

US EPA ARCHIVE DOCUMENT




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


OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

3/10/2011

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 707-GER
DP Barcode: D384999
Product Name: Bioban™ MT 20 Antimicrobial

From: Ian Blackwell, Biologist 
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader 
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Marshall Swindell, PM 33/ Zebora Johnson
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Rohm & Hass Company

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
2-Methyl-4-isothiazolin-3-one	20
<u>Other Ingredient(s):</u>	<u>80</u>
Total:	100

I **BACKGROUND:** The Rohm & Haas Company has submitted six documents to support the acute toxicity requirements for their pending registration of EPA File Symbol 707-GER. There are no acute toxicity or irritation study reports in this submission. The documents are:

1. MRID Number 482888-02: "Acute Oral Toxicity of Bioban™ MT 20 Antimicrobial: Rationale to Use Surrogate Acute Oral Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1023. 10/13/2010.
2. MRID Number 482888-03: "Dermal Toxicity Potential of Bioban™ MT 20 Antimicrobial: Rationale to Use Surrogate Dermal Toxicity Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1025. 10/13/2010.
3. MRID Number 482888-04: "Acute Inhalation Potential of 2-Methyl-4-isothiazolin-3-one Biocide, Rationale to Use Surrogate Inhalation Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1026. 10/13/2010.
4. MRID Number 482888-05: "Eye Irritation Potential of Bioban™ MT 20 Antimicrobial: Rationale to Use Surrogate Skin Irritation and Dermal Toxicity Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1027. 10/13/2010.
5. MRID Number 482888-06: "Eye Irritation Potential of Bioban™ MT 20 Antimicrobial: Rationale to Use Surrogate Skin Irritation and Dermal Toxicity Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1024. 10/13/2010.
6. MRID Number 482888-07: "Skin Sensitization Potential of Bioban™ MT 20 Antimicrobial: Rationale to Use Surrogate Skin Sensitization Data", by G.A. Hazelton, Ph.D. The Dow Chemical Company. Report 10R-1028. 10/13/2010.

The Chemistry and Toxicology Team (CTT) made a comparison of the percentages of active ingredient and the acute toxicity profiles relevant to this data evaluation.

Percent 2-Methyl-4-isothiazolin-3-one in Three Products	
EPA Reg. No. or File Symbol	Percent 2-Methyl-4-isothiazolin-3-one
707-GER	20.0%
707-256	51.65%
707-301	50.69%
707-298	9.7%

Please note that the "inert" ingredients found in the four products above were also an important part of this bridging evaluation.

Comparison of Acute Toxicity Profiles of Registration Numbers 707-256, 707-301 and 707-298*			
Study	707-256	707-301	707-298
Acute Oral Toxicity	II	II	III
Acute Dermal Toxicity	I	II	IV
Acute Inhalation Toxicity	II	II	II
Primary Eye Irritation	I	I	I
Primary Skin Irritation	I	I	I
Dermal Sensitization	Sensitizer	Sensitizer	Sensitizer

*The acute toxicity profiles come from the following reviews:

- 707-256: D358211, 1/4/2000.
- 707-301: D278808, 1/22/2002.
- 707-298: D280255, 1/23/2002.

II RECOMMENDATIONS:

1. Neolone 950 is not an EPA-registered product. EPA has no acute toxicity data or CSF for this product. CTT will not use this product to support bridging of 707-GER.
2. CTT bridged/ bracketed the acute toxicity profiles from 707-256, 707-301 and 707-298 to obtain the acute toxicity profile for 707-GER.
3. Note: As the acute toxicity profile for this product comes from cited data, other products will not be able to cite acute toxicity data from 707-GER to develop an acute toxicity profile.

The acute toxicity profile for File Symbol 707-GER is currently:

Acute Toxicity Profile for 707-GER		
Study	Toxicity Category	Study Status
Acute Oral Toxicity	II	Cited
Acute Dermal Toxicity	II	Cited
Acute Inhalation Toxicity	II	Cited
Primary Eye Irritation	I/ Corrosive	Cited
Primary Skin Irritation	I/ Corrosive	Cited
Dermal Sensitization	Sensitizer	Cited

III LABELING:

1. The Signal Word is "DANGER" based upon the toxicity categories of the primary eye and skin irritation studies.

2. The Precautionary Statements must state:

"Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear goggles, face shield or safety glasses. Wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/ NIOSH approval number prefix TC-23), or a canister approved for pesticides (MSHA/ NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter. Wear coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and chemical-resistant gloves. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."

The Precautionary Statements provided in the label (date punched 11/08/2010) submitted by the registrant do not *absolutely* match those that are required by the Label Review Manual. However, the submitted Precautionary Statements do offer at least the same amount of protection to users and others exposed to the product. CTT finds the 11/08/2010 label's Precautionary Statements to be an acceptable alternative to those recommended above.

A. The 1998 Methylisothiazolinone RED calls for the following Precautionary Statements:

"Mixers, loaders, and others exposed to methylisothiazolinone products must wear:

- long-sleeve shirt and long pants
- chemical-resistant gloves
- shoes plus socks."

"Users should remove clothing immediately if pesticide gets inside. Wash them thoroughly and put on clean clothing."

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly."

B. The 1998 Methylisothiazolinone RED calls for the following Precautionary Statements for products intended primarily for occupational use:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such

instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”

CTT does not typically require the above statements (seen in the Precautionary Statements recommended by CTT and the submitted label); however, the Methylisothiazolinone RED calls for this statement for “products intended primarily for occupational use.” While CTT does not object to these statements, PM Team 33 should decide if these statements are appropriate for File Symbol 707-GER.

3. An application restriction from the 1998 Methylisothiazolinone RED states:

“Do not apply this product in a way that will contact workers or other persons.”

4. The First Aid statements must state:

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 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.

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.”

“Have product container or label with you when calling a Poison Control Center or doctor for treatment advice.”

"For emergency information on [product, use, etc.], call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222."

5. This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye and skin irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider alternatives such as face shield or goggles (to mitigate the identified hazards). Please refer to the 40 CFR §152.170 for information on Restricted-Use products.
6. Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP **in addition to** Restricted-Use Classification. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that this product be assigned Restricted-Use classification; if not, this product should at least be packaged in CRP.