

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



Office of Pesticide Programs

Berma L. Johnson,
Burlin & Company, Inc,
P.O Box 270, Indianapolis, IN 46206

FEB 21 2013

Subject:	Product Name:	Maxima 128
	EPA Reg. No.:	106-72
	Notification Date:	1/22/12
	EPA Receipt Date:	1/24/12
	Submission #:	929808

Dear Berma Johnson,

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

Proposed Notification to:

- Add alternate brand name,
- Add additional packet packaging language,
- Add addition to label to clarify packet use

General Comments

Based on a review of the submitted material your notification as listed above is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble,
Product Manager, Team 31
Regulatory Management Branch
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 106-72	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Maxima 128	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Burlin & Company, Inc. PO Box 270, Indianapolis, IN 46206 <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

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name per PR Notice 98-10: Exact Packet Germicide.
 Notification of addition of packet packaging and addition to label to clarify packet use.
 See attachment for certification statement.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container 1.5, 6, 7.5oz 84, 42, 34	If "Yes" Package wgt. No. per container		
2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container			
4. Size(s) Retail Container 18, 0.5, 1, 2.5, 5.5 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other 'sleeves' 'screenprint'			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Berma L. Johnson	Title Compliance/Reg. Affairs M	Telephone No. (Include Area Code) 317 923-3211
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 or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Berma L. Johnson</i>	3. Title Compliance/Reg. Affairs Mgr.	
4. Typed Name Berma L. Johnson	5. Date 22 Jan 2012	

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MAXIMA 128

GERMICIDAL DETERGENT or GERMICIDAL CLEANER or GERMICIDAL DISINFECTANT or DISINFECTANT DETERGENT or DISINFECTANT CLEANER

STAPHYLOCIDAL PSEUDOMONACIDAL VIRUCIDAL* FUNGICIDAL MILDEWICIDAL

ACTIVE INGREDIENTS:

Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride.....	3.200%
Octyl decyl dimethyl ammonium chloride	2.400%
Didecyl dimethyl ammonium chloride	1.617%
Dioctyl dimethyl ammonium chloride	1.200%
OTHER INGREDIENTS:	91.583%
TOTAL.....	100.00%

DILUTION: 1 TO 128 . . . ONE OUNCE PER GALLON

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See Side Panel for First Aid and Additional
Precautionary Statements

EPA Reg. No. 106-72

EPA Est. No. 106-IN-1

NET CONTENTS 5 U.S. GALLONS

Manufactured and Sold By:

BRULIN & COMPANY, INC.

HOME OFFICE/PLANT: P. O. Box 270 • Indianapolis, IN 46206-0270

1-800-776-7149

INDIANAPOLIS IN • TAMPA FL • RICHMOND CA

MAXIMA 128 is a "one-step" multi-purpose germicidal detergent effective in hard waters up to 400 ppm hard water (calculated as CaCO₃) in the presence of 5% organic serum. The activity of MAXIMA 128 has been evaluated by the AOAC use dilution test (14th Edition, 1984) and found to be effective against the following pathogenic organisms:

Pseudomonas aeruginosa	Brevibacterium ammoniagenes	* Avian Infectious Bronchitis	Aspergillus niger
Staphylococcus aureus	Staphylococcus aureus (MRSA)	* Avian Influenza A/Michigan/ 2/79-H1N9	Candida albicans
Staphylococcus epidermidis	* HBV (Hepatitis B Virus)	* Rubella Virus, Vaccine Strain	Streptococcus faecalis
Salmonella typhi	* HCV (Hepatitis C Virus)	* Infectious Bovine Rhinotracheitis	Enterobacter aerogenes
Shigella flexneri	* HIV-1 (AIDS Virus)	* Canine Distemper	Escherichia coli
Shigella dysenteria	* Adenovirus Type 2	* Feline Leukemia	Serratia marcescens
Salmonella enterica	* Herpes Simplex Type 1	* Feline Picornavirus	Proteus vulgaris
Streptococcus pyogenes	* Influenza Type A/Mich.	Enterococcus faecalis - Vancomycin Resistant	Shigella sonnei
Enterobacter cloacae	* Vaccinia		Salmonella schottmuelleri
Klebsiella pneumoniae	* Adenovirus Type 4		Trichophyton mentagrophytes
Proteus mirabilis	* Herpes Simplex Type 2		Acinetobacter baumannii

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **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 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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (5 gallon or larger)

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.

DIRECTIONS FOR USE

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

USE: For institutional and commercial use only such as hospitals and nursing homes, schools and colleges, medical and dental offices, barber/beauty shops, and veterinary clinics. Use to clean and disinfect non-medical (i.e., industrial and fire-fighting) respirators in industrial, commercial and institutional premises.

CLEANING AND DISINFECTING WASHABLE HARD NON-POROUS SURFACES:

This product is for use on floors, walls, mirrors, glass, metal surfaces, conductive flooring, painted surfaces, bowl surfaces, empty basins, noncritical medical devices, hair/nail care instruments, showers, and lavatory fixtures, tanning beds and other hard, nonporous surfaces. Add one ounce of MAXIMA 128 to each gallon of water used. Always add MAXIMA 128 to premeasured water. Gently mix for a uniform solution. Apply solution by normal methods with brush, coarse spray devices, sponge, cloth or mop. Remove gross filth before cleaning and disinfecting begins. Thoroughly wet all surfaces, then remove excess solution with a wrung out applicator. Treated surfaces must remain wet for 10 minutes. Fresh solution is prepared daily or more often if the solution becomes diluted or soiled. Rinsing is not necessary unless floors are to be waxed. MAXIMA 128 is a complete product. Do not add other chemicals. Use only as directed.

VETERINARY CLINICS:

For cleaning and disinfecting the following hard, non-porous surfaces: utensils, instruments, cages, kennels, stables, and catteries. Not to be applied to equipment used for animal food or water. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from floors, walls, and surfaces of facilities occupied or transversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Saturate surfaces with a use solution of 1.0 oz. of Maxima 128 per gallon of water for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

* **KILLS HBV, HCV and HIV-1 on PRE-CLEANED 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 or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV, HCV AND HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Use 1.50 ounce of MAXIMA 128 to each gallon of water for HBV efficacy.

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of MAXIMA 128. This pre-cleaning may be accomplished with any cleaning solution including MAXIMA 128.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surfaces wet for 4 minutes for HIV-1 and 10 minutes for HBV and HCV, respectively. The 4 minute contact time will not control other common types of viruses and bacteria.

(Note to reviewer: The following directions are for one-time use portion control packets)

(For 1.5 ounce packet)

Mix each packet with 1 gallon of water. Refer to carton label for full instructions.

(For 6 ounce packet)

Mix each packet with 4 gallons of water. Refer to carton label for full instructions.

(For 7.5 ounce packet)

Mix each packet with 5 gallons of water. Refer to carton label for full instructions.

TOILET BOWL/URINAL DISINFECTANT/CLEANER APPLICATION

Remove gross filth or heavy soil prior to application of product.

From Concentrate. Add 0.75 oz. to the bowl. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

From Use Solution. Empty toilet bowl or urinal and apply a 1 oz./gal. use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or mechanical spray. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

CLEANING AND DISINFECTING HARD NON-POROUS SURFACES ON PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORS):

Preclean equipment if heavily soiled to ensure proper surface contact. Add one ounce of **MAXIMA 128** to each gallon of water used. Always add **MAXIMA 128** to premeasured water. Gently mix for a uniform solution. Apply solution to hard, non-porous surfaces of the respirator with brush, coarse spray device, sponge, cloth, or immersion. Thoroughly wet all surfaces to be disinfected. Treated surfaces must remain wet for 10 minutes. Remove excess solution from equipment prior to storage. Comply with all OSHA regulations for cleaning respiratory protection (29 CFR § 1910.134).

BARBER/BEAUTY SHOPS:

Use 1 oz. per gallon of water to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before reuse. Prepare a fresh solution daily or more often if the solution becomes visibly cloudy, dirty, or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

LAUNDRY ADDITIVE TO SANITIZE AGAINST BACTERIA IN COMMERCIAL - INDUSTRIAL - FACILITIES

Maxima 128 sanitizes laundry such as bedspreads, sheets, pillowcases, diapers, towels, and other wet linens by reducing the growth of bacteria. Add 16 ounces of Maxima 128 per 100 pounds of dry laundry to the final rinse cycle. At this level Maxima 128 is an effective sanitizer in hard water up to 200 ppm.

This product is not to be used as a terminal sterilant/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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in areas inaccessible to small children. Keep container closed when not in use. Do not reuse empty container.

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 guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

Optional marketing statement: "One (1) gallon (quart) of concentrate makes 128 gallons (quarts) of disinfectant."

