

Schering-Plough HealthCare Products, Inc.
3030 Jackson Avenue
Memphis, TN 38151

SAFETY DATA SHEET

Schering-Plough urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

SDS NAME: Solarcaine Aerosol

SYNONYM(S): Solarcaine Medicated First Aid Spray
Solarcaine Aerosol (First Aid)
Solarcaine Spray
LysmucoL Granulat

MSDS NUMBER: SP001274

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

SCHERING-PLOUGH MSDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Clear, Colorless
Aerosol
Characteristic odor

Highly Flammable.

May be harmful by inhalation.

May cause effects to:
central nervous system
respiratory system
blood

Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

EU CLASSIFICATION(S): R11

POTENTIAL HEALTH EFFECTS:

Benzocaine is a topical local anesthetic. Dermal or oral exposure may produce methemoglobinemia (the formation of methemoglobin in the blood). Secondary effects that may result from significant methemoglobinemia include nausea, vomiting, rapid beating of the heart, decreased blood pressure, deep or rapid breathing, cyanosis (blue or purple discoloration of the skin due to lack of oxygen), reduced awareness or alertness, confusion, increase of acidic products in the blood, respiratory distress, or coma.

Isobutane, the propellant component of this product, is a non-toxic gas. However, it is an asphyxiant and exposure to high concentrations may cause dizziness, fatigue, decreased vision, mood disturbances, numbness of extremities, headache, confusion, incoordination, cyanosis (blue or purple discoloration of the skin due to lack of oxygen), nausea, vomiting, coughing, pulmonary irritation, or anesthesia. Intentional misuse by deliberately concentrating and inhaling asphyxiant gases can be harmful or fatal. Direct contact with liquefied isobutane causes frostbite and/or burns.

Ethanol (ethyl alcohol) is an eye, nose, and mucous membrane irritant. It may cause skin irritation or sensitization after prolonged exposure. Acute effects of ethanol may include headache, dizziness, nausea, sensations of warmth and cold, numbness, fatigue, breathing difficulty, cough, tearing, vision impairment, incoordination, decreased reaction time, alteration of mood and personality, slurred speech, coma and respiratory depression. Chronic effects may include concentration difficulty, sleepiness, kidney and liver damage, and cardiac effects. Chronic ingestion of ethanol may cause cancer of the oral cavity, pharynx, larynx, esophagus, and liver. Oral ingestion of alcohol during pregnancy may cause Fetal Alcohol Syndrome (FAS) including joint, limb, and cardiac abnormalities and behavioral and learning impairment. There have been no reports of FAS as a result of occupational handling of ethanol.

LISTED CARCINOGENS

IARC (International Agency for Research on Cancer) has classified Alcoholic Beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Consumer product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed.

CHEMICAL COMPOSITION

CHEMICAL NAME	CAS NUMBER	EU NUMBER	EU CLASSIFICATION	PERCENT
Benzocaine.	94-09-7	2023035 Listed.		3
Isobutane.	75-28-5	2008572 Listed.		50-60
Ethyl Alcohol.	64-17-5	2005786 Listed.	R11 F	30-40
Propylene Glycol.	57-55-6	2003380 Listed.		< 10

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

See section 15 for EU hazard classification symbols and risk and safety phrases.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point:	-84.4 deg C (-120 deg F) (Isobutane)
Classification:	Flammable (US OSHA Criteria) Flammable (Canada WHMIS Criteria) Highly Flammable (EU Criteria)
UEL:	8.4 vol % (Isobutane)
LEL:	1.8 vol % (Isobutane)

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:

Contents under pressure. Keep containers adequately sealed during material transfer, transport, or when not in use.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:

Keep away from heat, sparks, open flames, and direct sunlight. Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE CONTROLS:

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection: None required for consumer use of this product.

Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

Skin Protection: None required for consumer use of this product.

Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

Eye Protection: None required for consumer use of this product.

Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: None required for consumer use of this product.

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

CHEMICAL NAME	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Ethyl Alcohol.	64-17-5	1000 ppm		

Refer to regional exposure limit lists for chemical specific guidance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Aerosol
COLOR: Clear, Colorless
ODOR: Characteristic odor
BOILING POINT / RANGE: -11.7 deg C (isobutane)
VAPOR PRESSURE: 45.1 psi @ 21.11 deg C
VAPOR DENSITY: > 1.29
SPECIFIC GRAVITY: < 1
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

CONDITIONS AND MATERIALS TO AVOID:
Keep away from heat, sparks, open flame, and direct sunlight. Oxidizers.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

Solarcaine Aerosol

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Latest Revision Date: 21-Mar-2008

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ACUTE TOXICITY DATA

INHALATION:

Isobutane caused CNS depression, rapid and shallow respiration, and apnea in mice exposed to high concentrations. In dogs, 45% isobutane caused anesthetic effects.

Ethanol, at high concentrations, caused dose dependent effects following inhalation exposure in rats on the central nervous system including drowsiness, incoordination, narcosis and excitation.

SKIN:

Benzocaine was slightly irritating to the skin of guinea pigs.

Ethanol was mildly to moderately irritating to the skin of rabbits.

EYE:

Benzocaine (4-20%) was not irritating to the eyes of rabbits.

Ethanol (95%) was irritating to the eyes of rabbits.

ORAL:

Benzocaine: Oral LD50: 3042 mg/kg (rat)

Ethanol: Oral LD50: 6.2 to 17.8 g/kg (rat); 5.5 to 6.6 g/kg (dog)

SENSITIZATION:

Ethanol has been shown to be a weak sensitizer in a human patch test. Ethanol was negative in the mouse ear sensitization assay.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:

Repeated oral and inhalation exposure to high concentrations of ethanol has caused kidney and liver damage in animals.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Ethanol: Exposure to large doses during gestation is reported to cause effects on reproduction, including fetotoxicity and growth retardation in mice, rats, and rabbits. However, no teratogenic effects were reported.

MUTAGENICITY / GENOTOXICITY:

Isobutane was negative in a bacterial mutagenicity study (Ames).

Ethanol was positive in a bacterial mutagenicity study (Ames) and negative in a mammalian mutagenicity study (mouse lymphoma).

CARCINOGENICITY:

Rats given 25 to 50% ethanol by oral gavage or in the drinking water for one to two years did not show a significant increase in tumors compared to the control groups. Mice given 43% ethanol in drinking water for three years showed an increase in papillomas of the forestomach, malignant lymphomas and lung adenomas. Ethanol was an effective promoter of liver tumors in rats given a single intraperitoneal dose of diethylnitrosamine followed by treatment of ethanol in the drinking water for 12 to 18 months.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Benzocaine: 96-hr LC50 (rainbow trout): 7.2-23 mg/L
Benzocaine: 96-hr LC50 (fathead minnow): 25.9-39.3 mg/L

Ethanol: 96-hr (static) LC50 (rainbow trout): 13 g/L
Ethanol: 96-hr (flow-through) LC50 (fathead minnow): 12.9-15.3 g/L

ENVIRONMENTAL DATA

There are no environmental data available for this product.

SECTION 13. DISPOSAL CONSIDERATIONS

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MATERIAL WASTE:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is not the preferred method of disposal. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

Refer to site-specific procedures and requirements for additional guidance.

IATA CLASSIFICATION:

Proper Shipping Name:	Aerosols, flammable
Hazard Class:	2.1
UN Number:	UN 1950
Packing Group:	None

ADR CLASSIFICATION:

Proper Shipping Name:	Aerosols
Hazard Class:	2
UN Number:	UN 1950
Packing Group:	None
Classification Code:	5F

IMDG CLASSIFICATION:

Proper Shipping Name:	Aerosols
Hazard Class:	2
UN Number:	UN 1950
Packing Group:	None

SECTION 15. REGULATORY INFORMATION

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

Indication of Danger: F - Highly flammable.



Risk Phrases:
R11 - Highly flammable.

Safety Phrases:
S 2 - Keep out of reach of children.
S46 - If swallowed, seek medical advice immediately and show this container or label.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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