

134-65

4/22/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 22 2009

Ms. Jennifer J. Sertfert
Manager of Regulatory Affairs for,
Hess & Clark, Inc.
110 Hopkins Drive
Randolph, WI 53956

Subject: DC&R® Disinfectant
EPA Registration Number 134-65
Your Notification Dated April 15th, 2009
EPA Received Date April 17th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add the phrase, "Dye-Free", to the product labeling, is acceptable.

The notification has been part of the permanent record of this file.

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

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

EPA	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other Notification	OPP Identifier Number
Application for Pesticide:			

Section I

1. Company/Product Number 134-65	2. EPA Chemical Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DC&R® Disinfectant	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Hess & Clark, Inc. 110 Hopkins Drive Randolph, WI 53956 <input type="checkbox"/> Check if this is a new address		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 II

Amendment - Explain Below Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application
 Notification - Explain below Other - explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II).
 NOTIFICATION OF Addition of Marketing Claim/Statement "Dye-Free", pursuant to PR-Notice 98-10 and notification of Agency acceptance of Dye-Free Formulation (see attached), for the product: DC&R® Disinfectant.

Section III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No <small>*Certification must be submitted.</small>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Unit Package Wt. No. Per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package Wt. No. Per Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) C
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container 1 gallon, 2.5 gallon, 15 gallon, 30 gallon, 55 gallon	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner In Which Label Is Affixed To Product <input type="checkbox"/> Lithograph Other (_____) <input checked="" type="checkbox"/> Paper Glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Jennifer J. Seifert	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (920) 326-2461
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs	
4. Typed Name Jennifer J. Seifert	5. Date April 15, 2009	

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Manufacturing
110 Hopkins Drive
Randolph, WI 53956
920/326-5141
Fax: 920/326-5135
inform@neogen.com
www.neogen.com

Neogen Corporation
944 Nandino Boulevard
Lexington, KY 40511
800/477-8201
859/254-1221
Fax: 859/255-5532
inform@neogen.com
www.neogen.com

HESS&CLARK, INC.

April 15th, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Fed Ex: 8693 4633 4619

RE: DC&R[®] Disinfectant
EPA Reg. No. 134-65

Gentlemen/Ladies:

Pursuant to PR-Notice 98-10, in regard to the subject product, we are hereby notifying the Agency of the addition of the Marketing Claim/Statement "Dye-Free", pursuant to PR-Notice 98-10 and notification of Agency acceptance of Dye-Free Formulation (see attached), for the product: DC&R[®] Disinfectant.

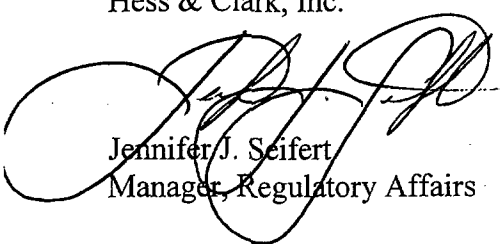
Following is my statement as required by PR-Notice 98-10:

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 for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with terms of PR-Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Attached please find the completed application form marked for Notification, as well as a "before" and "after" label, with the addition clearly marked. It is our understanding that it is allowable to use the subject claim for up to 6 months following Agency acceptance of this Notification.

If you should have any questions regarding this matter, please contact me at 920-326-2461.

Sincerely,
Hess & Clark, Inc.



Jennifer J. Seifert
Manager, Regulatory Affairs

Enclosure(s)

DC&R[®] Disinfectant

Bactericidal • Fungicidal • Virucidal*

For Control of Canine Parvovirus and Feline Panleukopenia in Veterinary Clinics and Kennels

Dye-Free

ACTIVE INGREDIENTS:

2-(Hydroxymethyl)-2-Nitro-1,3-Propanediol.....	19.20%
Alkyl (C ₁₂ -67%, C ₁₄ -25%, C ₁₆ -7%, C ₈ , C ₁₀ , C ₁₈ -1%) dimethyl benzyl ammonium chloride.....	3.08%
Formaldehyde.....	2.28%

INERT INGREDIENTS:

.....75.44%

TOTAL:100.00%

EPA Reg. No. 134-65

EPA Est. No. 61282-WI-1

**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 a poison control center or doctor for treatment advice.
If on skin or on clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If inhaled	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
If swallowed	Call a 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.

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.

FOR A MEDICAL EMERGENCY INVOLVING THIS PRODUCT, CALL: 1-800-498-5743

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive: Causes irreversible eye damage or skin burns. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid breathing vapor or spray mist. Prolonged or repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Pesticide handlers must wear: Long-sleeved shirt and long pants, chemical resistant gloves (such as any waterproof material, rubber, etc.), wear protective eyewear (goggles, face shield, or safety glasses), shoes plus socks. In addition, when engaged in pouring this product, a respirator with either an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash separately from other laundry. Users should wash hands 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. Users should remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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 EPA.

GENERAL: DC&R® Disinfectant is a non-flammable and non-corrosive formulation. DC&R® Disinfectant can be used in the following areas: Poultry and Turkey Farms, Hatcheries, Swine Operations, Dairy Farms, Cattle Farms, Veal Farms, Equine Farms, Emu and Ostrich Farms, Zoos, Veterinary Clinics, Kennels, Pet Shops, Federally Inspected Meat and Poultry Establishments except where meat and food products are handled, Animal Life Sciences Laboratories and in Fain Foot Baths. DC&R® Disinfectant can be used to disinfect pens, hutches, feeders, waterers, cages and livestock and poultry hauling vehicles and equipment.

DC&R® has proven effective as a disinfectant by the A.O.A.C. use dilution test modified for spray products against the following organisms. All dilutions 1:128 tested at 400 ppm water hardness (as calcium carbonate) and 5% calf serum.

<i>Mycoplasma pneumoniae</i>	<i>Salmonella choleraesuis</i>	<i>Salmonella typhimurium</i>
<i>Salmonella enteritidis</i>	<i>Pasturella multocida</i>	<i>Clostridium perfringens</i>
<i>Escherichia coli</i>	<i>Campylobacter jejuni</i>	<i>Klebsiella pneumoniae</i>
<i>Enterobacter aerogenes</i>	<i>Proteus vulgaris</i>	<i>Streptococcus pyogenes</i>
<i>Bordetella bronchiseptica</i>	<i>Actinobacillus suis</i>	

*DC&R® has proven virucidal efficacy for use on hard, nonporous, inanimate environmental surfaces. All dilutions 1:128 tested with 400 ppm water hardness (as calcium carbonate) and 5% bovine serum.

Pseudorabies	Newcastle disease	Avian laryngotracheitis
Transmissible gastroenteritis	Avian influenza	Swine influenza virus
Canine parvovirus**	Feline panleukopenia**	Infectious bronchitis virus
Infectious Bursal Disease Virus	Porcine Respiratory and Reproductive Syndrome (PRRS)	

**See specific instructions for Canine Parvovirus and Feline Panleukopenia.

DC&R® has proven effective fungicidal activity by the A.O.A.C. use dilution test modified for spray products. All dilutions 1:128 tested with tap water and 5% calf serum.
Candida albicans

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. To be used for disinfecting hard, non-porous surfaces of farm buildings and equipment which are used for poultry and livestock production and veterinary clinics, kennels and other non-livestock buildings. Especially suited for equipment, which may harbor or spread many germs or microorganisms within the farm operation, veterinary facility, or to other farms. Apply DC&R® Disinfectant with a mechanical spray device. Spray all surfaces to be disinfected until thoroughly wet. Dilute DC&R® Disinfectant one ounce per gallon of water. Use as follows:

Poultry and Livestock Buildings: Evacuate all animals from buildings. Remove all litter and manure 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 appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Spray all surfaces and allow DC&R® Disinfectant to saturate all surfaces for 10 minutes. Equipment inside the building (cages for laying hens, for example) should be first cleaned with soap or detergent, rinsed with water and then saturated as above with this product. Ventilate buildings, coops and other closed spaces. Do not house poultry, livestock or employ equipment until treatment has been absorbed, set or dried, then thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Equipment: Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all equipment surfaces (cages for laying hens, for example) with soap or detergent and rinse with water. Then thoroughly spray or soak all exposed parts of the cleaned equipment used in the poultry, livestock, or veterinary operation.

All treated feed racks, food bowls, mangers, troughs, automatic feeders, fountains and waterers must then be thoroughly scrubbed again with detergents and rinsed with potable water prior to reuse. Immerse cleaned halters, ropes and other types of equipment used in handling and restraining animals, forks, and all shovels and scrapers used for removing litter and manure or feces and allow DC&R® Disinfectant to saturate all surfaces for 10 minutes. Do not spray onto feed to be consumed by animals.

FOGGING: DC&R® Disinfectant can be used in fogging (wet mist) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. DC&R® at 1 to 2% is appropriate. A 1% to 2% mixture is achieved by mixing 1/4 to 2 1/2 ounces of DC&R® Disinfectant to 1 gallon (128 ounces) of water. Fog (wet mist) until the area is moist using automatic wet fogger according to manufacturer's use directions.

Reentry Restrictions: Entry by any person - other than a correctly equipped handler is PROHIBITED in the entire enclosed building/structure from the start of application until aeration reduces the air concentration level of formaldehyde in the working area to less than 0.75 ppm. The air concentration of

formaldehyde must be measured before reentry is permitted (OSHA issued a final rule for the PL of formaldehyde as 0.75 ppm, May 27th, 1992, Federal Register, Vol. 57, p. 22290). Any handler who enters the treated area during the entry-restricted period must wear: a respirator with either an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.

****FOR CANINE PARVOVIRUS and FELINE PANLEUKOPENIA: DC&R[®] Disinfectant is effective against Canine Parvovirus and Feline Panleukopenia when used at a three (3) ounces per gallon dilution. To control Canine Parvovirus thoroughly clean all surfaces and mix three (3) ounces of DC&R[®] Disinfectant in one gallon of water. Apply with a cloth, mop, sponge, as a spray or by soaking. Allow to air dry or area may be rinsed after 45 minutes. Except for the change in the dose, the identical animal removal, pre-cleaning, water rinse, treatment, second cleaning and second water rinse directions listed in the building and equipment sections above must be followed.**

ALL OTHER NON-LIVESTOCK BUILDINGS AND FACILITIES including Veterinary Clinics, Kennels, Pet Shops: Thoroughly clean all surfaces with soap or detergent and rinse with water. Spray all surfaces to be disinfected and allow to saturate all surfaces for 10 minutes. The use rate is one (1) ounce of DC&R[®] Disinfectant per gallon of water, unless the objective is to control Canine Parvovirus or Feline Panleukopenia, then you must follow the directions specific to that use. Ventilate buildings and other closed spaces.

STORAGE AND DISPOSAL

Household Label

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

STORAGE: Store in original container in a cool, dry place inaccessible to children and pets.

DISPOSAL: If empty: Do not reuse this container. Place in trash or offer for recycling if available.

Partly Filled Containers: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Non-Household Label

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

STORAGE: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product, and spoiled and unconsumed bait, may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. **MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

In no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

For non-emergency (e.g. current product information)
call: 1-800-621-6829

Manufactured By:
Hess & Clark, Inc.
110 Hopkins Drive
Randolph, WI 53956 U.S.A.

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Code (RN.NG.) NU.NO.

AFTER LABEL