

**MATERIAL SAFETY DATA SHEET**



<b>MANUFACTURER</b> Miles Inc. Consumer Healthcare Products 1127 Myrtle Street Elkhart, IN 46514 (219)264-8400	For accidental ingestion, or adverse reaction, call: 203/937-2373 or 1-800/468-0894 ask for: Professional Services Miles Inc., Pharmaceutical Division	<b>HMIS Code</b> Health 1 Fire 0 Reactivity 0 Pers.Prot. 0
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**SECTION 1 - IDENTITY**

<b>Common Name: (used on label)</b> (Trade Name & Synonyms) BACTINE Brand Hydrocortisone 0.5%		
<b>Product Code:</b> 2109	<b>Chemical Name:</b> Active ingredient: Hydrocortisone 0.5%	
<b>Chemical Family</b> Not applicable	<b>Formula</b> Mixture	<b>CAS No.</b> None

**SECTION 2 - HAZARDOUS INGREDIENTS**

<b>Hazardous Components - (chemical &amp; common names)</b> None	<b>Hazard</b> For additional information see Section 4.	<b>TLV Units</b>
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**SECTION 3 - PHYSICAL & CHEMICAL CHARACTERISTICS (Fire & Explosion Data)**

<b>Boiling Point</b> Not applicable.	<b>Specific Gravity (H<sub>2</sub>O = 1)</b> Not applicable.	<b>Vapor Pressure (mm hg)</b> Not applicable.
<b>Percent Volatile by Volume (%)</b> Not applicable.	<b>Vapor Density (Air = 1)</b> Not applicable.	<b>Evaporation Rate (=1)</b> Not applicable.
<b>Solubility in Water</b> Not applicable.	<b>Reactivity in Water/Air</b> None	
<b>Appearance and Odor</b> White cream in plastic tube		
<b>Flash Point</b>	<b>Flammable Limits in Air % by Volume</b> <u>Lower</u> <u>Upper</u>	<b>Auto-ignition Temperature</b>
Not applicable.	Not applicable.	Not applicable.
<b>Extinguisher Media</b>	Water	
<b>Special Fire Fighting Procedures</b>	None	

**Unusual Fire and Explosion Hazards** None

**SECTION 4 - HEALTH HAZARDS**

<b>OSHA Permissible Exposure Limit</b> Not established.	<b>ACGIH Threshold Limit Value</b> Not established.
<b>Other Exposure Limit Used</b> None	
<b>Signs and Symptoms - Acute Overexposure</b> Toxicity should not occur from an acute overexposure to this product.	
<b>Signs and Symptoms - Chronic Overexposure</b> Chronic overexposure may result in symptoms of adrenal suppression upon discontinuation: Weakness, anorexia, nausea, vomiting, fatigue, weight loss, hyperpigmentation, electrolyte abnormalities.	
<b>Medical Conditions Generally Aggravated by Exposure</b> Infection, diabetes, subcutaneous atrophy, delayed wound healing, hypersensitivity reaction to propylparaben (an inactive ingredient)	
<b>Primary Route(s) of Exposure</b> Topical, Oral	
<b>Emergency and First Aid Procedures</b> Contact your regional poison control center or physician immediately. Additional information may be obtained by contacting Miles Inc. at 203/937-2373 or 1-800/468-0894.	
<b>Hygienic Practices</b> Normal clinical.	
<b>Chemical Listed as Carcinogen or Potential Carcinogen</b> None	

Common Name: BACTINE Brand Hydrocortisone (0.5%)

SECTION 5 - PHYSICAL HAZARDS

Stability: Unstable [ ] Conditions to avoid  
Stable [x]

Incompatibility  
(Materials to Avoid) None

Hazardous  
Decomposition Products None

Hazardous May Occur [ ] Conditions to Avoid  
Polymerization Will Not Occur [x]

SECTION 6 - SPECIAL PROTECTION INFORMATION

Respiratory Protection  
None for normal use.

Ventilation None for normal use. Work Practices  
Not applicable.

Protective Gloves None for normal use. Eye Protection  
None for normal use.

Other Protective  
Clothing or Equipment None for normal use.

SECTION 7 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Precautions to be Taken  
in Handling and Storage None

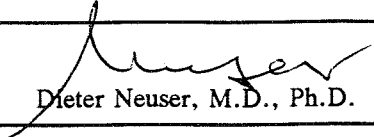
Steps to be Taken in Case  
Material is Released or Spilled  
Contain for disposal.

Waste Disposal  
Methods Dispose as normal solid waste.

SECTION 8 - ADDITIONAL INFORMATION

For external use only - avoid contact with eyes.

Signature of Person  
Responsible for Preparation

  
Dieter Neuser, M.D., Ph.D.

Date  
Prepared March 1991

Telephone No.  
219/264-8142

Date  
Revised November 1991

The opinions expressed herein are those of qualified experts within Miles, Inc. We believe that the information contained herein is current as of the date of this Material Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within the control of Miles, Inc., it is the user's obligation to determine the conditions of safe use of the product.