



MATERIAL SAFETY DATA SHEET

BAYER CORPORATION
PHARMACEUTICAL DIVISION
400 Morgan Lane
West Haven, CT 06516-4175

TRANSPORTATION EMERGENCY

CALL CHEMTREC: 800-424-9300
DISTRICT OF COLUMBIA: 202-483-7616

NON-TRANSPORTATION

BAYER EMERGENCY PHONE...: (203) 937-2000
BAYER INFORMATION PHONE.: (800) 662-2927

1. CHEMICAL PRODUCT IDENTIFICATION:

PRODUCT NAME.....: Otic Domeboro Solution
PRODUCT CODE.....: 431220
CHEMICAL FAMILY.....: 2% acetic acid/aluminum acetate
NDC NUMBER.....: 0026-4312-02

2. COMPOSITION/INFORMATION ON INGREDIENTS:

INGREDIENT NAME /CAS NUMBER	EXPOSURE LIMITS	CONCENTRATION (%)
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***** HAZARDOUS INGREDIENTS *****

Acetic Acid		
64-19-7	OSHA : 10.00 ppm TWA	Approx. 2 %
	25.00 mg/m3	
	ACGIH: 10.00 ppm TWA	
	25.00 mg/m3	

3. HAZARDS IDENTIFICATION:

* EMERGENCY OVERVIEW *
*
* WARNING! Color: Colorless; Form: Liquid; Clear; Odor: *
* Acetic acid odor; See Potential Health Effects if the *
* recommended dosage is exceeded; May cause skin irritation; *
* May cause allergic skin reaction; Causes eye irritation. *

POTENTIAL HEALTH EFFECTS:

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3. HAZARDS IDENTIFICATION (Continued)

ROUTE(S) OF ENTRY.....: Accidental: skin contact; eye contact; ingestion. Appropriate route of entry: instilled in the external auditory canal.

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE:

NOTE: This is a pharmaceutical material. Use only as directed. See product packaging and the Physicians' Desk Reference (PDR) for further information concerning adverse effects and drug interaction precautions.

ACUTE SKIN CONTACT.....: Overexposure may cause mild erythema and pruritus.

CHRONIC SKIN CONTACT.....: This product may cause a mild to severe skin sensitivity reactions.

ACUTE EYE CONTACT.....: Overexposure may cause eye irritation with symptoms of reddening, tearing, stinging, and swelling.

CARCINOGENICITY.....: The components of this product are not listed by NTP, IARC or regulated as a carcinogen by OSHA.

MEDICAL CONDITIONS

AGGRAVATED BY EXPOSURE.....: Persons with preexisting skin or eye disorders may be more susceptible to the effects of this product.

4. FIRST AID MEASURES:

FIRST AID FOR EYES.....: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

FIRST AID FOR SKIN.....: Flush skin with plenty of soap and water. Contact a physician if irritation develops.

FIRST AID FOR INHALATION: Remove subject to fresh air immediately.

FIRST AID FOR INGESTION.: Contact poison control center or 203-937-2000.

5. FIRE FIGHTING MEASURES:

FLASH POINT.....: Not Applicable

AUTO-IGNITION TEMPERATURE.....: Not Applicable

EXTINGUISHING MEDIA.....: Water; Carbon Dioxide; Dry Chemical; Foam

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

5. FIRE FIGHTING MEASURES (Continued)

UNUSUAL FIRE / EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES:

SPILL OR LEAK PROCEDURES.....: Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean up. Dike Spill. Prevent liquid from entering sewers, waterways, or low areas. Soak up with sawdust, sand or other absorbent material.

7. HANDLING AND STORAGE:

STORAGE TEMPERATURE(MIN/MAX): 86 F (30 C) Max.
SHELF LIFE.....: Do not use after expiration date.
SPECIAL SENSITIVITY.....: Protect from freezing.
HANDLING/STORAGE PRECAUTIONS: Keep this and all drugs out of the reach of children. Avoid contact with eyes and skin. Wash thoroughly after handling. Store in a dry place away from excessive heat. Reseal containers immediately after use. Use normal precautions for storage of a drug.

8. PERSONAL PROTECTION:

EYE PROTECTION REQUIREMENTS.....: Safety glasses.
SKIN PROTECTION REQUIREMENTS.....: Gloves, long sleeved shirts and pants. Lab coat. Employees should wash their hands and face before eating, drinking or using tobacco products.
VENTILATION REQUIREMENTS.....: Under normal conditions of use, special ventilation is not required.
RESPIRATOR REQUIREMENTS.....: Under normal conditions of use, respiratory protection is not required.
WORK PRACTICES.....: Normal clinical practice. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.
ADDITIONAL PROTECTIVE MEASURES.....: Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES:

PHYSICAL FORM.....: Liquid
APPEARANCE.....: Clear
COLOR.....: Colorless
ODOR.....: Acetic acid odor
pH: 4 - 6
BOILING POINT.....: Less than 212 F (100 C)
MELTING/FREEZING POINT.....: Greater than 32 F (0 C)
SOLUBILITY IN WATER: Soluble
SPECIFIC GRAVITY: Greater than 1.0
BULK DENSITY.....: Not Applicable
VAPOR PRESSURE: Not Applicable

10. STABILITY AND REACTIVITY:

STABILITY.....: This is a stable material.
HAZARDOUS POLYMERIZATION...: Will not occur.
INCOMPATIBILITIES.....: Avoid strong oxidizing agents. See product
 packaging and the Physicians' Desk Reference (PDR) for drug interaction.
INSTABILITY CONDITIONS.....: None known.
DECOMPOSITION PRODUCTS.....: CO, CO₂, oxides of nitrogen, and other potentially
 toxic fumes.

11. TOXICOLOGICAL INFORMATION:

See product insert for information concerning animal pharmacology.

12. ECOLOGICAL INFORMATION:

NO ECOLOGICAL INFORMATION AVAILABLE

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD.....: Incineration is recommended. Waste disposal
 should be in accordance with existing federal, state and local

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13. DISPOSAL CONSIDERATIONS (Continued)

environmental control laws.

14. TRANSPORTATION INFORMATION:

TECHNICAL SHIPPING NAME.....: 2% Acetic acid/Aluminum acetate
PRODUCT LABEL.....: Otic Domeboro Solution

DOT (DOMESTIC SURFACE)

HAZARD CLASS OR DIVISION: Non-Regulated

IMO / IMDG CODE (OCEAN)

HAZARD CLASS DIVISION NUMBER...: Non-Regulated

ICAO / IATA (AIR)

HAZARD CLASS DIVISION NUMBER...: Non-Regulated

15. REGULATORY INFORMATION:

OSHA STATUS.....: This product is not hazardous under the criteria
of the Federal OSHA Hazard Communication Standard
29 CFR 1910.1200.

TSCA STATUS.....: This product is exempt from TSCA Regulation under
Section 3 (2) (B) (vi) when used for pharmaceutical
application.

CERCLA REPORTABLE QUANTITY...: None

SARA TITLE III:

SECTION 302 EXTREMELY

HAZARDOUS SUBSTANCES...: None

SECTION 311/312

HAZARD CATEGORIES.....: Exempt from SARA Section 311/312

SECTION 313

TOXIC CHEMICALS.....: None

RCRA STATUS.....: If discarded in its purchased form, this product
would not be a hazardous waste either by listing
or by characteristic. However, under RCRA, it is
the responsibility of the product user to
determine at the time of disposal, whether a
material containing the product or derived from
the product should be classified as a hazardous
waste. (40 CFR 261.20-24)

ACTIVE INGREDIENT: Acetic acid INACTIVE INGREDIENTS: Water, Aluminum

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15. REGULATORY INFORMATION (Continued)

acetate, sodium acetate, boric acid

16. OTHER INFORMATION:

HMIS RATINGS: Health Flammability Reactivity
 1 0 0
 0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

Bayer's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS ratings are provided by Bayer as a customer service.

REASON FOR ISSUE.....: Update format.
PREPARED BY.....: R. Ruppel-Kerr
APPROVED BY.....: G. Toczyłowski
APPROVAL DATE.....: 08/20/96
SUPERSEDES DATE.....: 08/29/94
MSDS NUMBER.....: 26105

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