

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **ADATO Sil-OI-Silicone Oil**
Product Code • ES-5000S

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • ADATO SIL-OL 5000 is indicated for use as a prolonged retinal tamponade in selected cases of complicated retinal detachments where other interventions are not appropriate for patient management. Complicated retinal detachments or recurrent retinal detachments occur most commonly in eyes with proliferative vitreoretinopathy (PVR), proliferative diabetic retinopathy (PDR), cytomegalovirus (CMV), retinitis, giant tears, and following perforating injuries. ADATO SIL-OL 5000 is also indicated for primary use in detachments due to Acquired Immune Deficiency Syndrome (AIDS) related CMV retinitis and other viral infections.

Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
Telephone (General) • 1-800-553-5340

Emergency telephone number

Manufacturer • 1-800-535-5053

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Classification criteria not met

Label elements

UN GHS

Precautionary statements

Storage/Disposal • Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Other hazards

UN GHS • No data available

Section 3 - Composition/Information on Ingredients

Substances

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Silicone oil	CAS:63148-62-9	100%	UN GHS: Classification criteria not met

Mixtures

- Material does not meet the criteria of a mixture according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- No specific treatment is necessary since this material is not irritating to the eye.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.
- Emergency Procedures**
- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling**
- No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

- Engineering Measures/Controls**
- Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

- Respiratory**
- No respiratory protection required during normal handling.
- Eye/Face**
- No eye protection is required during normal handling.
- Hands**
- Gloves are not required under normal handling conditions.
- Skin/Body**
- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

- Environmental Exposure Controls**
- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Clear, oily liquid in single-use, preservative-free disposable syringe.
Color	Clear Colorless .	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	> 140 C(> 284 F)	Melting Point/Freezing Point	-55 C(-67 F)
Decomposition Temperature	> 200 C(> 392 F)	pH	Not relevant
Specific Gravity/Relative Density	= 0.913 @ 25 C(77 F) Water=1	Water Solubility	Slightly Soluble
Viscosity	5000 to 5900 Centipoise (cPs, cP) or mPas @ 25 C(77 F)		
Volatility			
Vapor Pressure	< 7 hPa @ 25 C(77 F)	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	316 C(600.8 F) CC (Closed Cup)	UEL	Not relevant
LEL	Not relevant	Autoignition	> 400 C(> 752 F)
Flammability (solid, gas)	Not relevant		
Environmental			
Half-Life	Not relevant	Octanol/Water Partition coefficient	No data available

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Silicone oil (100%)	63148-62-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • >24 g/kg; <i>Gastrointestinal:Hypermotility, diarrhea</i>

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met

Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Other

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Silicone oil	63148-62-9	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Silicone oil 63148-62-9 Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Silicone oil 63148-62-9 Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Silicone oil 63148-62-9 Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Silicone oil 63148-62-9 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Silicone oil 63148-62-9 Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Silicone oil

63148-62-9

Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Silicone oil

63148-62-9

Not Listed

Section 16 - Other Information**Last Revision Date**

- 08/July/2015

Preparation Date

- 08/July/2015

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