

Material Safety Data Sheet (SDS)

Elyptol Antimicrobial Hand Gel

Date of Issue: 05/1/2015

SECTION 1 - IDENTIFICATION OF MATERIAL AND SUPPLIER

Product Name: Elyptol Antimicrobial Hand Gel
Other Names: Elyptol Antibacterial, Antimicrobial & Moisturizing Hand Sanitizing Gel
Effective Date: 05/01/2015
Recommended Uses: Topical skin antiseptic, instant hand sanitizer, surgical hand sanitizing Gel.
Company: Elyptol Inc.
FDA Reg (NDC Code): 69343
DUNS No: 079594781
Address: Elyptol Inc. 2500 Broadway, Building F, Suite F-125, Santa Monica, CA 90403, USA
Contact Tel No: +1 424 500 80 99
Website URL: <http://www.elyptol.com>
Emergency: Contact your local emergency control Centre. Poison's Information Centre 1-800-222-1222
Elyptol Emergency No: +1 (888) 424-9874

Transportation Emergency (24 Hour) Contact INFOTRAC North America: +1-800-535-5053
 Outside North America: +1-352-323-3500

Medical Emergencies: Contact your local poison control centre.
HMIS Rating: Health 1, Flammability 3, Physical hazard 0
DOT: CONSUMER COMMODITY, ORM-D
IATA: CONSUMER COMMODITY, ID8000, Class 9
IMDG: UN1170, ETHANOL SOLUTION, Class 3, LTD QTY

SECTION 2 - HAZARDS IDENTIFICATION

HAZARDOUS SUBSTANCE

DANGEROUS GOODS FLAMMABLE LIQUID CONTENT



Emergency Overview:

The liquid material contained in the product packaging and if in bulk, is a flammable liquid.
 Storage and handling is to be followed as per the product labels, the shipper packaging and this SDS.
Hazard Classification: Flammable Liquid, Cat. 3 Signal Word(s): Warning Hazard Symbol(s):
Hazard Statement: Flammable liquid and vapor.

RISK	
▪ R10	Flammable liquid Class 3
▪ UN1170	Ethanol Solution
▪ Packaging Group	2

SAFETY	
▪ S2	Keep out of reach of children
▪ S7	Keep container tightly closed
▪ S16	Keep away from sources of ignition - No Smoking

Precautionary Statements:

- FLAMMABLE. Keep away from fire or flame.
- Avoid contact with eyes. In case of eye contact, flush thoroughly with water and if pain persists seek medical attention.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients considered hazardous as defined by OSHA, 29 CFR 1910.1200, WHMIS under the HPA (Canada), or ESIS (Europe).

Chemical Name	CAS Number	Proportion %
Ethanol 95BP	64-17-5	70 v/v
Eucalyptus Oil	84625-32-1	-
Eucalyptol/Cineole 99.5% USP/BP	470-82-6	< 10

Note:

* The excipient ingredients are listed by the FDA as GRAS

* The active substance is 70% v/v ethanol undenatured listed by the FDA as GRASE 1

SECTION 4 – FIRST AID MEASURES FOR SPILL EXPOSURE

Swallowed	<ul style="list-style-type: none"> If swallowed do NOT induce vomiting. Unpalatable and will cause reflux to occur If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Contains alcohol, if stupor, seek medical attention for potential alcohol inducement Contains Cineole, Seek medical attention if swallowed as can cause stomach intestinal problems. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.
Eye	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> Flush eye with fresh running water for a minimum of 15 minutes, keep moving the eyes to ensure complete flushing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. Seek Medical attention promptly if irritation persists or loss of vision occurs.
Skin	<ul style="list-style-type: none"> Immediately remove contaminated clothing. Wash / rinse contaminated skin with water Seek medical attention if Irritation occurs. Launder contaminated clothing before re-use.
Inhaled	<ul style="list-style-type: none"> Over exposure may cause dryness of throat. Drink water, & seek medical attention if unwell.
Notes to Physician	<p>If poisoning occurs, contact a doctor or Poisons Information Centre right away 1-800-222-1222. There is no specific antidotes. Treat symptomatically as for poisons.</p>

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media	<ul style="list-style-type: none"> • Use water spray or fog. • Dry chemical powder • Alcohol stable foam. • Carbon dioxide.
Fire/Explosion Hazard	<ul style="list-style-type: none"> • Liquid and vapor are flammable. • Low fire hazard when exposed to heat or flame. • Burning can produce carbon monoxide and/or carbon dioxide. • No applicable hazards are known to be associated with this product.
Precautions For Firefighters and Special Protective Equipment	<ul style="list-style-type: none"> • Alert fire brigade and tell them the fire location. • Use water to cool exposed containers. • If safe to do so, remove containers from path of fire. • For major fires or where atmosphere is Oxygen deficient or contains unacceptable levels of combustion products, firefighters must wear self-contained breathing apparatus with full-face mask and protective clothing. • If safe, switch off electrical equipment until vapor fire hazard is removed. • Thermal decomposition may include oxides of carbon and nitrogen.
Fire Incompatibility	Avoid contamination with strong oxidizing agents as ignition may result.
HAZCHEM	<ul style="list-style-type: none"> • 2Y • Flash Point & Method 24°C (76°F) Flammability Class OSHA Flammable Liquid, Class IC Tag Closed Cup Flammability Limits (% by vol) Lower Upper 3.3%* 19.0%* (*for ethanol)
Other	<ul style="list-style-type: none"> • Flash Point & Method 24°C (76°F) Flammability Class OSHA Flammable Liquid, Class IC Tag Closed Cup Flammability Limits (% by vol) Lower Upper 3.3%* 19.0%* (*for ethanol)

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency Procedures	<ul style="list-style-type: none"> • Spills should be reportable to the National Response Center
Prevent Area from Spark or Flame	<ul style="list-style-type: none"> • If spark or flame is present, evacuate area and call the NRC. • Wear appropriate personal protective equipment to prevent skin and eye contamination and breathing of vapors. • Isolate hazard area. • Keep unnecessary and unprotected personnel from entering. • Ventilate area well and ensure the atmosphere is safe before allowing personnel to return to the work area.
Methods and Materials for Containment and Clean Up Procedures	<ul style="list-style-type: none"> • Contain and recover gel when possible. • Collect Gel in an appropriate container and place in a chemical waste container • Collected Gel can then be disposed of through local government waste removal services.

SECTION 7 – HANDLING & STORAGE

Precautions for Safe Handling	<ul style="list-style-type: none"> Protect against physical damage. Make certain the containers are well sealed and upright when not in use. Keep away from Children. Use good occupational work practice. Observe manufacturer's storing and handling requirements.
Conditions for Safe Storage	<ul style="list-style-type: none"> Store in a cool, dry well ventilated location away from direct sunlight. Keep containers upright & closed at all times.
Incompatibilities	<ul style="list-style-type: none"> Not to be stored with explosives, flammable gases in bulk, poisonous gases, spontaneously combustible substances, oxidizing agents, organic peroxides or radioactive substances.
Storage Requirements	<ul style="list-style-type: none"> Store in original containers and packaging in approved flammable liquid storage areas. DO NOT store in pits, depressions, basements,

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

EU & USP Exposure Standards	
Ethanol	<ul style="list-style-type: none"> TWA- 1000ppm (1,880 mg/m3) STEL – None Allocated Carcinogen Category – None Allocated Notices – None Allocated As published by EPA and global EU Health and Safety standards TWA is an Exposure Standard for a time-weighted average airborne concentration over an eight-hour working day, for a five-day working week over an entire working life. According to the current knowledge this concentration should neither impair the health nor cause any undue discomfort to nearly all workers. STEL (Short Term Exposure Limit) is the average airborne concentration over a 15 minute period which should not be exceeded at any time over an 8-hour working day.
Incompatibilities	<ul style="list-style-type: none"> Not to be stored with explosives, flammable gases in bulk, poisonous gases, spontaneously combustible substances, oxidizing agents, organic peroxides or radioactive substances.
Storage Requirements	<ul style="list-style-type: none"> Store in original containers and packaging in approved flammable liquid storage areas. DO NOT store in pits, depressions, basements,
Engineering Controls	<ul style="list-style-type: none"> Local and/or general exhaust is recommended to keep employee exposures below the Permissible Exposure Limits.
Personal Protective Equipment for major spills:	<ul style="list-style-type: none"> Safety eyewear gloves and organic vapors respirator to protect from exposure.
Eye Protection	<ul style="list-style-type: none"> Chemical safety goggles or safety glasses with side shields. Maintain eye wash fountain and drench facilities in the work area.
Skin Protection	<ul style="list-style-type: none"> Impervious protective clothing (gloves, lab coat, apron or coveralls, as appropriate) to prevent skin contact. Neoprene and Nitrile Gelber are recommended materials.
Respiratory Equipment	<ul style="list-style-type: none"> None required under normal circumstances if engineering, storage and

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handling controls are adequate. In high vapor concentrations or confined areas where vapor concentration is likely to exceed 400ppm an approved respirator with organic vapor cartridge must be worn.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance	▪ Plastic PET container containing Eucalyptus scented alcoholic liquid Gel solution, Eucalyptus Oil scent low, alcohol scent low.
Odor	▪ 5.5 – 7.5PH
Vapour Pressure	▪ N/A
Vapour Density	▪ 2.1 (Air = 1)
Boiling Point/Range	▪ Not Applicable
Melting Point	▪ Not Applicable
Solubility	▪ Not Applicable
Specific Gravity	▪ Not Applicable
Flash Point	▪ 17 deg C tag closed cup
Lower Explosive Limit	▪ 3.3%
Upper Explosive Limit	▪ 19%
Ignition Temperature	▪ >200 deg C
Volatile Organic Content	▪ >80% v/v
Percent Volatile	▪ >80% v/v

SECTION 10 – STABILITY & REACTIVITY

Chemical Stability	▪ Stable
Conditions to Avoid	▪ Heat, sparks, flame and build-up of static electricity
Incompatible Materials	▪ Will react with strong oxidizing agents
Hazardous Decomposition Products	▪ Soot, Carbon Dioxide, Carbon Monoxide
Hazardous Reactions	▪ Will not polymerize

SECTION 11 – TOXICOLOGICAL INFORMATION

Inhaled	▪ Mild irritation to the nose, throat and upper respiratory tract can occur at concentrations above 7000ppm. Higher concentrations can lead to throat dryness and vomiting. Not known to cause asthma or allergy reactions.
Swallowed	▪ Accidental ingestion of the material may be damaging to the health of the individual. ▪ Ingestion of alcohol may produce nausea, vomiting, gastrointestinal bleeding, abdominal pain and diarrhea. ▪ Small amount may cause throat irritation and vomiting. Large amount [1 litre+] will cause severe stomach cramps, nausea, vomiting, drowsiness.
Eye	▪ The vapor is irritating to the eyes at concentrations above 7000ppm. Direct eye contact with the product may cause eye irritation, including pain and redness.
Skin	▪ Non primary skin irritant – Non primary skin sensitizer – dermatology tested. Recommended Not for baby skin
Acute Effects – Acute Toxicity	▪ LD50/oral/rat NA

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	<ul style="list-style-type: none">• LD50/dermal/rat NA• LC50/inhalation/rat NA• Irritant dose/dermal/rabbit NA• Irritant dose/ocular/rabbit NA• Not listed as carcinogen when used as directed
Long Term Effects Chronic	<ul style="list-style-type: none">• When used as according to directions, there are no long term negative effects expected.



SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity	<ul style="list-style-type: none">• Toxicity to fish N/A.
Persistence and Degradability	<ul style="list-style-type: none">• Degree of elimination >90%
Mobility	<ul style="list-style-type: none">• No data is available on mobility in soil.
Environmental Impact	<ul style="list-style-type: none">• The product ingredients are expected to be safe for the environment at concentrations predicted under normal use and accidental spill scenarios. Empty packaging components are compatible with the conventional solid waste management practices for normal waste recycling
Not tested on Animals	

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal	<ul style="list-style-type: none">• Dispose of container and unused contents in accordance with federal, state and local requirements.
Lid & Container	<ul style="list-style-type: none">• Empty container and lid can be recycled as per local government waste recycling regulations.
Content	<ul style="list-style-type: none">• Product content must not be disposed of to the sewerage system, drains or waterways.
Disposal Methods	<ul style="list-style-type: none">• Unused product is RCRA ignitable hazardous waste (D001). Dispose of according to local, state, and federal regulation.

SECTION 14 – TRANSPORT INFORMATION

Labels Required	
Marine Pollutant	<ul style="list-style-type: none">• No (HAZCHEM: 2YE; 2Y)
IMDG (vessel) UN1170 ETHANOL SOLUTION 3 III, LTD QTY	
UN number	<ul style="list-style-type: none">• 1170
Class	<ul style="list-style-type: none">• 3
Packaging Group	<ul style="list-style-type: none">• 2

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Subsidiary Risk EU	<ul style="list-style-type: none"> S 25, S 29, S 46, S 47, S 59, S 62
Packaging Group	<ul style="list-style-type: none"> 2
Hazchem Code	<ul style="list-style-type: none"> 2Y
Special Precautions	<ul style="list-style-type: none"> Not to be stored with explosives, flammable gases in bulk, poisonous gases, spontaneously combustible substances, oxidizing agents, organic peroxides or radioactive substances, near sparks or ignition.
Note	<ul style="list-style-type: none"> This product is a Class 3 Dangerous Good as content is flammable due to Alcohol content

SECTION 15 – REGULATORY INFORMATION

Classification	<ul style="list-style-type: none">USA FDA This product is regulated as an Over-The-Counter (OTC) drug under the Federal Food, Drug, and Cosmetics Act and complies with FDA regulations.						
Poisons Schedule	<ul style="list-style-type: none">Not Scheduled						
USA FDA	<ul style="list-style-type: none">This product is regulated as an Over-The-Counter (OTC) drug under the Federal Food, Drug, and Cosmetics Act and complies with FDA regulations.						
EPA SARA Title III Sections 302/304, 311/312, and 313 chemical listings:	<ul style="list-style-type: none">None or none present in regulated quantities.						
CAA Section 112 listings (TQ)	None						
CERCLA Reportable Quantity (RQ): RCRA D001/Unlisted Ignitable Hazardous Waste Ethyl Alcohol = 100 lbs.							
California Proposition 65	This product is not subject to warning labeling. State Right-To-Know The following ingredients are present in the finished product and are listed on the following state right-to-know lists:						
	<table><tr><td>Ingredient</td><td>CAS No.</td><td>Percent State</td></tr><tr><td>Ethyl Alcohol</td><td>64-17-5</td><td>MA, NJ, PA, RI, Canada.</td></tr></table> <p>This product is regulated as a Natural Health Product (NHP) under the Food and Drugs Act and complies with Health Canada regulations. All chemical components of this product are listed on DSL, NDSL, ICL or exempt.</p>	Ingredient	CAS No.	Percent State	Ethyl Alcohol	64-17-5	MA, NJ, PA, RI, Canada.
Ingredient	CAS No.	Percent State					
Ethyl Alcohol	64-17-5	MA, NJ, PA, RI, Canada.					
Europe EU Classification	Category 3 - Flammable liquid and vapor						
EU Risk Phrases	R10 - Flammable.						
EU Safety Phrases	S 6 Keep out of reach of children. Keep away from eyes.						
Green	Certified for Green Procurement.						
<ul style="list-style-type: none">* If swallowed, seek medical advice immediately and show this container or label.* Please dispose of empty container in a normal recycle bin.							

SECTION 16 – OTHER INFORMATION & CONTACT POINTS

Contact	<ul style="list-style-type: none"> Further information can be obtained from Elyptol Inc. www.elyptol.com
Reason for issue:	<ul style="list-style-type: none"> Elyptol Inc. products made in USA according to FDA TFM monogram for topical skin antiseptics
Issue Date:	<ul style="list-style-type: none"> 05/01/2015
Document Name:	<ul style="list-style-type: none"> SDS Elyptol Inc. Antimicrobial Hand Gel
Further Information:	<ul style="list-style-type: none"> Elyptol Inc. www.elyptol.com
Elyptol Gels	<ul style="list-style-type: none"> Have been dermatology tested and repeat skin patch tested, deemed as primary non skin irritant or sensitiser. Tested as a moisturiser and deemed to improve skin hydration. Microbiology efficacy studies of the Antimicrobial hand gel and hand rub conducted by AMS Laboratories in Sydney, Australia. Gel has 'passed' the EN 1500 hand rub study, and the TGA option D topical skin antiseptic study.
Information Only	<ul style="list-style-type: none"> This product is regulated as an Over-The-Counter (OTC) drug under the Federal Food, Drug, and Cosmetics Act and complies with FDA regulations. AMS Laboratories Pty Ltd are licensed for analysis and testing by the Australian Therapeutic Goods Administration (Licence No. MI-15112007-LI-002191-11), Australian Pesticides & Veterinary Medicines Authority (Licence No. 6139), and accredited by NATA to ISO 17025:2005 (Accreditation No: 15773)
Literature & References	<p>Australian Government - National Occupational Health and Safety Commission Web Site www.nohsc.gov.au National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011 (2003)] National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012 (1994)] Dermatest - Technical Consultancy Services Pty Ltd 20 King St Rockdale NSW 2216 Australia AMS Laboratories Pty Ltd - 8 Rachael Close Silverwater NSW 2128 Australia List of Designated Hazardous Substances [NOHSC:10005 (1999)] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004)] 3rd Edition Storage and Handling of Workplace Dangerous Goods [NOHSC:2017 (2001)]</p> <p>Australian Government – Department of Transport and Regional Services Web Site http://www.dotars.gov.au/index.htm http://www.dotars.gov.au/transreg/dgoods.htm</p> <p>ADG Code based on the 'UN Recommendations on the Transport of Dangerous Goods - Model Regulations' Australian Government – Attorney-General's Department ROAD TRANSPORT REFORM (DANGEROUS GOODS) ACT 1995 http://scaleplus.law.gov.au/html/pasteact/2/1187-top.htm</p> <p>NOHSC Online Hazardous Substances Information System http://hsis.ascc.gov.au/Default.aspx Australian Standards AS 1940-1993 The storage and handling of flammable and combustible liquids</p> <p>United Nations ADN 2005 (The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)</p>

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<http://www.unece.org/trans/danger/adrreg2005.html>

United Nations ADR 2005 (The European Agreement concerning the International Carriage of Dangerous Goods by Road)

http://www.unece.org/trans/danger/publi/adr/adr_c.html

UN Recommendations on the Transport of Dangerous Goods. Model Regulations. Thirteenth revised edition.

http://www.unece.org/trans/danger/publi/unrec/rev13/13files_c.html

Guidance Note on the Interpretation of Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:3008 (1995)] 3rd Edition (Updated for Amendments)

<http://www.nohsc.gov.au/OHSInformation/NOHSCPUBLICATIONS/fulltext/docs/h3/34.htm>

Australian Inventory of Chemical Substances

<http://www.nicnas.gov.au/obligations/aics/>

CSR Distilleries Operations Pty Ltd. Material Safety Data Sheet Ethanol 03/2005.

Legend ACGIH American Conference of Governmental Industrial Hygienists IMO International Maritime Organization GAA Clean Air Act N/A Not Applicable CAS Chemical Abstract Service NDSL Non-Domestic Substances List (Canada) CERCLA CERCLA Hazardous Substances N/E Not Established CFR Code of Federal Regulations NTP National Toxicology Program DOT Department of Transportation OSHA Occupational Safety & Health Administration DSL Domestic Substances List (Canada) PEL Permissible Exposure Limits EINECS European Inventory of Existing Chemical Substances RCRA Resource Conservation and Recovery Act Chemical Substances SARA Superfund Amendments and Reauthorizations Act EPA Environmental Protection Agency TLV Threshold Limit Values FDA Food and Drug Administration TQ Threshold Quantities HPA Hazardous Products Act (Canada) TWA Time Weighted Average IARC International Agency for Research on Cancer VOC Volatile Organic Compounds IATA International Air Transport Association WHMIS Workplace Hazardous Materials Information System.

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SDS formatted to Globally
Harmonized
System. Contact
Information

The information contained in this material safety data sheet was obtained from current and reliable sources. It is the user's responsibility to use the products as directed by the labelling. Please use as directed, in order to determine safe conditions for use of these products. The user will assume for loss, injury, damage or expense resulting from any improper use of these products. Products are flammable due to alcohol content and for external use only.