Safety Data Sheet

SECTION 1. Product and Company Identification

Product Identifiers:	**DynaLube – Sterile** Dynarex Reorder # 1250 1251 1252 1254
Other means of identification:	Sterile Lubricating Jelly
Recommended use of the chemical	A sterile lubricating jelly intended for medical purposes to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices. Reapply as desired. Contents sterile in un-opened, undamaged package.
And restrictions on use	Warning: If irritation or discomfort occurs, discontinue use and consult a physician. Keep out of eyes and ears. Keep out of reach of children.
Manufacturer Name:	Dynarex Corporation
Manufacturer's Address:	155 Chestnut Ridge Rd., Suite 2202 Montvale, NJ 07645
Emergency Phone No.:	Toll Free: 1-888-DYNAREX Phone: (845) 365-8200 At other times, contact the local Poison Control Center

SECTION 2. 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, 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 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 produces mild laxative effects.

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.

SECTION 3. 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.

SECTION 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 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 are difficulties in breathing, obtain medical attention immediately.

SECTION 5. Fire Fighting Measures

Extinguishing Media
Product is not flammable. Use foam, dry chemicals, sand or carbon dioxide, and use appropriate media. 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.

SECTION 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,

SECTION 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.

SECTION 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.

SECTION 9. Physical and Chemical Properties

Physical State	Gel
Colour	Clear colourless and odourless gel.
Odour	Odourless gel
pH	No data.
Boiling Range/Point	No data
Melting Point (°C/F)	No data
Flash Point (PMCC)	No data
Vapour Pressure	No data.
Density	1.01±0.05 gram/ml
Solubility in Water	Soluble
Vapour Density (Air = 1)	No data
Viscosity (cSt)	No data

SECTION 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

SECTION 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.

SECTION 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.

SECTION 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.

SECTION 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 Transport (IATA): None
The goods are not regulated for transport by IATA.

SECTION 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 Sodium Hydroxide.

PA Right to Know Law
This product does not contain any 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: Sodium Hydroxide.

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.

SECTION 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:

This Safety Data Sheet, which takes into consideration the requirements of Directive 76/768/EC and subsequent amendments and Directive 1999/45/EC plus subsequent amendments, has been prepared in accordance with Directive (EC) 1907/2006. It is believed to be correct and corresponds to the latest scientific/technical knowledge, but all data, instructions, recommendations and/or suggestions are made without guarantee. No warranty, expressed or implied, is made and Dynarex Corp. assumes no legal responsibility or liability resulting from its use.

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