#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 29 1997

Kari E. Mavian
H&S Chemicals Division
970 East Tipton Street
Huntington, IN 46750

SUBJECT: Formulation HWS-128

EPA Registration No. 47371-130 Notification Per PR-Notice 95-2

Dear Ms. Mavian:

This will acknowledge receipt of your notification, to delete three organisms (canine parvovirus, porcine parvovirus, and feline panleukopenia) from this product's label, submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,

Wanda Y. Mitchell Notification Coordinator Antimicrobial Program Branch Registration Division (7505)

		CONCURRENC	ES .		
5YMBOL ) 7505C					
SURNAME Mitchell					
DATE 1/29/97				************	

EPA Form 1320-1A (1/90)

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SEPA Environmental Protect Weshington, DC 20	ion Agency 0460	Registration Amendment  Other	OPP Identifier Number 243650				
Application for Pesticide - Section I							
Company/Product Number 47371-130		2. EPA Product Manager Marion Johnson 3. Proposed Classification					
Company/Product (Nerna) Formulation HWS-128	PM# 31						
Name and Address of Applicant Include ZIP Code)  H&S Chemicals Division  c/o Lonza Inc.  17-17 Route 208  Fair Lawn, NJ 07410  Check if this is a new address	1 .	EPA Reg. No.  JAN 29 1997					
	Section - II						
Amendment - Explain below.  Resubmission in response to Agency letter dated	Agency le	Finel printed lebels in response to Agency letter dated "Me Too" Application.  Other - Explain below.					
Explanation: Use additional page(s) if necessary. (For secti	ion I and Section II.)						
Notification per PR Notice 95-2 to delete organisms from the label.  BEST AVAILABLE COPY							
	Section - III						
1. Material This Product WM Be Packaged In:	,						
Child-Resistant Packaging  Yes  No  No	Water Soluble Packaging Yes No	2: Type of Container  Metal Plactic Glass					
* Certification must be submitted If "Yea" Unit Packaging wgt. No. per container	If "Yes" No. per Package wgt contains	Paper Other (S	pecify)				
3. Location of Net Contents Information 4. Size(s) Re	etall Container	5. Location of Label Direction	ne				
Label Container		On Labeling accom	penying product				
5. Manner in Which Label is Affixed to Product Litho Pape Sten	graph Other or glued cited						
	Section - IV						
1. Contact Point (Complete items directly below for identificati	ion of individual to be contacted	. If necessary, to process this	application. j				
Name Kari E. Mavian, Lewis & Harrison 122 C St., NW, #740, WDC 20001	Title Agent	Telephone No. (Include Area Code) ent 202-393-3903					
Certification  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 of the complete o							
both under applicable lew.							
2. Signature	3. Title	,,,,	) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) )				
	3. Title Agent 5. Date	22733 1 3 1 3 1 1 2 1 1 2 2 3					

PELIGRO: SI NO PUEDE LEER EN INCLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DILUTION: 1:12# (600 ppm qual)

I OUNCE PER GALLON OF WATER

#### DIRECTIONS FOR USE

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

This product is not to be used as a terminal sterilars/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 devices prior to sterilization or high-level disinfection.

#### GRNERAL USE DIRECTIONS

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, federally inspected most and poultry establishments, equine farms. tack shops, pet shops, simports, kennels, hotels, motels, poultry farms, turkey farms, dairy farms, hog farms, breeding establishments, greening establishments, funeral homes, and households. Disinfects, cleans, and deodorizes floors, walls, metal surfaces, stainless steel surfaces, glazed porcellain, plastic surfaces (such as polypropylene, polystyrene, etc.), and other hard, non-porous surfaces.

APPLICATION: Remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 1 curies of the concentrate per gallon of water. The solution can be applied with a cloth, mop, aponge, or coarse apray, or soaking. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished. Prepara a fresh solution daily or more often if the solution becomes visibly dirty or diluted. USDA: For use in federally inspected mest and poultry plants on all hard, nonporcus surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.

USDA: For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging material must be removed from the room or carefully protected. All surfaces must be thoroughly

USDA: For use in federally inspected meat and poultry plants as a disinfectant agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying diluted solution around the bowl and up under the rire. Stubborn stains may require brushing. To disinfect, first remove or expelover the inner trap the residual bowl water. Pour in three ounces of the diluted solution. Swab the bowl completely using a scrub brush or mon, making sure to get under rim. Let stand for 10 minutes or overnight, then flush.

MILDEWSTATIC INSTRUCTIONS: Will effectively control the growth of mold and mildew play the cylors essaged by them when applied to hard, non-porous surfaces such as walls, flours, and table tops, Apply solution (I conce per gallors of water) with a cloth strong specific of coarge siway. Make sure to wet all surfaces completely. Let air-try, Repeal application weekly or when growth reappears.

# **BEST AVAILABLE COPY**

### **FORMULATION HWS-128/** Formulación HWS-128

ONE-STEP.

GERMICIDAL DETERGENT AND DEODORANT

Disinfectant Pseudomonacidal Staphylocidal Salmonellacidal Bactericidal Fungicidal Mildewstatic \*Virucidal

\*Adenovirus type 4

\*Avian polyomavinas

\*Canine distenuer

\*Feline picomavirus

\*Hernes simplex type I

\*Hernes simplex type 2

\*Influenza A/Hong Kong

\*Infectious bovine rhiaotracheitis

\*Infectious bronchitis (Avian IBV)

\*Respiratory syncytial virus (RSV)

\*Transmissible gastrocnicritis virus (TGE)

\*Rubella (German Measles)

Trichophyton mentagrophytas

\*HIV-1 (AIDS virus)

\*Pseudorabies

\*Rabies

\*Vaccinia

Asporgilius nigor Candida albicana

\*Felino leukemis

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO<sub>2</sub>) in the presence of a moderate amount of soil (5% organic serum) according to the AOAC Use-dilution Test. Disinfects, cleans, and deodorizes in one labor-saving step. Effective against the following pathogens:

Pseudomonas aeruginosa Staphylococcus aureus

Salmonella choicraesuis Acinetobacter calcoaceticus

Bordetella bronchiseptica Chlanydia psittaci Enterobacter acrogenes

Enterobecter cloacae Recherichia coli<sup>1</sup> Fusobacterium necronhorum

Klebsiella pneumoniae<sup>1</sup> Legionella pneumophila

Listeria monocytogenes Pasteurella multocida

Proteus mirabilis Proteus vulgaris Salmonella enteritidis

Salmonella typhi Salmonella typinimurium Serratia marcoscens

Shigella flexmeri Shigelia sonnei Staphylogogous sureus.

(methicillin recutant) Staphylococcus enidermidis<sup>2</sup> Streptococcus faccalis

Streptococcus pyogenes Enterococcus faccalis (Vanconvein Resistant)

ATCC & antibiotic-resistant strain <sup>2</sup> antibiotic-registant strain only

ACTIVE INGREDIENTS:

n-Alkyl (C14 50%, C15 40%, C14 10%) INERT INGREDIENTS: 92.32%

## KEEP OUT OF REACH OF CHILDREN DANGER/PELIGRO

(See side panel for additional precautionary and practical treatment statements)

EPA Reg. No. 47371-130

EPA Est. No. 47371-IN-01

NET CONTENTS \_\_\_\_

HAS CHEMECALS DIVISION 970 East Tipton Street, Hundington, IN 46750 (219) 356-7073

#### STATEMENT OF PRACTICAL TREATMENT

in case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. If swallowed, immediately drink a large quantity of water. Avoid alcohol. Get medical attention.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS .

CORROSIVE: Causes eye damage and severe skin initation. Harmful if smallowed. Do not get in eyes, on skin, or on clothing. When handling product, protect eyes by wearing goggles or face shield and protect skin by wearing rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARD

Do not discharge offluent containing this product into lakes, aircams, ponds, catuaries, occars, or other waters unless in accordance with the requirements of a National Pollutant Discharge Blimination 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.

#### STORAGE AND DISPOSAL

Keep product under locked storage, inaccessible to children. Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not rouse empty container.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, array mixture, or rineate 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 guidanos.

#### CONTAINER DISPOSAL

PLASTIC CONTAINERS

Triple rines (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of amoke.

(FOR I GALLON OR LESS)

Do not reuse empty container. Rinse thoroughly, securely wrap in several layers of newspaper, and diseard empty container in trash.

FIBER DRUMS WITH LINERS

Completely empty liner by shaking and tapping skids and bottom to loosen clineing particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incincration if allowed by state and local authorities. If dram is contaminated and cannot by reused, dispose of in the same INMERCACIO

Triple rines (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or dispose of by other procedures approved by state and local authorities.

Page 2 of 4 (label directions for use continued)

## **FORMULATION HWS-128**

\*Kills HIV-1 (AIDS virus) on precleaned, environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human immunodeficiency virus Type I (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures.

Cleaning Procedures: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (room temperature). Use a 10-minute contact time for other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

[For use as package insert or hang tag or place on label.]

# **BEST AVAILABLE COPY**

Page 3 of 4 (label directions for use continued)

## **FORMULATION HWS-128**

#### GERMICIDAL DETERGENT

	_	FARM PREMISE, LIVESTOCK, POUTREX & TURKEY HOUSE DISINFECTANT
*	DI	LUTION: 1:128
		DIRECTIONS FOR USE
	1.	Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
	2.	Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
	3.	Empty all troughs, racks, and other feeding and watering appliances.
	4.	Thoroughly clean all surfaces with soap or detergent, and rinse with water.
	5.	Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
	6.	Immerse all halters, ropes, and other types of equipment used in handling and restraining

7. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.

animals, as well as forks, shovels, and scrapers used for removing litter and manure.

8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[For use as package insert or hang tag or place on label.]

# **BEST AVAILABLE COPY**

Page 4 of 4 (label directions for use continued)

# **FORMULATION HWS-128**

CLEANSING OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS: This product removes body secretions, soil, and blood, along with their accompanying malodor, from the surfaces and orifices of human remains. Using a sponge or washcloth, bathe the entire body with a solution of 1 ounce per gallon of water. A soft handbrush may be employed on surfaces other than the face. Prepare a fresh solution for each remains or when solution becomes visibly dirty or diluted.

[For use as package insert or hang tag or place on label.]

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