz) of Peraclean™ 15% per 1000 gallons of solution as a continuous or intermittent slug treatment. This will provide 1.8 -9 ppm peroxyacetic acid (12-60 ppm Peraclean™ 15%). Repeat treatment as required to maintain control.

CONTROL OF BACTERIA AND FUNGI IN COATING PRESERVATION

Not for use in manufacture of material intended for food contact.

Peraclean™ 15% can be used as an in-container preservative for the control of bacteria and fungi in water-based coatings such as paper coatings.

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Add 0.1 to 0.5 lbs. (1.4 to 6.85 fl oz) of Peraclean™ 15% to each 1000 lbs. of preservative. This will provide 15-75 ppm peroxyacetic acid (100-500 ppm Peraclean™ 15%).

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STORAGE AND DISPOSAL

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

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Storage: Never return Peraclean™ 15% to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute Peraclean™ 15% with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedures for Leak or Spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. Peraclean™ 15% which is to be discarded should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal: > 5 gallon plastic drums: 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.

>5 gallons plastic tote bin liners: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.