

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	HRT GEL BASE
PRODUCT CODE	2257
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 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 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

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		
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable		
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable	
	Response	Not applicable	
	Storage	Not applicable	
	Disposal	Not applicable	
HMIS CLASSIFICATION	Health Hazard	0	Flam
	Reactivity	0	Pers

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME
 BOTANICAL NAME
 SYNONYM
 CHEMICAL FORMULA
 CHEMICAL FAMILY
 CAS NUMBER
 ALTERNATE CAS NUMBER
 MOLECULAR WEIGHT
 COMPOSITION

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
Mixture	Not applicable	Not applicable	*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.

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

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.

SUITABLE & UNSUITABLE 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.

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.

Store at controlled room temperature. 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.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: Mixture CAS #: Not applicable

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
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/m³

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.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

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

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

Not available

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

4.0-8.0

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

0.9 - 1.030

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

VAPOR DENSITY (AIR = 1)

Not available

VAPOR PRESSURE

Not available

VISCOSITY

110 000 - 140 000 cps

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions.
INCOMPATIBLE MATERIALS	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.
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Contains Phenoxyethanol, SD Alcohol and Sodium hydroxide, Polydimethylsiloxane and Potassium sorbate that may cause irritation.
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	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA ETHANOL is listed. No other component of this product, present at $\geq 0.1\%$, is listed.</p> <p>NTP ETHANOL is listed. No other component of this product, present at $\geq 0.1\%$, is listed.</p> <p>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.</p> <p>California Proposition 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.</p>
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.
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN
TOXICITY - REPEATED
EXPOSURE
ASPIRATION HAZARDS
SIGNS AND SYMPTOMS OF
EXPOSURE**

Due to lack of data the classification is not possible.

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

ROUTES OF EXPOSURE:

Dermal

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

POTENTIAL HEALTH EFFECTS

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

ECOTOXICITY

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

Very slightly soluble in cold water.

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

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	EPA 40 CFR Part 355 Appendix A	Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
Mixture Not applicable	N/L	N/L	N/L	N/L	X	X	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
Mixture Not applicable	N/L	Listed as Schedule 5	N/L	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	PIC - Prior Informed Consent Regulation	EC 2012/18
Mixture 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.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

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

02/2023

SUPERSEDES

03/2019

For a list of changes to the SDS since the last version, please communicate with MEDISCA at 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.