

SAFETY DATA SHEET

1. <u>Identification</u>

Product Identifier: BAL in Oil™ (dimercaprol injection, USP)

Synonyms: Dimercaprol Injection; Dithioglycerol; British anti-

Lewisite; BAL; Dimercaprol; 2,3-Dimercapto-1-propanol.

National Drug Code (NDC): 17478-526-03

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.

1925 West Field Court, Suite 300

Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. <u>Hazard(s) Identification</u>

Physical Hazards: Not classifiable.

Health Hazards: Harmful if swallowed Category 4

Skin irritation Category 2

Eye irritation Category 2A

Specific target organ toxicity -

single exposure Category 3



Symbol(s):

Signal Word: Warning.

Hazard Statement(s): H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.



Precautionary Statement(s):	P233	Keep container tightly closed.	
	P261	Avoid breathing dust/fumes/gas/mist/vapors/spray.	
	P264	Wash potentially exposed skin thoroughly after handling.	
	P270	Do not eat, drink, or smoke when using this product.	
	P271	Use only in a well-ventilated area.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P304 + P312	IF INHALED: Call a POISON CENTER/doctor/physician if you feel unwell.	
	P340	Remove person to fresh air and keep comfortable for breathing.	
	P301 + P312	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician if you feel unwell.	
	P330	Rinse mouth.	
	P302 + P352	IF ON SKIN: Wash with plenty of water.	
	P362 + P364	Take off contaminated clothing and wash it before reuse.	
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	P321	Specific treatment (see Section 4).	
	P403 + P405	Store in a well-ventilated space. Store locked up.	
	P501	Dispose of contents/container in accordance with local/provincial/federal regulations.	
Hazards Not Otherwise Classified:	Possible allergen with anaphylactic response.		

None.

Supplementary Information:



Composition/Information on Ingredients 3.

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
2,3-Dimercapto-1- propanol	59-52-9	Dithioglycerol; British anti-Lewisite; BAL; Dimercaprol	C ₃ H ₈ OS ₂	124.22	10%
Benzyl Benzoate	120-51-4	Benzoic Acid Benzyl Ester; Benzyl Benzenecarboxylate; Benzyl Phenylformate	C ₁₄ H ₁₂ O ₂	212.24	20%
Peanut Oil	120-51-4	Arachis oil	Not Applicable	Not Applicable	70%

4.

		Benzyl Phenylformate			
Peanut Oil	120-51-4	Arachis oil	Not	Not	70%
			Applicable	Applicable	
. First Aid Meas	SIIFAS				
I HOLFAIG MCGC	341 00				
Ingestion:		that vomit will n mouth with wat immediately an symptomatically personnel are a	nits place them in not reenter the man are. If swallowed, d show the contractive and supportive aware of the man protect themselver.	outh and thro seek medica ainer or label. ely. Ensure tha terial(s) involv	at. Rinse I advice Treat at medical
Eye Contact:		amounts of wat persists or sign Provide sympto Ensure that me	ource of exposurer for at least 15 s of toxicity occumatic/supportive dical personnel lived and are awayes.	ominutes. If ir ur, seek medio e care as neco are aware of t	ritation cal attention. essary. the
Skin Contact:		contaminated of amounts of wat irritation persist attention. Provincessary. Ens	ource of exposulothing and show er for at least 20 s or signs of tox de symptomaticative that medications involved and are lives.	es. Flush with) minutes. Use icity occur, se /supportive ca I personnel ar	copious e soap. If ek medical ire as e aware of
Inhalation:		fresh air. Give a breathing and c toxicity occur, s symptomatic/su medical person	ource of exposu artificial respirati call emergency reek medical atte apportive care as nel are aware of of precautions to	on if individua nedical servic ention. Provid s necessary. E f the material(II(s) are not e. If signs of e Ensure that s) involved
Protection of F	irst-Aiders:	Use personal p	rotective equipm	nent (see sect	ion 8).



Signs and Symptoms: Nausea; vomiting; headache; burning sensation in the

lips, mouth and throat; feeling of constriction/pain in the throat, chest, or hands; conjunctivitis; lacrimation; eyelid spasm; runny nose; salivation; tingling of the hands; sweating; abdominal pain; appearance of painful sterile Abscesses; eye inflammation; skin inflammation.

Abscesses, eye ililaminalion, skin ilil

Medical Conditions Aggravated

by Exposure:

Liver disease; kidney disease; hypersensitivity to any of

the components of the product.

Notes to Physician: None.

5. <u>Firefighting Measures</u>

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides,

and sulfur oxides.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/ Precautions for Firefighters:

Wear self-contained breathing apparatus and full and

protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch

damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with

inert material. Recover product and place in an appropriate container for disposal in accordance with

local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements,

confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.



7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product

insert information. Handle in accordance with good

industrial hygiene and safety practices.

Conditions for Safe Storage,

Including Any Incompatibilities: Store according to label and/or product insert

information. Store away from acids, bases, oxidizing

agents, reducing agents, alkali metals.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits		
Dimercaprol	No data available.		
Benzyl Benzoate	No data available.		
Peanut Oil	OSHA PEL: 5 mg/m³ (as oil mist) OSHA PEL: 15 mg/m³ (total dust) NIOSH REL: 5 mg/m³ (respirable) NIOSH REL: 10 mg/m³ (mist)		

Engineering Controls: Engineering controls should be used as the primary

means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or

control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29

CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended.

Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in

the work area.

Hand Protection: Chemically compatible gloves. For handling solutions,

ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should

be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment.



9. **Physical and Chemical Properties**

Physical State/Color: Semi-solid/Colorless to light yellowish translucent.

Odor: Pungent.

Odor Threshold: No data available. pH: No data available. **Melting Point:** No data available. Freezing Point: No data available. **Boiling Point:** No data available. Flash Point: No data available. **Evaporation Rate:** No data available. Flammability (solid, gas): No data available. Flammability Limit - Lower: No data available. Flammability Limit - Upper: No data available. Vapor Pressure: No data available. Vapor Density: No data available. **Relative Density:** No data available.

Solubility(ies): Slightly miscible in water.

Partition Coefficient

(n-octanol/water):No data available.Auto-Ignition Temperature:No data available.Decomposition Temperature:No data available.Viscosity:No data available.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static

discharge, shock, or vibration): No data available.

Incompatible Materials: Acids, Bases, Oxidizing agents, Reducing agents, Alkali

metals.

Hazardous Decomposition

Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be harmful if inhaled. May cause respiratory tract

irritation.

Ingestion: May be toxic if swallowed.

Skin Contact: May be harmful if absorbed through the skin. May cause

skin irritation.

Eye Contact: May cause eye irritation.



Symptoms Related to the Physical,

Chemical and Toxicological

Characteristics: See Section 4. To the best of our knowledge, the

chemical, physical and toxicological properties have not

been thoroughly investigated.

Delayed and Immediate Effects of

Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Dimercaprol	Mouse	Oral	LD ₅₀	217 mg/kg
Benzyl Benzoate	Rabbit	Oral	LD ₅₀	1,680 mg/kg
Benzyl Benzoate	Rat	Oral	LD ₅₀	1,700 mg/kg
Benzyl Benzoate	Rabbit	Oral	LD ₅₀	4,000 mg/kg

Acute Toxicity - Dermal: No data available. Acute Toxicity - Inhalation: No data available. Corrosivity: No data available. Dermal Irritation: No data available. No data available. **Eve Irritation:** Sensitization: No data available. Toxicokinetics/Metabolism: No data available. **Target Organ Effects:** No data available. **Reproductive Effects:** No data available. Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on

Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health

Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity:No data available.Aspiration Hazard:No data available.

12. <u>Ecological Information</u>

Ecotoxicity

Aquatic:
Terrestrial:
No data available.
Persistence and Degradability:
Bioaccumulative Potential:
Mobility in Soil:
Mobility in Environment:
Other Adverse Effects:
No data available.
No data available.
No data available.
No data available.



13. <u>Disposal Considerations</u>

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:
UN Proper Shipping Name:
Not applicable.
Transport Hazard Class(es):
Not applicable.
Not applicable.
Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport

Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous

Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act

(TSCA): This product is a drug regulated by the Food and Drug

Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity:

Quantity: Not listed.

SARA 313: Not listed. SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.

New Jersey: Dimercaprol; Benzyl Benzoate; Peanut oil extractives

and their physically modified derivatives.

Pennsylvania: Dimercaprol; Benzyl Benzoate; Peanut oil extractives

and their physically modified derivatives.

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California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating: HMIS Classification: Health: 2 Health:

Flammability: 1 Flammability: 1 Reactivity: 0 Physical Hazard: 0



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