

134-65

10/31/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 2001

Hess and Clark, Inc.
7 and Orange Streets
Ashland, OH 44805

Mail To: **Wendy A. McCombie, Agent**
Lewis and Harrison
122 C Street, N.W. Suite 740
Washington, D. C. 20001

Subject: DC & R Disinfectant
EPA Registration No. 134-65
Amendment Dated September 21, 2001

The amendment is in response to your eight product reregistraton response for Tris (hydroxy-methyl)-nitromethane RED. According to our records, all science reviews for this product have been reviewed; however, since this product contains multiple active ingredients, it may not be reregistered until a favorable eligibility decision is made for all active ingredients. The Agency will issue an amended reregistration at this time.

The labeling, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, to remove the virucidal claims (Foot and Mouth Disease and Vesicular Stomatitis) and to incorporate other label revisions in conjunction with the Tris(hydroxymethyl)-nitromethane RED, is acceptable. A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

CONCURRENCES

SYMBOL								
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ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 31 2001

SPECIMEN LABEL

DC&R[®] Disinfectant

BROAD SPECTRUM HOSPITAL DISINFECTANT
Bactericidal • Fungicidal • Virucidal*

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

134-65

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

Active Ingredients:

- 2-(Hydroxymethyl)-2-Nitro-1, 3-Propanediol 19.20%
- Alkyl (C₁₂-67%, C₁₄-25%, C₁₆-7%, C₈, C₁₀, C₁₈-1%) dimethyl benzyl ammonium chloride 3.08%
- Formaldehyde 2.28%

Inert Ingredients 75.44%

TOTAL • 100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

EPA Reg. No. 134-65
EPA Est. No. 134-OH-1

Hess & Clark, Inc.
Ashland, OH 44805

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

**IN CASE OF A MEDICAL EMERGENCY INVOLVING THIS PRODUCT CALL
TOLL-FREE: 1-800-228-5635, EXT. 136, OR CALL COLLECT: 612-851-8180, EXT. 136.**

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

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

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. 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.), and shoes plus socks. In addition, when engaged in pouring this product, 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.

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 public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer treatment plant authority. For guidance contact your local State Water Board of Regional Office of EPA.

SPECIMEN LABEL

GENERAL: DC&R Disinfectant is a vapor phase broad-spectrum surface disinfectant effective against gram positive and gram negative microorganisms. 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, Mushroom Farms, Potato Farms, Federally Inspected Meat and Poultry Establishments except where meat and food products are handled, Animal Life Sciences Laboratories and in Farm 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.

- | | |
|---------------------------|-------------------------|
| Staphylococcus aureus | Mycoplasma pneumonia |
| Salmonella choleraesuis | Salmonella typhimurium |
| Salmonella enteritidis | Pasteurella multocida |
| Pseudomonas aeruginosa | Clostridium perfringens |
| Escherichia coli | Campylobacter jejuni |
| Klebsiella pneumoniae | Enterobacter aerogenes |
| Proteus vulgaris | Streptococcus pyogenes |
| Bordetella bronchiseptica | Actinobacillus suis |

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in EPA Letter Dated:
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Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended for the purpose of registered under FIFRA 134-65

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** | Porcine Respiratory and Reproductive Syndrome (PRRS) |
| Feline Panleukopenia** | Infectious Bronchitis virus |

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.

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|------------------|-----------------------------|
| Candida albicans | Trychophyton mentagrophytes |
|------------------|-----------------------------|

DIRECTIONS FOR USE:

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

To be used in the disinfection 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, by mopping, or by soaking. Spray or mop 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. 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 surfaces 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 be thoroughly scrubbed 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.

SPECIMEN LABEL

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. 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 ounces per gallon dilution. To control Canine Parvovirus and Feline Panleukopenia 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.

ALL OTHER NON-LIVESTOCK BUILDINGS AND FACILITIES: Thoroughly clean all surfaces with soap or detergent and rinse with water. Spray or mop all surfaces to be disinfected and allow to saturate all surfaces for 10 minutes. Ventilate buildings and other closed spaces.

STORAGE AND DISPOSAL:

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

STORAGE- KEEP UPRIGHT WHILE MOVING AND IN STORAGE. Container equipped with a pressure relief closure. KEEP FROM FREEZING. Store in original container only, in safe manner. Do not store under conditions, which might adversely affect the container or its ability to function properly. Reduce stacking height where local conditions can affect package strength. Open container in a well-ventilated area, avoid breathing vapor. Keep container tightly closed when not in use.

SPILL CONTROL- Soak up spill in a dry absorbent such as clay. Sweep it up, put into disposal containers and dispose as directed below. Wear protective clothing and equipment consistent with good pesticide handling procedures while exposed to spilled material.

PESTICIDE DISPOSAL- Pesticide wastes are toxic. 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 representatives 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.

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