

## 1 Identification

- **Product identifier**
- **Trade name: Oto-Ease®**
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Product description** Personal/professional (clinical) lubricant.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
HR® Pharmaceuticals, Inc.  
2651 Carnegie Road  
York, PA 17402-3706  
Phone: (717)-252-1110  
Fax: (717) 685-2590  
www.hrpharma.com.
- **Emergency telephone number:** (877) 302-0111

## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.
- **Label elements**
- **GHS label elements** Non-Regulated Material
- **Hazard pictograms** Non-Regulated Material
- **Signal word** Non-Regulated Material
- **Hazard statements** Non-Regulated Material
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Hazard(s) not otherwise classified (HNOC):** None known

## \* 3 Composition/information on ingredients

CAS: 7732-18-5 RTECS: ZC 0110000	water, distilled, conductivity or of similar purity	60-90%
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- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

### · **Dangerous Components:**

CAS: 57-55-6 RTECS: TY 2000000	Propylene Glycol		5-10%
CAS: 9004-65-3	Hydroxypropyl Methylcellulose	Combustible Dust	≤ 2.5%

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**Trade name: Oto-Ease<sup>®</sup>**

#### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Not a normal route of entry.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Flush eyes with plenty of 1% physiological saline solution. If no saline is available, flush with copious amounts of water.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

#### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**  
If involved in a fire, the packaging materials may produce poisonous gas.
- **Advice for firefighters**
- **Protective equipment:**  
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

#### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Product is slippery when spilled.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to section 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

#### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:**  
If involved in a fire, the packaging materials may produce poisonous gas.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

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## 8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see section 7.

· **Control parameters**

· **Components with occupational exposure limits:**

**57-55-6 Propylene Glycol**

WEEL Long-term value: 10 mg/m<sup>3</sup>

· **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures for handling chemicals should be followed.

· **Breathing equipment:** Not required.

· **Protection of hands:** Not required.

· **Material of gloves:** Not required.

· **Penetration time of glove material:** Not applicable.

· **Eye protection:**



Goggles recommended during refilling.

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Gel

**Color:** Translucent

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** 5.6-6.7

· **Change in condition**

**Melting point/Melting range:** Not determined.

**Boiling point/Boiling range:** Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:**

**Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

**Lower:** Not determined.

**Upper:** Not determined.

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- **Vapor pressure:** Not determined.
- **Density @ 20 °C (68 °F):** 1.01 g/cm<sup>3</sup> (8.428 lbs/gal)
- **Relative density** Not determined.
- **Vapor density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with Water:** Soluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - **Dynamic:** Not determined.
  - **Kinematic:** Not determined.
- **Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**  
If involved in a fire, the packaging materials may produce poisonous gas.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

#### 57-55-6 Propylene Glycol

Oral	LD50	20000 mg/kg (rat)
Dermal	LD50	20800 mg/kg (rabbit)
Inhalative	LC50/96 hours	52930 mg/l (Pimephales)
	Intravenous	6630 mg/kg (mouse)
		6423 mg/kg (rat)
		6500 mg/kg (rabbit)

- **Primary irritant effect:**
- **on the skin:** No irritating effect.
- **on the eye:** No irritating effect.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients are listed.

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**· NTP (National Toxicology Program)**

None of the ingredients are listed.

**· OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients are listed.

**12 Ecological information**
**· Toxicity**
**· Aquatic toxicity:**
**57-55-6 Propylene Glycol**

EC50 &gt;10000 mg/l (daphnia)

- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
- **Recommendation:** Small quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

- **UN-Number**
- **DOT, ADN, IMDG, IATA** Non-Regulated Material
- **ADR** Non-Regulated Material  
Not Regulated
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

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Trade name: **Oto-Ease®**
**15 Regulatory information**

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

- **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **California Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

- **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients are listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients are listed.

- **GHS label elements** Non-Regulated Material

- **Hazard pictograms** Non-Regulated Material

- **Signal word** Non-Regulated Material

- **Hazard statements** Non-Regulated Material

- **National regulations:**

The product is subject to be classified according with the latest version of the regulations on hazardous substances.

- **State Right to Know**

CAS: 7732-18-5 RTECS: ZC 0110000	water, distilled, conductivity or of similar purity		60-90%
CAS: 57-55-6 RTECS: TY 2000000	Propylene Glycol		5-10%
CAS: 9004-65-3	Hydroxypropyl Methylcellulose	Combustible Dust	<2.5%

All ingredients are listed.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**16 Other information**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not

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**Safety Data Sheet (SDS)**

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

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**Trade name: Oto-Ease<sup>®</sup>**

establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision** 05/28/2015 / 1

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

· **\* Data compared to the previous version altered.**

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