# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Jennifer Seifert Manager, Regulatory Affairs HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956

SUBJECT:

BioSentry 904

EPA Registration Number: 61282-55 Application Date: November 21, 2008 Receipt Date: November 24, 2008

Dear Ms. Seifert:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Add Alternate Brand Name

Based on a review of the submitted information, this notification is acceptable. Your proposed alternate brand name: "BioSentry 904 Disinfectant" is acceptable.

## **General Comments**

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

7510P:T.Lantz:12/8/08:61282-55notification

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SYMBOL	7510P					
SURNAME	5. Fast					***********
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Manufacturing Plant 110 Hopkins Drive Randolph, WI 53956-1316 920 / 326-5141 920 / 326-5135 www.hacco.com

Fed Ex:

Registration Office 110 Hopkins Drive Randolph, WI 53956-1316 920 / 326-5141 920 / 326-5135 www.hacco.com

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November 21st, 2008

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

RE:

BioSentry 904

EPA Reg. No. 61282-55

January 2030-15

Gentlemen/Ladies:

Pursuant to PR-Notices 98-10, in regard to the subject product, we are hereby notifying the Agency of the following alternate brand name: BioSentry® 904 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 alternate brand name clearly marked.

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

Sincerely,

Vennifer J(Seife

Manager, Regulatory Affairs

HACCO, Inc.

Enclosure(s): 2

Please read instructions or	n reverse before comp		( Form	Approved. OMB No. 2070-0066	
(A)	United States Environmental Protect	ion Agency 🗌 Reg	jistration	OPP Identifier Number	
EDA	Office of Pesticide Programs (H	7505C)	endment		
EPA	Washington, DC 20460	☐ Othe	r		
	Application for Pesti	cide: Notification			
		Section I			
1. Company/Product Numb 61282-55	per	EPA Chemical Manager     Velma Nobel	3. Proposed C		
4. Company/Product (Nam	ne)	PM#	│ □ None □	Restricted	
BioSentry 904  5. Name and Address of A	pplicant (Include ZIP Code)	6. Expedited Review. In accord	dance with FIFRA	Section 3(c)(3)(b)(i), my	
HACCO, Inc.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	product is similar or identical in c			
110 Hopkins Drive		EPA Reg. No.	<u>_</u>		
Randolph, WI 53956		Product Name			
☐ Check if this is a ne	w address .			·	
		Section II		·	
☐ Amendment - Expla	in Below	☐ Final printed labels in res	ponse to Agency	letter dated	
Resubmission in res	ponse to Agency letter dated			•	
Ajangaanaa Foots	a holow	Other avalate below	•	•	
Notification - Explain	n below al page(s) if necessary. (For Section I and	Other - explain below			
		·			
		Section III			
Material This Product	t Will Be Packaged In:		•		
Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Cor	ntainer	
☐ Yes*	Yes	Yes	☐ Metal		
□ No	□ No	│	Plastic		
*Certification must be submitted.		If "Yes." No. Per	☐ Glass		
	If "Yes," No. Per Unit Package Wt. Container	Package Wt. Container	☐ Paper		
Location of Net Content		Size(s) of Retail Container	Other (Specify) C  5. Location of Label Directions		
o. Eddation of Not Comone			☐ On Label		
☐ Label ☐ Cor	ntainer		On Labeling accompanying product		
6. Manner In Which Label	Is Affixed To Product Lithograph	Other (		)	
•	☐ Paper Glue	.d		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	☐ Stenciled	-			
		Section IV			
Contact Point (Complete)	ete items directly below for identification o	f individual to be contacted, if neces	ssary, to process	this application.)	
Name Jennifer J. Seifert		Title Manager, Regulatory Affairs	Telephone No. (920) 326-24	(Include Área Code) 461	
I acknowledge that any knowledge	Certification s I have made on this form and all attachm owingly false or misleading statement may	nents thereto are true, accurate and be punishable by fine or imprisonm	complete.	€ C. Date Application  Received (Syamped)	
under applicable law.  2. Signature	1011	3. Title		(6,411)	
auf	y aft	Manager, Regulatory Affair	rs .	<del> </del>	
4. Typed Name Jennifer J. Seifert	<u> </u>	5. Date November 21 <sup>st</sup> , 2008			
	-94Y Previous editions are obso	olete. White - EPA Fi	le Copy (original)	Yellow - Anplicant Copy	

#### PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrostve: Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves when handling. Harmful or fault if swallowed or inhaled. Avoid breathing vapors or spray mist. Avoid contamination of food. Wash thoroughly with some and water after handling. Remove and wash contaminated clothing before reuse.

## PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame.

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. 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.

BROAD SPECTRUM GERMICIDAL ACTION IN HARD WATER AND UNDER SOIL LOAD CONDITIONS: At 1/2 ounce per gallon (1:256) in official A.O.A.C. Use Dilution and Pungicidal Tests, BioSentry® 904 Disinfectant is effective in water up to 400ppm hardness (as CaCO<sub>3</sub>) and an organic soil load of 5% serum against the following organisms:

ATCC 10894

ATCC 18804

ATCC 9533

BACTERIA .			
ATCC 27088			
ATCC 19411			
ATCC 8748			
ATCC 35086			
ATCC 19395			
ATCC 19410			
ATCC 63809			
ATCC 6569			
ATCC 11229			
ATCC 4352			
ATCC 25934			
ATCC 19708			
ATCC 15302			
ATCC 19705			
ATCC 7707			
ATCC 25933			
ATCC 25830			
ATCC 15442			
ATCC 6939			
ATCC 6538			
ATCC 10708			
ATCC 4931			
ATCC 9184			
ATCC 9120			
ATCC 6539			
ATCC 264			
ATCC 13313			
ATCC 29930			
ATCC 33398			
ATCC 27916			
ATCC 9547			
ATCC 43079			
FUNGI			

Aspergillus fumigatus

Trichophyton mentagrophytes var.

Candida albicans

interdicitale

## AFTER LABEL

# BioSentry® 904 Disinfectant

Bactericide • Fungicide • Virucide\*

\* See Side Panels for Specific Claims

## FOR INDUSTRIAL AND COMMERCIAL USE ONLY

\* Poultry Hatchery Disinfectant

fectant \* Farm Premise
Disinfectant

- \* Veterinary and Animal Care Disinfectant \* For Chicken, Turkey, Duck, Quall, Ostrich and Other Avian Hatcheries
  - For Poultry, Swine, and Livestock Premises \* For Veterinary, Laboratory Animal, Kennel and Animal Breeder Facilities
- \* Effective in 400-ppm Hard Water as (CaCO<sub>3</sub>) \* Disinfects in 5% Orgainte Soil Load

#### **ACTIVE INGREDIENTS:**

Dideoyl dimethyl ammonium ohloride9.2%	
Alkyl (C <sub>12</sub> -61%, C <sub>14</sub> -23%, C <sub>16</sub> -11%, C <sub>18</sub> -2.5%, C	8 & C <sub>10</sub> ,
2.5%) dimethyl benzyl ammonium chloride	9.2%
Alkyl (C <sub>12</sub> -40%, C <sub>14</sub> -50%, C <sub>16</sub> -10%)	
dimethyl benzyl ammonium chloride	4.6%
bis-n-tributyltin oxide	1.0%
INERT INGREDIENTS:	<u>76.0%</u>
TOTAL:	

EPA Reg. No. 61282-55 EPA Est. No. 10183-MI 01

# KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

*	, FIRST AID			
Have k	ibel with you when obtaining treatment advice.			
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.			
If on skin or on clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.			
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.			
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.			
container or label wi for treatment.	center or doctor for treatment advice. Have the product th you when calling a poison control center or doctor or going ergency information on this product, call 1-800-498-5743			

(US & Canada) or 1-651-523-0138 (all other areas)

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NET WEIGHT: 1 gallon

Manufactured For: HACCO, Inc. 110 Hopkins Drive Randolph, WI 53956

BioSentry®is a Registered Trademark of Neogen Corporation.

VIRUSES: Using accepted virus propagation and hard surface test methods, BioSentry<sup>®</sup> 904 Disinfectant is effective at 1:256 in 400ppm hard water and 5% serum against the following viruses:

TOHOWING VITUSES:				- 1	د
Avian influenza	a	⇒ ATCC VR-//98	•	د د	۵ .
Avian laryngotracheitis	22.	→ ATCC VR-783	3	2 0	٠,
Canine distemper	J	Onderstepoort strai	100	د ر	Ç
Canine herpesvirus	ب	ATCC VP-552	-	. )	٠,
Canine parvovirus		ATCC VE SUS		_	
Equine herpesvirus	0 - 0	ATCC VR-700			
Equine influenza A		ATCC VR-297			
Feline infectious peritonitis		Strain DF-2			
Infectious bronchitis		ATCCVR-2000	ပ္သ		
Infectious bursal disease		ATCC VR-473	ر ن	٠.	
(Gumboro)		ے در ر			
Newcastle's disease		A CC VR-109	2 -	Ĵ	
Parsinfluenza		ATICC VR-28	ū	-	
Porcine parvovirus		ATCC VR-742			
Pseudorabies		ATCC VR-135			
Swine PRRS virus		Reference Strain, N	VSL		
Transmissible gastroenteritis		ATCC VR-763			
Vesicular stomatitis virus		Indiana			

BioSentry® 904 Disinfectant is a complete, chemically balanced disinfectant providing clear use solutions even in hard water – is a residual bactericatet and inhibits bacterial growth on moist surfaces – contains rust and corrosion inhibitors – deodorizes by killing most microorganisms that cause offensive odors – kills a broad range of gram-negative and grampositive bacteria, fungi and viruses associated with the avian hatching industry, poultry, swine and livestock premises, laboratory mimal facilities and kennels. (See mitimicrobial efficacy chart on side panels). Contains sequestering agents, to prevent the precipitation of minerals and metals from hard water.

#### DIRECTIONS FOR USE

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

#### DIRECTIONS FOR USE ON POULTRY, SWINE AND LIVESTOCK FARMS GENERAL FARM DISINFECTANT USES:

(1/2 ounce per gallon)

- (a) Remove all livestock and feeds from premises, trucks, coops or crates to be treated.
   (b) Remove all litter, bedding and manure from floors, walls and surfaces of facilities
- (c) Empty all feeding devices and watering appliances.

traversed or occupied by animals.

- d) Clean all surfaces with water or water and a compatible detergent.
- e) Saturate all surfaces with this product diluted at 1/2 ounce per gallon of water using a brush, cloth, mop or mechanical spraying device. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure. Treated surfaces must remain moist for at least 10 minutes for proper germicidal action.
- (f) Ventilate buildings, trucks, coops and other closed spaces. Do not house livestock or use equipment until treatment has thoroughly dried.
- (g) Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

FOR DISINFECTING PRECLEANED SURFACES: Use BioSentry® 904 Disinfectant to disinfect precleaned surfaces including hatchers, setters, trays, racks, egg flats, walls, floors, ceilings and other surfaces in the hatchery environment. It is also excellent for chickboxes, egg cases, vans and trash containers. Preclean the surface to be disinfected with BioSentry® 453 or another compatible BioSentry® hatchery cleaner. Rinse and if possible let surfaces dry. Then, apply BioSentry® 904 Disinfectant at 1/2 ounce per gallon by immersion, by flowing solution over treated surfaces, by use of a soft coarse spray, or with a clean mop, cloth or through a foaming apparatus. Thoroughly wet surfaces. Surfaces should remain moist for 10 minutes for complete disinfection. Do not ruse. Leave treatment on treated surfaces to maintain a bacteriostatic effect on moist surfaces.

NOTE: Do not smay BioSentry® 904 Disinfectant disinfecting solutions unless workers are protected from breathing the spray mist.

DISINFECTING CHICK VANS, EGG TRUCKS, HATCHERY AND FARM VEHICLES: Clean and inuse vehicles and disinfect with 1/2 ounce BioSentry® 904 per callon. If desired rinse after 10 minutes of contact or leave unrinsely.

VEAL, CALVING, HOG, CATTLE AND HORSE OPERATIONS: Between depopulations of facilities, cleaning and disinfection of pens, butches, aisles, ventilation equipment, utensils and other environmental surfaces may be required. Flush soils from these areas and clean and disinfect with 1/2 ounce per gallon of BioSenty® 904 Disinfectant. Take care to avoid disinfectant use solution contact with animals, feed, feed equipment, water or watering devices. If gray contacts feeders or waterers, scrub them and rinse well with potable water before they are reused.

BOOT BATH: Use 1 cunce per gallon in boot baths. Change solution daily and enytime it becomes visibly soiled. Use a nylon bristled brush to clean soils from boots.



SANITIZING HATCHERY ROOMS USING THE BIOSENTRY® FOGGER 185 OR agMISTER: Close room of so fog is confined to room to be treated. Mix one (1) part BioSentry® 904 Disinfectant to five (3) parts water (1/2 gallon BioSentry® 904 Disinfectant to 2.5 gallons water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute for each 4,000 cubic feet of space in the room with the BioSentry® fogger 185. If using the agMister, fog for 3 minutes for each 4,000 cubic feet of space in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

NOTE: The fog generated by the BioSentry® Fogger 185 and the agMister is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally I at hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

SANITIZING INCUBATORS AND HATCHERS BY FOGGING: Prepare a stock solution of 6 fluid ounces BioSenty® 904 Disinfectant to 122 ounces of water. Fog 3-8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours into hatchers. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. Contact your BioSentry® Technical Remresentative if you need assistance.

It is also satisfactory to fog setters and hatchers with a 1/2 ounce per gallon solution of BioSontry 904 Disinfectant. If this is done, fog for 30-99 seconds once per hour or once every two hours. Contact your BioSontry Technical Representative for assistance

SANITIZING POULTRY HOUSES AND LIVESTOCK BUILDINGS USING BIOSENTRY® 904 DISINFECTANT THROUGH THE BIOSENTRY® FOGGER 185: After the house has been depopulated and cleaned as in (a) (b) (c) and (d) under "General Farm Disinfectant Uses," double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, louvers, curtains, etc. making the house as closed and tight as possible. Mix one (1) part BioSentry 904 Disinfectant with two (2) parts water in the reservoir of the BioSentry® Fogger 185 or agMister. With the setting on maximum output, fog the treatment into the room or building to be sanitized. Use a total of one (1) gallon of BioSentry® 904 Disinfectant for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use two (2) gallons per 6000-8000 square feet of floor space. In multi-story buildings, the application must be repeated for each floor that is to be sanitized. The fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kent closed for twenty-four hours. After twenty-four hours, the fog should have settled and the house can now be opened and aired. The house should be opened for a minimum of twenty-four hours before it is repopulated with poultry or livestock.

NOTE: The fog generated by the BioSentry® Fogger 185 and the agMister is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 2-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NICSH/MSHA, goggles, long shirt sleeves and pants. If feeders and waters were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they should be washed with detergent and water before use for noultry or livestock.

Do not use BioSentry® 904 Disinfectant on vaccination equipment, needles or diluent bottles as the residual germicide may render the vaccines ineffective. BioSentry® 904 Disinfectant should not be mixed with other cleaning or disinfecting compounds or products.

DIRECTIONS FOR USE IN VETERINARY CLINICS, ANIMAL CARE FACILITIES, ANIMAL RESEARCH CENTERS, ANIMAL BREEDING FACILITIES, KENNELS AND ANIMAL QUARANTINE AREAS: BioSentry® 904 Disinfectant is a one-step germicide, fungicide, scapless cleaner and deodorant effective in the presence of organic soil (5% serum). It is non-selective and when used as directed, will not harm tile, terrazzo, resilient flooring, concrete, painted or varnished wood, glass or metale.

For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, does not manure from floors, walls and surfaces of facilities occupied or traversed by animals

Thoroughly clean all surfaces with scap or detergent and rinse with water. Saturate surfaces with a use solution of 1/2 ounce per gallon of water (or equivalent dilution) for a period of 10 minutes. Apply by immersion, flushing solution over treated surfaces or

with a mop, sponge, cloth or bowl mop to thoroughly wet surfaces. To clean badly soiled areas, use up to 1½ cunces per gallon of water. To control mold and mildew growth on previously cleaned, hard nonporous surfaces, use 1/2 cunce per gallon. Allow to dry without wiping. Reapply as new growth appears. Prepare fresh solutions daily or when solution becomes diluted or soiled.

Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with scap or detergent, and rinse with potable water before reuse.

## STORAGE AND DISPOSAL

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

For Container Sizes 1 Gallon or Less:

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

For Container Sizes Greater than 1 Gallon:

PESTICIDE STORAGE:

Do not store on side. Avoid creasing or impacting of side walls

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 cruidance

CONTAINER DISPOSAL:

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incincation, 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 Warrarty 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 medical emergencies or questions involving this product, call 1.800.498.5753.