54289-3

08/11/2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 1 1 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Tiana Roasmilia Product Safety Specialist for, Degussa Corporation 379 Interpace Parkway, P.O. Box 677 Parsippany, NJ 07054-0677

Subject: Peraclean 5%

EPA Registration Number 54289-3 Your Notification Dated July 13th, 2006 EPA Received Date July 13th, 2006

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to remove the dilution range in the mixing directions and the phrase, "such as", from the first line of directions in the section in the identification of organisms, is acceptable.

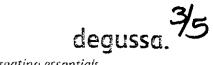
This notification has been made part of your permanent record.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33 Regulatory Management Branch I Antimicrobial Division(7509C)

Please read instructions	on reverse before comp		tion per PR			OMB No. 2070	2/4 0-0060, Approval expires 2-28-5	
ЕРА	United States Environmental Protection Agency Washington, DC 20460					Registratio Amendme Other		
······································		Application		ide				
1. Company/Product Number 54289-3			2. EPA Product Manag Marshall Swindell				3. Proposed Classification	
4. Company/Product (Name) Peraclean 5%			PM# 33					
5. Name and Address of Applicant (Include ZIP Code) Degussa Corporation 379 Interpace Parkway, P.O. Box 677 Parsippany, NJ 07054-0677			 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No Product Name 					
			Section -					
Amendment – Exp Resubmission in re Notification – Expl	tated	Section	Final printed labels in response to Agency letter dated "Me Too" Application Other – Explain Below.					
Explanation: Use add	itional page(s) if necessa	ary. (For Section 1	and Section I	l.)				
Notification to clarify dosage rate and identification of organisms in "Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers" use directions pursuant to a request made by the California Dept. of Pesticide Regulation in review of a pending label amendment. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. 1 understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. 1 further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this								
product may be in violat	on of FIFRA and I may	be subject to entor	rcement action	and	penalties under se	ections 12 and 1	4 of FIFRA.	
		<u> </u>	Section - I	II				
Material This Produ Child-Resistant Packaging Yes No * Certification must be submitted	ct Will Be Packaged In Unit Packaging Yes No If "Yes" Unit Packaging wgt.	Init Packaging W Yes Image: Constraint of the second seco			No, per Container	2. Type of Container Metal Plastic Glass Paper Other (Specify)		
3. Location of Net Cont	ents Information	4. Size(s) Retail	Container				or of Label Directions	
<u> </u>	Container	Lithograph	<u> </u>			🛛 🗌 On La		
		Paper Glue	d		····			
			Section - I	_				
1. Contact Point <i>(Comp</i> Name Tiana Rosamilia	lete items directly below	Titl				Tele	s this application) phone No. (Include Area Code) -541-8049	
	ements I have made on t 1y knowingly false or mi v	sleading statement	tachments thei t may be punis					
2. Signature			3. Title Product Safety Specialist					
 Typed Name Tian 	na Rosamilia	5. 1	Date	Ju	ly 13, 2007			
	Previous editions are obsolete.					- EPA File Copy ((original) Yellow - Applicant copy	



creating essentials

Degussa Corporation

379 Interpace Parkway P.O. Box 677 Parsippany, NJ 07054-0677

Direct: (973) 541-8049 Fax: (973) 541-8040

Tiana.Rosamilia@degussa.com www.degussa.com

July 13, 2006

Via HAND DELIVERY

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

Attention: Marshall Swindell Product Manager, Team 33 Antimicrobials Division

Product: Peraclean[™] 5% (EPA Reg. No. 54289-3)

Dear Mr. Swindell:

Pursuant to PR Notice 98-10, Degussa Corp. hereby notifies EPA of the clarification of use directions under the heading "Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers." At this time Degussa wishes to make the following changes to this section:

• Remove the dilution range in the mixing directions leaving only the upper delution rate currently approved by EPA; and,

• Remove the phrase "such as" in the first line of directions in this section in the identification of organisms.

These changes are required by the California Department of Pesticide Regulation in order to approve a pending label amendment.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of

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FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions please contact me at (973) 541 - 8049. Thank you for your attention to this matter.

Best regards,

Trant

Tiana Rosamilia Product Safety Specialist

DIRECTIONS FOR USE It is a violation of Federal taw to use this product in a manner inconsistent with its labeling.	Peraclean® 5%	DIRECTIONS FOR USE (Continued)
SANTIZATION NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be reused for 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 it the solution becomes diluted or solied. Peraclean@ 5% peroxyacetic acid sanitizer is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in daries, breweries, whereles, heverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. This product is effective as a santizer when solution is prepared in water of up to 400 ppm hardness as CaCO. 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 a potable water rinse. Saritize with a concentration of 1.0 ounce Peraclean@ 5% dissolved in 5 gains of water (0.16% viv concentration). At this dilution Peraclean@ 5% is effective against Staphylococcus aureus and Escherichia coli.	(Peroxyacetic Acid Solution) Peraclean® 5% 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 Hard Surface Disinfection in: Dairies Schools Wineries Colleges Breweries Veterinary Clinids Animal Food and Beverage Plants Life Science Laboratories Disinfecting Poultry Premises Industrial Facilities Poultry Hatcheries Office Buildings Animal Housing Facilities Rescreational Facilities	DISINFECTION OF POUL TRY PREM Remove all poultry and feeds from pr occupied or traversed by poultry. En detergent and ringe with water. Satu buildings, coops and other closed spi scrub treated feed racks, troughs, au your technical representative for spec <u>Poultry Hachery Disinfection</u> Remove all poultry and feeds from pr occupied or traversed by poultry. En detergent and rinse with water. Satu buildings, coops and other closed spi scrub treated feed racks, troughs, au your technical representative for spec <u>Disinfection And Deodorizing Of Antra</u>
should be exposed to the sanifizing solution for a penod of at least 60 seconds or more if specified by governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse. <u>Sanifizing, Eating, Drinking, And Food Prep Utensils</u> Remove gross food particles by a prescrape, a preflush and, when necessary, a presoak treatment. Wash with a recommended detergent. Rinse	Refail and Wholester Establishments Active Ingredients: Hydrogen Peroxide 20.5% Peroxyacetic Acid 4.9%	Do not use in miking stalls, miking pa vehicles, and enclosures. Remove fit facilities and fixtures occupied or travi- surfaces with detergent and rinse with munutes. Immerse all halters, ropes, i
with clean water. Sanitize in a solution of 1 0 ounce Peraclean® 5% dissolved in 5 gallons of water. Immerse all utensits for at least 60 seconds or contact time specified by governing sanitary code. Drain and air dry Sanitizing Tableware	Inert Ingredients:68.6%EPA Reg. No. 54289-3Total:100%EPA Estab. No.	scrapers used for removing litter and equipment until treatment has been a fountains, and waterers with soap or
semicant a autoware For sanitizing tableware in low temperature warewashing machines, inject Peraclean® 5% into the final rinse water at a concentration of 1.0 ounce Peraclean® 5% dissolved in 5 gallons of water Do not exceed 0.16 % v/v Air dry.	Before Using This Product, Please Read This Entire Label Carefully. KEEP OUT OF REACH OF CHILDREN	For Sanitizing Of Hatching Eggs Prepare a solution of Peraclean® 5% solution as a coarse spray so as to #g
To insure that the Peraclean® 5% sanitzer concentration does not fall below 0 1%, periodically test the nnse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your technical service representative for assistance and further information on sanitzing tableware in warewashing machines.	DANGER	NOTE This product at its use dilution surface, it is recommended that you a
Fingt Sanitizing Bottle Rinse Peraclear® 5% may be used as a final sanitizing rinse for returnable and non-returnable bottles at a 0 16% dilution (1 0 ounce Peraclear® 5% dissolved in 5 gallons of water).	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.	STORAGE AND DISPOSAL Do not contaminate water, food or fee Storage: Never return Peraclean@ 59
<u>Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers;</u> To reduce the number of non-pathogenic beverage spollage organisms. Effective against Aspergillus versicolor, Byssochiamys fulva, Pediocoocus damnosus, Lactobacillus buchten, and Saccharomyces cerevisae.	If on skin or dothing: 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	reducing agents and metals. Contam contamer, douse container with cool s closed at all times when not in use. It
 Prepare Peraclean® 5% solution by adding 31 fl. oz. to 5 gallons potable water. This provides 2.632 ppm peroxyacetic acid. Apply antimicrobial rinse at a temperature of 40°C (104°F to 140°F) and allow a munimum seven-second contact period Allow containers to drain thoroughly, and then rinse with sterile or potable water. 	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.	store on wooden pallets. Procedures for Leak or Spill Stop leat tools. Keep combustible and organic
HARD SURFACE DISINFECTION Peraclean® 5% disinfects as it cleans in one operation. Peraclean® 5% 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, refingerators, coolers, tile, linoleum, vinyl, asphatt	If inhaled: Move person to fresh air If person is not breathing, call 911 or an ambutance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.	confined spaces. Pesticide Disposal: Pesticide wastes Federal Law If these wastes cannot Agency, or the Hazardous Waste rep
porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.	Note to Physician: Probable mucosal damage may contraindicated the use of gastric lavage.	Agency, or the Hazardous Waste rep method of disposal is to dilute with at

Areas of use in hospitals, use Peraclean@ 5% for surgical and obstetrical surtes, housekeeping services; physical therapy departments, nursing services; autopsy facilities. Also, use Peraclean@ 5% in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratones, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments

This product is not to be used as a terminal sterilart/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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Combination Disinfection and Cleaning

Peraclean@ 5% is effective against Staphylococcus aureus, Safmonella choleraesuis, Pseudomonas aeruginosa, Trichophyton mentagrophytes, and Escherichia coli 0157:H7 at 0.23% (1.5 oz./5 gal.) in hard water (400 ppm as CaCO-) 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® 5% is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and fivestock quarters. When used as directed, Peraclean@ 5% 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@ 5% 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 nnsed with potable water before reuse.

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

(Continued on last panel)

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 Peraclear® 5% 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 phor 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.

degussa.

Manufactured by: Degussa Corporation 379 Interpace Parkway, P.O. Box 677 Parsippany, New Jersey 07054-0677

IN OF POULTRY PREMISES, TRUCKS,

outiny and feeds from premises, trucks, co raversed by pouttry. Empty all troughs, ra rinse with water. Saturate surfaces with ios and other closed spaces. Do not hous feed racks, troughs, automatic feeders, fi representative for specific recommendation

tery <u>Disinfection</u> Nultry and feeds from premises, trucks, co raversed by poultry. Empty all troughs, ra d rinse with water. Saturate surfaces with os and other closed spaces. Do not hous feed racks, troughs, automatic feeders, for representative for specific recommendation

nd Deodorizing Of Animal Housing Facili milking stalls, milking parlors, or milk hou enclosures. Remove litter, waste matter. ixtures occupied or traversed by animals detergent and rinse with water Saturate erse all halters, ropes, and other types o for removing litter and manure. Ventilat to treatment has been absorbed, set, or o waterers with soap or detergent, and no

Of Hatching Eggs

ution of Peraclean® 5% by diluting 1.0 ou coarse spray so as to lightly wet all shell :

product at its use dilution is compatible w ecommended that you apply product to a

VD DISPOSAL

nanate water, food or feed by storage or d

er return Peraclean® 5% to the original of nts and metals. Contamination and imput ise container with cool water and diute P mes when not in use. Keep container ou den oallets.

or Leak or Spill Stop leak of this can be d ombustible and organic materials away. es.

xosal: Pesticide wastes are acutely haza If these wastes cannot be disposed of by e Hazardous Waste representative at the posal is to dilute with at least 20 volumes state, and Federal environmental laws, rules, regulation by location, regulatory agencies should be contacted b hazardous waste after contacting the appropriate local

Container Disposal: > 5 gallon plastic drums: Triple nn a santary landfill, or incineration, or, if allowed by State

>5 gallons plastic tote bin liners: Completely empty ba incineration, or, of allowed by State and local authorities