

**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>WITEPSOL® H-15</b>
<b>PRODUCT CODE</b>	<b>1699</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>USES</b>	Suppository base for pharmaceutical compounding.

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Based on available data, the classification criteria are not met.			
<b>PICTOGRAM</b>	Not Applicable			
<b>SIGNAL WORD</b>	Not applicable			
<b>HAZARD STATEMENT(S)</b>	Not applicable			
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not applicable			
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Not applicable		
	<b>Response</b>	Not applicable		
	<b>Storage</b>	Not applicable		
	<b>Disposal</b>	Not applicable		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>	0	<b>Flammability</b>	1
	<b>Reactivity</b>	0	<b>Personal Protection</b>	A

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

CHEMICAL NAME	Not applicable			
BOTANICAL NAME	Not applicable			
SYNONYM	Not applicable			
CHEMICAL FORMULA	Not applicable			
CAS NUMBER	Not applicable			
ALTERNATE CAS NUMBER	Not applicable			
MOLECULAR WEIGHT	Not applicable			
COMPOSITION	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
	Not applicable	Not applicable	Not applicable	Not applicable

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES** A mixture of Saturated Polyglycolysed Glycerides (C12-18)

## SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Not expected to be a skin hazard under normal use. Wash with soap and water if irritation occurs. Seek medical attention if irritation develops and persists.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Not expected to be a hazard under anticipated conditions of normal use. Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
<b>SYMPTOMS AND EFFECTS</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b>	Not applicable
<b>FLAMMABLE PROPERTIES</b>	May be combustible at high temperature
<b>HAZARDOUS COMBUSTION PRODUCTS</b>	Under fire conditions, hazardous fumes will be present.
<b>SUITABLE &amp; UNSUITABLE EXTINGUISHING MEDIA</b>	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
<b>PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS</b>	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>PERSONAL PRECAUTIONS</b>	Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
<b>METHODS &amp; MATERIAL FOR CONTAINMENT</b>	On land, sweep or shovel into suitable containers.

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**CLEANUP PROCEDURE**

Shut off all sources of ignition. Evacuate the area. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**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.

## SECTION 7: HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 5° and 30°C (41° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range. Due to melting point 33-35°C (91.4-95°F) product may become liquid. To preserve its consistency, ship with ice packs or at controlled room temperatures.

**SPECIFIC END USE(S)**

See Section 1

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: Not applicable CAS #: Not applicable

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Not needed for normal use. Operate according to good working practices.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>PHYSICAL STATE</b>	Solid				
<b>DESCRIPTION</b>	White to off-white pellets, almost odorless and greasy to the touch.				
<b>SOLUBILITY</b>	Practically insoluble in water; slightly soluble in anhydrous ethanol.				
<b>ODOR</b>	Almost odorless				
<b>FLAMMABILITY</b>	May be combustible at high temperature				
<b>AUTO-IGNITION TEMPERATURE</b>	Not self-igniting	<b>BOILING POINT</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not explosive	<b>FLASH POINT</b>	>200°C, >392°F
<b>log P (OCTANOL-WATER)</b>	Not available	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(33.5-35.5)°C, (92.3-95.9)°F
<b>ODOR THRESHOLD</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	Not available
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

**SECTION 10: STABILITY AND REACTIVITY**

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established

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**CONDITIONS TO AVOID**

Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

**ACUTE TOXICITY**

GLYCERIDES, C12-18:  
 Oral: Rat: LD50: (mg/kg): > 2000  
 Dermal: Rat LD50: (mg/kg): > 2000  
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**

Based on available data, the classification criteria are not met.  
 Skin irritation test (rabbit) : no irritation

**SERIOUS EYE DAMAGE/EYE IRRITATION**

Based on available data, the classification criteria are not met.

**RESPIRATORY SENSITIZATION**

Based on available data, the classification criteria are not met.  
 No sensitization species: guinea pig OECD 406 (Buehler Test)

**SKIN SENSITIZATION**

Based on available data, the classification criteria are not met.

**GERM CELL MUTAGENICITY**

Due to lack of data the classification is not possible.

**CARCINOGENICITY**

**OSHA** No component of this product, present at ≥0.1%, is listed.  
**NTP** No component of this product, present at ≥0.1%, is listed.  
**IARC** No component of this product, present at ≥0.1% has been evaluated.  
**California Proposition 65** No component of this product, present at ≥0.1% is known to the State of California to cause cancer, birth defects, or any other reproductive harm: .

**ADDITIONAL CARCINOGENICITY INFORMATION**

Based on available data, the classification criteria are not met.

**REPRODUCTIVE TOXICITY**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS**

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** Not expected to be harmful if inhaled. May cause irritation to mucous membranes and respiratory tract.  
**Ingestion** May be harmful if swallowed.  
**Skin** Not expected to be harmful under normal use.  
**Eyes** May cause eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

**TOXICITY**

EC50: 48 Hr: Crustacea: (mg/L): Not available  
 LC50: 96 Hr: Fish: (mg/L): Not available  
 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Not available

**BIOACCUMULATIVE POTENTIAL**

Not available

**MOBILITY IN SOIL**

Practically insoluble in water

**OTHER ADVERSE EFFECTS**

Not available

This product is not intended to be released into the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**
**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**AUSTRALIA**
**HAZCHEM**

Not Applicable

**EU**
**TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE**

Not listed

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING INFORMATION**

Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
Not applicable	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
Not applicable	N/L	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	EC 649/2012	EC 2012/118
Not applicable	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SECTION 16: OTHER INFORMATION****REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

**LAST REVISION**

02/2021

**SUPERSEDES**

02/2018

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.