

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	HRT GEL BASE (Men)
PRODUCT CODE	2257
SUPPLIER	MEDISCA Inc. 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 MEDISCA Pharmaceutique Inc. 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 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Topical compounding vehicle for hormones

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.			
PICTOGRAM	Not Applicable			
SIGNAL WORD	Not applicable			
HAZARD STATEMENT(S)	Not applicable			
AUSTRALIA-ONLY HAZARDS	Not applicable			
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable		
	Response	Not applicable		
	Storage	Not applicable		
	Disposal	Not applicable		
HMS CLASSIFICATION	Health Hazard	0	Flammability	0
	Reactivity	0	Personal Protection	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	% BY WEIGHT
ETHANOL (SD alcohol)	64-17-5	*Proprietary
GLYCERIN	56-81-5	*Proprietary
PROPYLENE GLYCOL	57-55-6	*Proprietary
SODIUM HYDROXIDE	1310-73-2	*Proprietary

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 translucent carbomer-based silicone-in-water gel with quick-drying and vanishing properties.

*Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Not expected to be a hazard under anticipated conditions of normal use. Wash with soap and water if irritation occurs. Seek medical attention if irritation develops and persists.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

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.

SYMPTOMS AND EFFECTS

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

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers.

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.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Avoid contact with eyes. 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 unlabelled 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 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours. Keep in well-closed containers at controlled room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: ETHANOL (SD alcohol) CAS #: 64-17-5

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	1000 ppm (1900 mg/m ³)	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	1000 ppm (1900 mg/m ³)	N/L	N/L	1000 ppm (1900 mg/m ³)	3300 ppm 10%LEL (See: 64175)	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	1000 ppm (1880 mg/m ³)	N/L	N/L	-	-	-
HSE	1000 ppm (1920 mg/m ³)	N/L	N/L	-	-	-

Chemical Name: GLYCERIN CAS #: 56-81-5

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	15 mg/m ³ (total); 5 mg/m ³ (resp)	N/L	-	-	-	total dust
ACGIH TLV	10 mg/m ³	N/L	N/L	-	-	mist
NIOSH	15 mg/m ³ (total); 5 mg/m ³ (resp)	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	10 mg/m ³	N/L	N/L	-	-	-

YOUR TRUSTED PARTNER IN COMPOUNDING

Chemical Name: PROPYLENE GLYCOL CAS #: 57-55-6

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	10 mg/m ³	N/L	N/L	-	-	-
Safe Work Australia HSIS	10 mg/m ³	N/L	N/L	-	-	-
HSE	10 mg/m ³	N/L	N/L	-	-	-

Chemical Name: SODIUM HYDROXIDE CAS #: 1310-73-2

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	2 mg/m ³	2 mg/m ³	-	-	-	-
ACGIH TLV	N/L	2 mg/m ³	N/L	-	-	-
NIOSH	2 mg/m ³	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	2 mg/m ³	N/L	N/L	-	-	-
HSE	N/L	N/L	2 mg/m ³	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Not needed for normal use. Operate according to good working practices. **Skin:** No special precaution must be adopted for normal use. Operate according to good working practices. **Clothing:** Not needed for normal use. Operate according to good working practices. **Respirators:** Not needed for normal use. Operate according to good working practices.

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Viscous translucent gel, with faint odor.

SOLUBILITY

Very slightly soluble in cold water.

ODOR

Faint odor

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD

Not available

pH

4.0-8.0

MELTING POINT

Not available

BOILING POINT

Not available

FREEZING POINT

Not available

FLASH POINT

Not available

SPECIFIC GRAVITY

0.9 - 1.030

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)

Not available

LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)

Not available

VAPOR PRESSURE

Not available

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VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	Not available
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	110 000 - 140 000 cps

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions.
MATERIALS TO AVOID	Strong oxidants.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.
HAZARDOUS POLYMERIZATION	Will not occur.
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): Not available Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Phenoxyethanol, SD Alcohol and Sodium hydroxide that may cause irritation.
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Phenoxyethanol, SD Alcohol and Sodium hydroxide, Polydimethylsiloxane and Potassium sorbate that may cause irritation.
RESPIRATORY OR SKIN SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Based on available data, the classification criteria are not met. Contains soy based Lecithin that may cause an allergic reaction.
GERM CELL MUTAGENICITY CARCINOGENICITY	Due to lack of data the classification is not possible.
OSHA	ETHANOL is listed. No other component of this product, present at $\geq 0.1\%$, is listed.
NTP	ETHANOL is listed. No other component of this product, present at $\geq 0.1\%$, is listed.
IARC	ETHANOL is listed in group 1 (carcinogenic to humans). CARBOMER (Polyacrylic acid) is listed in group 3 (not classifiable as to its carcinogenicity to humans). No other component of this product, present at $\geq 0.1\%$ has been evaluated.
California Proposition 65	This product contains the following chemical known to the State of California to cause cancer and birth defects or other reproductive harm: ETHANOL No other component of this product, present at $\geq 0.1\%$ is known to the State of California to cause cancer, birth defects, or any other reproductive harm.
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	Due to lack of data the classification is not possible.

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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	<table border="0"> <tr> <td>Inhalation</td> <td>Not expected to present a significant hazard under anticipated conditions of normal use.</td> </tr> <tr> <td>Ingestion</td> <td>May be harmful if swallowed.</td> </tr> <tr> <td>Skin</td> <td>Not expected to present a significant hazard under anticipated conditions of normal use. May cause skin irritation. May cause an allergic reaction.</td> </tr> <tr> <td>Eyes</td> <td>May cause serious eye irritation.</td> </tr> </table>	Inhalation	Not expected to present a significant hazard under anticipated conditions of normal use.	Ingestion	May be harmful if swallowed.	Skin	Not expected to present a significant hazard under anticipated conditions of normal use. May cause skin irritation. May cause an allergic reaction.	Eyes	May cause serious eye irritation.
Inhalation	Not expected to present a significant hazard under anticipated conditions of normal use.								
Ingestion	May be harmful if swallowed.								
Skin	Not expected to present a significant hazard under anticipated conditions of normal use. May cause skin irritation. May cause an allergic reaction.								
Eyes	May cause serious eye irritation.								

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	<p>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</p>
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Very slightly soluble in cold water.
OTHER ADVERSE EFFECTS	<p>Not available</p> <p>This product is not intended to be released into the environment</p>

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

<u>UNITED STATES & CANADA</u>	
UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
<u>AUSTRALIA</u>	
UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	Not Applicable

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Right-to-know			California Prop 65
			Appendix A	Appendix B	Pennsylvania	New Jersey	Massachusetts	
PROPYLENE GLYCOL, 57-55-6	N/L	N/L	N/L	N/L	X	X	N/L	N/L
SODIUM HYDROXIDE, 1310-73-2	X	N/L	N/L	N/L	X	X	X	N/L
ETHANOL (SD alcohol), 64-17-5	N/L	N/L	N/L	N/L	X	X	X	X
GLYCERIN, 56-81-5	N/L	N/L	N/L	N/L	X	X	X	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
PROPYLENE GLYCOL, 57-55-6	N/L	N/L	N/L
SODIUM HYDROXIDE, 1310-73-2	N/L	Listed as Schedule 7	Listed as Category III
ETHANOL (SD alcohol), 64-17-5	N/L	N/L	Listed as Category III
GLYCERIN, 56-81-5	N/L	N/L	N/L

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

03/2019

SUPERSEDES

04/2017

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.