



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 21, 2020

Wendy McCombie
Senior Associate
Agent for Ortho-Clinical Diagnostic, Inc.
c/o Lewis & Harrison, LLC
2461 South Clark Street, Ste. 710
Arlington, VA 22202

Subject: Label Amendment – Incorporating Chloroxylenol Interim Registration
Review Decision Mitigation Measures
Product Name: CLXL PRESERVATIVE
EPA Registration Number: 90963-2
Application Date: December 20, 2018
Decision Number: 547320

Dear Ms. McCombie:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Chloroxylenol Interim Decision, and has concluded that your submission is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

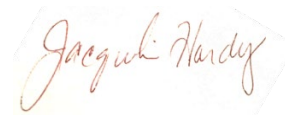
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Srinivas Gowda by phone at 703-308-6354, or via email at gowda.srinivas@epa.gov.

Sincerely,



Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division 7510P

Enclosure: Stamped Accepted Label

CLXL Preservative

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

DANGER

CORROSIVE: Causes irreversible eye damage. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT: Handlers must wear goggles, face shield or safety glasses, chemical-resistant gloves, long pants, and either a long-sleeved shirt or apron and sleeve covers. When handling dry powder during the pre-weighing process and during the open pouring of dry powder to make the liquid stock solution, use chemical fume hood or localized exhaust. When handling dry powder during the repackaging of chloroxylenol from shipping containers to dispensing containers, use a walk-in chemical fume hood or localized exhaust and a NIOSH approved filtering face piece respirator with a N95 filter (TC-84A). You may also use other NIOSH approved particulate respirators that offer more protection such as:

- Half face respirator with a N95 filter (TC-84A)
- Full face respirator with a N99 filter (TC-84A)
- Powered air purifying respirator with an HE filter (TC-21C)

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic organisms. 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.

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in original container, tightly closed and in a safe place.

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. Open dumping is prohibited.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.

Completely empty plastic drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. When completely empty offer for recycling if available, or dispose of liner and drum in a sanitary landfill or by incineration if allow by State and local authorities.

ACTIVE INGREDIENT:

4-Chloro-3,5 - xylenol	98.5%
INERT INGREDIENTS	1.5%
TOTAL	100.0%

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 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 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 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 treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency call toll free: 1-800-424-9300	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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

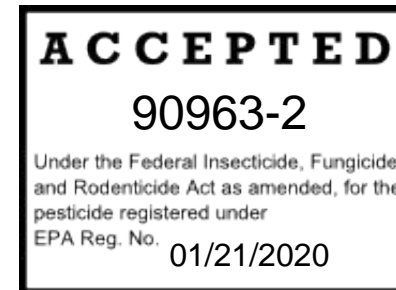
Uses of this product include use as a preservative in the control of bacteria, fungi, and mold in aqueous preparations containing gelatin, solution polymers and latexes used in the manufacture of:

- Medical Imaging Film
- Industrial Film
- Scientific Films (Electron Micrography Films, Autoradiography films, Autoradiography)
- Film Based Diagnostics Reagents

Use Concentration (% w/w):

Add CLXL Preservative at concentration ranging from 0.0001-0.50% by weight of the material being preserved (gelatin, solution polymers and latexes).

The exact concentration of CLXL Preservative required for preservation or fungistatic effectiveness will vary with formulation and production conditions. Do not exceed maximum use rates listed on this label in final preparations used in finished products.



EPA Reg. No. 90963-2
NET Weight: 25 Kg

EPA Est. No. 081910-GBR-001
Batch No.

Manufactured for:

Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics, Inc.
1001 U.S. 202
Raritan, NJ 08869