

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME ORAL SYRUP™ (Flavored Vehicle)

PRODUCT CODE 2511

SUPPLIER MEDISCA Inc.

Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 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

National Chemical Emergency Centre 44(0)1235239670

RECOMMENDED USES Manufacturing and Compounding

RESTRICTIONS ON USE

SECTION 2: HAZARDS IDENTIFICATION

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

Not applicable

PICTOGRAM Not Applicable
SIGNAL WORD Not applicable

HAZARD STATEMENT(S)

May be harmful if swallowed in large quantities.

May cause eye irritation.

ADVERSE PHYSIOCHEMICAL, HUMAN

HEALTH AND ENVIRONMENTAL

EFFECTS

PRECAUTIONARY STATEMENT(S) Prevention Not applicable

Response Not applicable
Storage Not applicable
Disposal Not applicable

HMIS 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

CHEMICAL FAMILY

CAS NUMBER Not applicable
ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT Not applicable

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
GLYCERIN	56-81-5	200-289-5	*Proprietary
SUCROSE	57-50-1	57-50-1	*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 *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 Not expected to be a hazard under anticipated conditions of normal use. Call a physician. Wash out mouth with

water. Do not induce vomiting without medical advice.

IF INHALEDNot 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

This product is an aqueous mixture which will not burn.

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Water spray, CO₂, dry chemical, or foam.

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

REFERENCE TO OTHER SECTIONS

CONTAINMENT

CLEANUP PROCEDURE

On land, sweep or shovel into suitable containers.

Shut off all sources of ignition. Evacuate the area. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Avoid raising dust. 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. Vertilate and clean the affected area. Do not flush into sowerage system or to drains

disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

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: GLYCERIN CAS #: 56-81-5

	Country	Country Limit value-8 hours		Limit value	Limit value-Short Term		REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
OSHA	USA	N/L	15(1) 5(2)	N/L	N/L	N/L	N/L	N/A	(1)Inhalable dust
	\								(2)Respirable dust
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	10(1)	N/L	N/L	N/L	N/L	N/A	(1) This value is for inhalable
									dust containing no asbestos
									and < 1% crystalline silica.
HSE	UK	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Belgium	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Ontario	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Quebec	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Finland	N/L	20	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	France	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A



GESTIS	Germany-AGS	N/L	200(1)	N/L	400(1)(2)	N/L	N/L	N/A	(1) Inhalable fraction (2) 15
									minutes average value
GESTIS	Germany-DFG	N/L	200(1)	N/L	400(1)(2)	N/L	N/L	N/A	(1) Inhalable fraction (2) 15
									minutes average value
GESTIS	Ireland	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Poland	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Singapore	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Switzerland	N/L	50(1)	N/L	100(1)	N/L	N/L	N/A	(1) Inhalable aerosol

Chemical Name: SUCROSE CAS #: 57-50-1

	Country	Limit value-8 hours		Limit valu	Limit value-Short Term		REL	Advisory	Notes
		ppm	mg/m³	ppm	mg/m³				
OSHA	USA	N/L	15(1) 5(2)	N/L	N/L	N/L	N/L	N/A	(1)Inhalable aerosol
									(2)Respirable aerosol
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	10(1) 5(2)	N/L	N/L	N/L	N/L	N/A	(1)Total dust (2) Respirable
									fraction
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) This value is for inhalable
									dust containing no asbestos
									and < 1% crystalline silica.
HSE	UK	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Belgium	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Ontario	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Quebec	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	France	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Ireland	N/L	10	N/L	20(1)	N/L	N/L	N/A	(1) 15 minutes reference
									period
GESTIS	New Zealand	N/L	10(1)	N/L	N/L	N/L	N/L	N/A	(1) The value for inhalable
									dust containing no asbestos
									and less than 1% free silica.
GESTIS	Singapore	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	10	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

Last Revision: 04/2021

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

DESCRIPTION Clear to slightly tinted, cherry flavored liquid.

SOLUBILITY Freely miscible in water.

ODOR Sweet fruity odor

FLAMMABILITY This product is an aqueous mixture which will not burn.

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	рН	4.0-5.0 (25.0°C)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.2250-1.2450 (25.0°C)	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY	Not available	VAPOR PRESSURE	Not available	VISCOSITY	100-350cPs

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

(AIR = 1)

PRODUCTS

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

(25.0°C)



HAZARDOUS POLYMERIZATION

POSSIBLITY OF HAZARDOUS

REACTION

CONDITIONS TO AVOID

Will not occur

Not established

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/IRRITATIONDue to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE

IRRITATION

RESPIRATORY SENSITIZATION

Due to lack of data the classification is not possible.

Due to lack of data the classification is not possible.

SKIN SENSITIZATIONDue to lack of data the classification is not possible.

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 No component of this product, present at ≥0.1% is known to the State of California to cause

Proposition 65 cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY

INFORMATION

Due to lack of data the classification is not possible.

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY -

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

REPRODUCTIVE TOXICITY

SIGNS AND SYMPTOMS OF

EXPOSURE

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

ROUTES OF EXPOSURE:

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

DELAYED HEALTH EFFECT FROM EXPOSURE:

POTENTIAL HEALTH EFFECTS Inhalation Not expected to present a significant hazard under anticipated conditions of normal use.

Ingestion May be harmful if swallowed in large quantities. May cause abdominal pain, swelling and

mild diarrhea.

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

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cause skin irritation.

Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION



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 Freely miscible in water.

OTHER ADVERSE EFFECTS Not expected to be a hazard under anticipated conditions of normal use.

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

<u>AUSTRALIA</u>

HAZCHEM Not Applicable

<u>EU</u>

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE

ANNEX II OF MARPOL 13/16 AND THE

IBC CODE

Not Listed

ENVIRONMENTAL HAZARDS
SPECIAL SHIPPING INFORMATION

Not available 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		Right-to-know Pennsylvania New Jersey Massachusetts			California Prop 65
SUCROSE, 57-50-1	N/L	N/L	N/L	N/L	X	N/L	X	N/L
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

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Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
SUCROSE, 57-50-1	N/L	N/L	N/L	N/L	N/L	N/L
GLYCERIN 56-81-5	N/L	N/L	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
SUCROSE, 57-50-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L
GLYCERIN 56-81-5	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 - Instituto 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

04/2021

SUPERSEDES

04/2019

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.