ALDAHOL ® 1.8 MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: Aldahol® 1.8 High Level Disinfectant

Manufactured by:
Alden Medical, LLC
360 Cold Spring Avenue
West Springfield MA, 01089, USA

Emergency Telephone: 800-441-8227

Licensed by:
DFB Technology, LTD.
3909 Hulen Street
Fort Worth, TX 76107
817.900.4050

Intended Use: High level disinfection and sterilization of heat-sensitive, semi-critical medical devices

Contact Person: DFB Technology, LTD.

2 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration*
Isopropyl Alcohol	67-63-0	< 23%
Antimicrobial activity additive	127-08-2	< 7%
Glutaraldehyde	111-30-8	< 4%

* All concentrations are percent by weight. *Also contains proprietary buffers.

3 HAZARDS IDENTIFICATION

Emergency Overview
Avoid ignition sources.
Use only in well ventilated areas.
May be harmful if swallowed. Irritating to skin eyes and respiratory tract.

Physical State: Liquid
Color: Unactivated solution is clear to light yellow, and activated solution is red.
Odor: Alcohol

Potential Health Effects

Inhalation: Inhalation of vapors may cause respiratory tract irritation. May cause allergic reaction/ sensitization.

Eye Contact: Vapor causes eye irritation and tearing. Solution contact causes corneal injury.

Skin Contact: May cause allergic skin reaction. Exposure may cause redness, itching and inflammation. May aggravate existing dermatitis. May cause temporary discoloration of the skin.

Ingestion: Harmful if swallowed. Ingestion may cause vomiting, nausea or diarrhea.

Chronic Health Effects: Exposure causes sensitization.

Target Organ(s): The manufacturer is unaware of any target organ toxicity.

4 FIRST AID MEASURES

Inhalation: Move to fresh air. If breathing stops, provide artificial respiration. For breathing difficulties, oxygen may be necessary. Seek medical attention immediately.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Seek medical attention immediately.

Skin Contact: Immediately flush with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes. Seek medical attention if irritation develops or persists.

Ingestion: Drink one or two glasses of milk if patient is alert and able to swallow. Seek immediate medical attention. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Note to Physician: Possible damage to the mucosa from oral exposure can contraindicate use of gastric lavage.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with foam, carbon dioxide, dry powder or water fog.

Unsuitable Extinguishing Media: Not applicable.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

Unusual Fire & Explosion Hazards: None known.

Hazardous Combustion Products: Carbon Oxides, Phosphorus Oxides

6 ACCIDENTAL RELEASE MEASURES

Personal Precautions: Wear protective clothing as described in section 8 of this safety data sheet when handling material during clean up.

Spill Cleanup Methods: Absorb in vermiculite, dry sand or earth and place into containers.

Environmental Precautions: Avoid discharge into drains, water courses or on the ground.

7 HANDLING AND STORAGE

1) Handling: Contain or exhaust the glutaraldehyde and isopropanol fumes. Use only in a well ventilated area. Avoid ignition sources. Avoid extremes of heat (greater than 120 F) and sources of ignition. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Wash at the end of each work shift and before eating, smoking and using the toilet. Observe good industrial hygiene practices.

Storage: Store under controlled temperature conditions 15-25° C. Store away from strong acids, bases and oxidizing agents.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Chemical Name	Source	Type	Exposure Limits	Notes
Glutaraldehyde	CA. Alberta OELs	Ceiling	0.05 ppm 0.2 mg/m³	
Glutaraldehyde	CA. British Columbia OELs	Ceiling	0.05 ppm	
Glutaraldehyde	CA. Ontario OELs	Ceiling	0.05 ppm	
Glutaraldehyde	MEX. OELs	Ceiling	0.2 ppm 0.7 mg/m³	
Glutaraldehyde	US. ACGIH TLV	Ceiling	0.05 ppm	
Isopropyl Alcohol	CA. Alberta OELs	STEL	500 ppm 1230 mg/m³	
Isopropyl Alcohol	CA. Alberta OELs	TWA	400 ppm 983 mg/m³	
Isopropyl Alcohol	CA. British Columbia OELs	TWA	200 ppm	
Isopropyl Alcohol	CA. British Columbia OELs	STEL	400 ppm	
Isopropyl Alcohol	CA. Quebec OELs	TWA	400 ppm 983 mg/m³	
Isopropyl Alcohol	CA. Quebec OELs	STEL	500 ppm 1230 mg/m³	
Isopropyl Alcohol	MEX. OELs	STEL	500 ppm 1225 mg/m³	
Isopropyl Alcohol	MEX. OELs	TWA	400 ppm 980 mg/m³	
Isopropyl Alcohol	US. ACGIH TLV	TWA	200 ppm	
Isopropyl Alcohol	US. ACGIH TLV	STEL	400 ppm	
Isopropyl Alcohol	US. NIOSH Guide	IDLH	2000 ppm	
Isopropyl Alcohol	US. OSHA Z-1 PEL	TWA	400 ppm 980 mg/m³	

Engineering Controls: Contain and/or exhaust the fumes. Provide ventilation sufficient for Class IC liquids. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors.

Respiratory Protection: If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 63 FR 1152, January 8, 1998. Respirator type: Air-purifying respirator with an appropriate,

government approved (where applicable), air-purifying filter, cartridge or canister. Contact health and safety professional or manufacturer for specific information.

Eye Protection: Wear approved safety goggles.

Hand Protection: Wear chemical-resistant gloves. Contact glove manufacturer for specific information. Butyl rubber gloves are recommended, but be aware that the liquid may penetrate the gloves. Frequent change is advisable.

Skin Protection: Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene Measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental Exposure Controls: Environmental manager must be informed of all major spillages.

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Unactivated solution is clear to light yellow, and activated solution is red.
Odor: Alcohol
Odor Threshold: No data available.
Physical State: Liquid
pH: 6.5 - 7.9
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: 79° C (174° F) ASTM D92, Cleveland Open Cup Test
Does not sustain combustion below 141° F (60.5° C)
Evaporation Rate: No data available.
Flammability Limit - Upper (%): No data available.
Flammability Limit - Lower (%): No data available.
Vapor Pressure: No data available.
Vapor Density (Air=1): No data available.
Specific Gravity: 1.01 (@ 20°C (68°F))
Solubility in Water: Completely Soluble
Solubility (Other): No data available.
Partition Coefficient (n-Octanol/water): No data available.
Autoignition Temperature: No data available.
Decomposition Temperature: No data available.
Viscosity: No data available.
Explosive Properties: No data available

10 STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Conditions to Avoid: Extremes of temperature. Direct sunlight. Ignition sources.

Incompatible Materials: Strong oxidizing agents, strong acids and bases.

Hazardous Decomposition Products: At Elevated Temperatures: None known

Possibility of Hazardous Reactions: None known.

11 TOXICOLOGICAL INFORMATION

Specified Substance(s)
Acute Toxicity:

Chemical Name	Test Results
Acetic acid	Dermal LD50 (Rabbit): 1060 mg/kg
Acetic acid	Oral LD50 (Rat): 3310 mg/kg
Glutaraldehyde	Dermal LD50 (Rabbit): 402 mg/kg
Glutaraldehyde	Inhalation LC50 (4 hour(s), Rat): 480 mg/m³
Glutaraldehyde	Intravenous LD50 (Rat): 140 mg/kg
Isopropyl Alcohol	Dermal LD50 (Rabbit): 12800 mg/kg
Isopropyl Alcohol	Inhalation LC50 (8 hour(s), Rat): 16000 ppm (v)
Isopropyl Alcohol	Oral LD50 (Rat): 5045 mg/kg

Carcinogenicity Classification

Chemical Name	IARC	NTP	OSHA	ACGIH
Glutaraldehyde	Not Listed	Not Listed	Not Listed	A4 = Not classifiable as a human carcinogen
Isopropyl Alcohol	Not Listed	Not Listed	Not Listed	A4 = Not classifiable as a human carcinogen

Aldahol® 1.8 High Level Disinfectant is not a carcinogen or suspected carcinogen.

Product Information
Acute Toxicity:
Test Results: No test data available for the product.

Other Acute: Causes skin and eye irritation. Causes respiratory tract irritation. Harmful if inhaled, or swallowed. May cause allergic respiratory and skin reactions.

Chronic Toxicity: May cause allergy. May cause hypersensitivity.

Mutagenic, Reproductive and Developmental Effects: Manufacturer is unaware of any evidence that the product is mutagenic or teratogenic. All customers should use an abundance of caution with glutaraldehyde based disinfectants.

12 ECOLOGICAL INFORMATION

Ecotoxicity: Glutaraldehyde is toxic to aquatic organisms.

Chemical Name	Test
Glutaraldehyde	LC50 (96 hour(s), Fish): <1 mg/l
Isopropyl Alcohol	LC50 (96 hour(s), Oryzia latipes): 9640 mg/l

Mobility: The product is water soluble and may spread in water systems.

Persistence and Degradability: Glutaraldehyde is biodegradable at low concentrations.

Bioaccumulation Potential: No data available on bioaccumulation.

Other Adverse Effects: No data available.

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of waste and residues in accordance with local authority requirements.

Disposal Methods: Disposal recommendations are based on material as supplied. Disposal must be in accordance with current applicable laws and regulations, and material characteristics at time of disposal. Confirm disposal procedures with environmental engineer and local regulations.

14 TRANSPORT INFORMATION

Consumer commodity may be transported as ORM-D. Transport in accordance with all applicable federal, state, and local regulations.

DOT: Class 3, PG III, UN 1993
Proper Shipping Name: Flammable liquid, n.o.s. (Isopropanol Solution)

TDG: Class 3, PG III, UN 1993
Proper Shipping Name: Flammable liquid, n.o.s. (Isopropanol Solution)

IATA: Class 3, PG III, UN 1993
Proper Shipping Name: Flammable liquid, n.o.s. (Isopropanol Solution)

IMDG: Class 3, PG III, UN 1993
Proper Shipping Name: Flammable liquid, n.o.s. (Isopropanol Solution)

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33.

Mexican Dangerous Statement: This product is dangerous according to Mexican regulations.

Inventory Status

This product or all components are listed or exempt from listing on the following inventory: DSL, TSCA

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4):

Chemical Name	RQ
Acetic acid	5000 lbs
Isopropyl Alcohol	100 lbs
Trisodium phosphate	5000 lbs

Section 311/312 (40 CFR 370):

☒ Acute (Immediate) ☒ Chronic (Delayed) ☒ Fire ☐Reactive ☐Pressure Generating

Section 313 Toxic Release Inventory (40 CFR 372):

Chemical Name	CAS-No.	Reporting threshold for other users	Reporting threshold for manufacturing and processing
Isopropyl Alcohol	67-63-0	10000 lbs	25000 lbs

For reporting purposes: the De Minimis Concentration for a toxic chemical in a mixture is 0.1% for carcinogens as defined in 29 CFR 1910.1200(d)(4) or 1% for others.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Acetic acid; Trisodium phosphate

State Regulations

16 OTHER INFORMATION

HAZARD RATINGS

OSHA Regulatory Status: This product is hazardous according to OSHA 29CFR 1910.1200.

Supercedes Date: 22-March-2013

Disclaimer: To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.