UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 1 5 2004

John Batt/Marla Cochran Atofina Chemicals, Inc. 2000 Market Street Philadelphia, PA 19103-3222

Subject:

Biomet TBTO (Manufacturing Use Product)

EPA Reg. No. 5204-1

Re-submission Dated 3/19/04

The re-submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised label which voluntarily deletes the broad use for "Antifoulant Coatings" (except for antifoulant protection of ocean conductivity instruments), due to the agreement with the Agency and to the world-wide phase out of the active ingredient for these antifoulant uses, and clarifies other uses, is acceptable providing you submit, within 90 days of this letter, three copies of a final printed label which makes the following label changes:

1. Under the product name, the following statement is not acceptable and must be clarified, "For use in the formulation of wood preservatives, microbiocides, and fungicides".

As stated, it can imply application for formulating this product into microbiocide and fungicide uses which are not listed on this Manufacturing Use label (MP). MP's can be used only for the uses listed on their labels, and these uses must be as specific as possible. The MP can not be used for uses which are not listed on the MP label. These other uses must be listed on the End Use label and supported by that product. Therefore, restate as "For use in the formulation of wood preservatives, microbiocides, and fungicides for the uses listed on this label", or "For formulating use only". You can always add any of the currently approved specific TBT uses from the extensive list that was provided to you.

A copy of the label stamped "Accepted with comments" is attached. This label supercedes all prior versions. If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I

SYMBOL SYMBOL DATE

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DATE

Printed on Recycled Paper

Antimicrobials Division (7510C)

CONCURRENCES

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OFFICIAL FILE COP



BIOMET® TBTO®

FOR USE IN THE FORMULATION OF WOOD PRESERVATIVES, MICROBIOCIDES, AND FUNGICIDES

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed or inhaled. Harmful if absorbed through the skin. Do not get in eyes, skin or on clothing. Wear protective eyewear such as goggles, safety glasses or face shield. Wear chemical resistant gloves, long sleeved shirt and long pants, socks and shoes. Do not breath dust, vapor, or spray mist. Wear a respirator with an organic vapor removing cartridge with a pre—fixer approved for pesticides (MSHA/NIOSH approval number prefix TC—23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC—14G), or a NIOSH approved respirator with an organic vapor catridge or canister with any N, R, P, or HE pre—fixer. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARD

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 sawer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not apply directly to water. Do not contaminate water when disposing of equipment wash waters or rinsate.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame. Avoid contact with acids and oxidizers.

In Case of Emergency: Call Chemtrec 1 - 800 - 424 - 9300 (24 hrs) Outside of the US call collect: (703) 527 - 3887 ATOFINA CHEMICALS INC., 2000 Market Street, Philadelphia, PA 19103 - 3222. Made in U.S.A.

LOT NO:

GROSS: 0

TARE: 0

CONT#:

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NET: 0

ACTIVE INGREDIENTS:	¢	•	g t i	•	ŧ	•	
Sis (tributykin) oxide					,,,,,,,,,,,	93,3%	
THER INGREDIENTS:							

KEEP OUT OF REACH OF CHILDREN DANGER!

FIRST AID

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 drink several glasses of water. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

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 INHALED, Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artifical respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for treatment advice.

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

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chemtrec 1-800-424-9300 (24 hours). Outside of the United States call collect: (703) -527-3887 for emergency treatment information.

EPA Registration No.: 5204-1

EPA Establishment No.: 5204-AL-1

PROPER SHIPPING NAME:

Corrosive liquid, toxic, n.o.s.; (Tributyltin oxide); UN 2922; Marine Pollutant

Please affix CORROSIVE, TOXIC and MARINE POLLUTANT labels

immediately to the right of this label.

DIRECT

It is a violation of Federal inconsistent with its labell preservatives: in microbios industrial and/or commerc water cooling systems and subsurface injection system formulations for industrial microbiocide and fungicide laboratory and institutions and livestock premises, ve breeder facilities; and in a conductivity sensors in occ may be used to formulate the MP label if the formula submission requirements product may not be used t For Commercial Use Only!

STORAGE A

PESTICIDE STORAGE: Sto Prevent exposure to heat o oxidizers. Keep container t

PESTICIDE SPILL PROCEDI absorbant material. Put sa container for treatment or

PESTICIDE DISPOSAL: Pe instructions must be dispostate procedures under Su Recevery Act.

CONTAINER DISPOSAL: Treconditioning, recycling of landfilt or by other approve Local procedures.