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	Version	1

MATERIAL SAFETY DATA SHEET

For lubricant gel without carbomer and paraben in sachets

1. Company and Product General Information

Family: Lubricant Gel

Products: Lubricant Gel without Carbomer and Parabens in Sachets 3 gr

54J805-3011-518-2

Supplier:

Sion Biotext Medical

5, Kopenhagen Str, 8714519 Sderot, Israel

Tel. 972-8-6898650

Fax 972-8-6898572

sales@sn-medical.com

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Australia Contact:

Medical Industries Australia

87 Mars Road, Lane Cove NSW 2066

Tel. (02) 9490 6200

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sales@medind.com.au

www.medind.com.au

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2. Composition/Information on Ingredients

Component	CAS NUMBER	Concentration %	Risk Phrase	Safety phrase
Water	7732-18-5	>50		
Hydroxyethylcellulose	9004-62-0	1...5	R61	S53
Glycerin	56-81-5	5...10		
Propylene Glycol	57-55-6	5...8		
Polysorbate 20	9005-64-5	0.1...1.0		S24/25; S37/39
Lactic Acid	50-21-5	<0.1	R37/38; R41	S26; S37/39
Sodium Hydroxide	1310-73-2	<0.1	R35	S 24/25; S26; S36/37/39; S45
Sodium Benzoate	532-32-1	0.1...1.0	R 36	S 26
Sodium EDTA	6381-92-6	0.1...1.0	R 36/38	S 26 S 37/39
Final product		100%	R36	S2,S16,S25,S26

The above ingredients are raw materials that undergo processing, dilution and filled into a three-layer (12 micron Polyethylene/7 micron Aluminum foil/60 micron Polyester) sachet. Upon completion of the manufacturing process the material does not possess the occupational health risks associated with the exposure to any of the ingredients above and the finished product.

3. Hazards Identification

Flash Point:	>200°F (93°C)
	Health: 1
	Flammability: 1
Hazard Rating (NFPA):	Reactivity: 0
	Specific: None

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HMIS Ratings

HMIS Code for Flammability – 1

HMIS Code for health -1

HMIS Code for Reactivity – 0

HMIS Code for Personal Protection – See Section 8

EU Main Hazards

Not flammable

Irritating to eyes

Routes of Entry

- Absorption – Eye contact – Ingestion – Inhalation – skin contact

Carcinogenic Status

Not considered carcinogenic by **NTP, IARAC** and **OSHA**.

Target Organs

- Skin – Eye – Respiratory system

Health Effects – Eyes

The Sterile Lubricating Gel rarely will cause conjunctival irritation and possibly corneal damage.

Health Effects – Skin

No effects on skin for prolong and short term use. The gel is for external and internal use. May rarely causes allergic reaction in sensitive individuals.

Health Effects – Ingestion

Swallowing may have the following effects:

- Irritation of mouth, throat and digestive tract

A large dose may have the following effects:

- Irritation of stomach and rarely vomiting. May produces mild laxative effect.

Health effects – Inhalation

Exposure to vapor may have the following effects:

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- Irritation of nose, throat and respiratory tract.

Exposure to vapor at high concentration may have the following effect:

- Headache.

4. First Aid Measures

Eyes: Immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open.

Obtain medical attention if soreness or redness persists.

Skin (for sensitive individuals): Immediately flood the skin with large quantities of water, preferably under shower. Remove contaminated clothing. Contaminated clothing should be washed or dry cleaned before re-use. Obtain medical attention if blistering occurs or redness persists.

Ingestion: Drink 1-3 glass of water to dilute stomach contents if necessary (in large amount of product) induce vomiting (consult medical attention).

Inhalation: Remove from exposure to fresh air. If there is difficulties in breathing give oxygen. Obtain medical attention immediately.

5. Fire Fighting Measures:

Extinguishing Media

Product is not flammable Use foam, dry chemical, sand or carbon dioxide, use media appropriate. Keep containers and surroundings cool with water spray.

Unusual Fire and Explosion Hazards


Cool endangered containers externally with water.

Hazard from combustion products

Combustion may produce toxic fumes.

Protective Equipment for Fire-Fighting

Do not inhale combustion gases. Wear full protective clothing and self-contained breathing apparatus.

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6. Accidental Release Measures

Clean area with (hot) water and detergent. Note that spillage will become slippery
 Avoid contact with hot products Contain and absorb using earth, sand or other inert material. Transfer into suitable containers for recovery or disposal. Wear appropriate protective clothing.

Environment Precaution: Do not allow spilled product to enter drains, surface water or ground water. Do not allow product to enter soil/ subsurface. Large spillages must be notified to appropriate authority

7. Handling and Storage

Special precautions are not necessary if use correctly. Keep in tinted close light protecting containers. Use in well ventilated area. Use local exhaust ventilation. Avoid inhaling vapour. Avoid contact with eyes and clothing. Store away from sources of heat or ignition. Storage area should be: - cool - dry - well ventilated - away from incompatible materials (strong oxidizing agents) and heat.

8. Exposure Controls/Personal Protection

Occupational Exposure Standards

There are no specific occupational exposure limits known for product or its ingredients

Engineering Control Measures

Good general room ventilation is expected to be adequate to control airborne levels.

Respiratory Protection

Not required under normal conditions and appropriate ventilation.

Hand Protection

Wear oil resistant gloves made from PVC or nitril.

Eye Protection

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Not required under normal conditions

Body Protection

Not required under normal conditions Wear Lab Coat if necessary.

Industrial Hygiene

Do not eat, drink, smoke or inhale during work.

9. **Physical and Chemical Properties:**

Product

Physical State	Gel
Color	Clear colorless
Odor	Odorless
pH	5.0...5.5
Boiling Range/Point (°C)	98.0 ... 102.0
Melting Point (°C)	-2.0 ... 2.0
Flash Point (PMCC)	N/A
Vapor Pressure	3.0...3.3
Relative vapor density(% , 1 atm=100%)	1.97...2.96
Density	1.01±0.05 gram/ml
Solubility in Water	Soluble
Viscosity (cPs at Brookfield, spindle 5 at 3.0 rpm, at 25°C)	28,000-34,000
Primary Packaging	
Maximal continued use temperature (°C)	65
Melting point (°C)	110

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10. Stability and Reactivity

Stability

Stable under normal conditions.

Conditions to Avoid

- Heat - High temperatures - Static discharge - Exposure to direct sunlight - Mechanical shock

Materials to Avoid

- Strong oxidizing agents

Hazardous Polymerization

Will not occur.

Hazardous Decomposition Products

- Oxides of carbon

11. Toxicological Information

Acute Toxicity

Skin: Rarely cause allergic reaction in sensitive individuals.

Eyes: Rarely cause allergic reaction in sensitive individuals.

Inhalation: No hazards under normal conditions of use.

Chronic Toxicity/Carcinogenicity

This product is not expected to cause long term adverse health effects.

This product is non carcinogenic.


When swallowed: there is no damage to health.

Genotoxicity

This product is not expected to cause any mutagenic effects.

Reproductive/Developmental Toxicity

This product is not expected to cause reproductive or developmental health effects.

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12. Ecological Information

Mobility

Product is soluble in water.

Persistence/Degradability

According to the test criteria of OECD the product is not readily biodegradable but inherently biodegradable.

Bio-accumulation

The product has no bio accumulation.

Ecotoxicity

Product is not expected to be harmful.

13. Disposal Considerations

Dispose of in accordance with all applicable local and national regulations. Labels should not be removed from containers until they have been cleaned. Do not cut, puncture or weld on or near to the container. Do not incinerate closed containers. Empty containers may contain hazardous residues. Dispose of containers with care.

14. Transport Information

DOT CFR 172.101 Data	Not Regulated per 49 CFR 173.4 Small Quantity Exemption
Proper Shipping Name	None
Class	None
UN Number	None
Packing Group	None
Classification for AIR	None
Transport(IATA):	

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15. Regulatory Information

EU Label Information

Classification and labelling have been performed according to EU directives 67/548/EEC and 99/45/EC including amendments.

EU Hazard Symbol and Indication of Danger

Xi - Irritant

R phrases

R36 - Irritating to eyes.

S phrases

S2 - Keep out of reach of children.

S16 - Keep away from sources of ignition - No smoking.

S25 - Avoid contact with eyes.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

US REGULATIONS(Federal, State) and INTERNATIONAL CHEMICAL REGISTRATION LAWS

TSCA Listing

This product contains ingredients that are listed on or exempt from listing on the EPA Toxic Substance Control Act Chemical Inventory.

EINECS Listing

All ingredients in this product are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) or are exempt from listing.


DSL (Canadian) Listing

All ingredients in this product are listed on the Domestic Substance List (DSL).

MA Right To Know Law

PA Right To Know Law

This product contains the following chemicals found on the Pennsylvania Hazardous Substance List

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NJ Right To Know Law

This product contains the following chemicals found on the NJ Right To Know Hazardous Substance List:

California Proposition 65

This product does not contain materials which the State of California has found to cause cancer, birth defects or other reproductive harm.

SARA Title III Sect. 302 (EHS)

This product does not contain any chemicals subject to SARA Title III Section 302.

SARA Title III Sect. 304

This product does not contain any chemicals subject to SARA Title III Section 304.

SARA Title III Sect. 311/312 Categorization

- Immediate (Acute) Health Hazard
- Delayed (Chronic) Health Hazard
- Flammable

SARA Title III Sect. 313

This product does not contain a chemical which is listed in Section 313 at or above the minimum concentrations.

16. Other Information

Abbreviations

- N/A: Denotes no applicable information found or available
- CAS#: Chemical Abstracts Service Number
- ACGIH: American Conference of Governmental Industrial Hygienists
- OSHA: Occupational Safety and Health Administration
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- STEL: Short Term Exposure Limit

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NTP: National Toxicology Program

IARC: International Agency for Research on Cancer

EU: European Union

R: Risk

S: Safety

17. Updates Tracking:

Version	Updated By	Section Updated	Date	Change Description
01	Holenberg Yulia		04/2017	Document format

Disclaimer:

The information furnished herein is believed to be accurate and represents the best data currently available to us. No warranty, expressed or implied, is made and Sion Biotext Medical Ltd. assumes no legal responsibility or liability resulting from its use.

This MSDS has been compiled in accordance with - EC Directive 91/155/EC - OSHA's Hazcom Standard (29 CFR 1910.1200).

Use product for intended purpose only, within its expiration date.