

 <p>Misgav-Am 12155, Upper Galilee, ISRAEL Tel. 972-4-6953116, Fax. 972-4-6953150, Email: sbmedical@sb-medical.com</p>	Document No. 03-MSDS-19
	Version: 2
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<b>Material Safety Data Sheet</b> <b>Sterile and Non Sterile</b> <b>Lubricating Jelly.</b>	Effective Date: April 2010

## **1. Product and Company Identification**

Product/Trade Name: Sterile and Non Sterile Lubricating Jelly Sachets/Tubes  
 Manufacturer's Name: Sion Biotext Medical Ltd.  
 Manufacturer's Address: Misgav-Am 12155, Mobile Post Upper Galilee. ISRAEL  
 Emergency or Information 00972-46953116 during normal working hours  
 Phone No.: At other times, contact the local Poison Control Centre  
 Chemical Name: Mixture

## **2. Composition/Information on Ingredients**

Component	CAS NUMBER	Concentration %	Risk Phrase	Safety phrase
Purified water	7732-18-5	<80%	R 36	S2,S16,S25,S26
Ultrez 10 (Carbomer)	195739-91-4	>1%		
Peg 400	25322-68-3	<5%		
Methylparaben	99-76-3	>1%		
Propylparaben	94-13-3	>1%		
Sodium Hydroxide	1310-73-2	>1%		

The above ingredients are raw materials that undergo processing, dilution and filled into a three layer sealed laminate / seven layers tube. 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 (>90°C)

Hazard Rating (NFPA):  
 Health: 1  
 Flammability: 1  
 Reactivity: 0  
 Specific: None

### **HMIS Ratings**

HMIS Code for Flammability – 1

HMIS Code for health -0

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, IARC 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 prolonged and short term use. The gel is for external and internal use. May rarely cause 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 produce mild laxative effect.

### **Health effects – Inhalation**

Exposure to vapor may have the following effects:

- 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:** Give victim 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.

#### **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**

Chemical goggles or safety glasses with side shields

### **Body Protection**

Wear oil resistant protecting clothing, overall or apron (if sensitive to the product or ingredients)

### **Industrial Hygiene**

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

## **9. Physical and Chemical Properties:**

<b>Physical State</b>	Gel
<b>Colour</b>	Clear colourless and odourless gel.
<b>Odour</b>	Odourless gel
<b>pH</b>	No data.
<b>Boiling Range/Point</b>	No data
<b>Melting Point (°C/F)</b>	No data

<b>Flash Point (PMCC)</b>	No data
<b>Vapour Pressure</b>	No data.
<b>Density</b>	1.01±0.05 gram/ml
<b>Solubility in Water</b>	Soluble
<b>Vapour Density (Air = 1)</b>	No data
<b>Viscosity (cSt)</b>	No data

## **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.

## **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**

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

## **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**

All components have been checked for inclusion on the Massachusetts Substance List (MSL). Those components present at or above the minimum concentration include

**PA Right To Know Law**

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

**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

NTP: National Toxicology Program

IARC: International Agency for Research on Cancer

EU: European Union

R: Risk

S: Safety

**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.