

#### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME ORA SWEET SF® (Sugar-Free Oral Syrup Vehicle)

PRODUCT CODE 2343

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 Not applicable

#### **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) Not applicable

ADVERSE PHYSIOCHEMICAL, HUMAN

HEALTH AND ENVIRONMENTAL

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**EFFECTS** 

PRECAUTIONARY STATEMENT(S) Prevention Not applicable

Response Not applicable

Storage Not applicable

Disposal Not applicable

HMIS CLASSIFICATION Health Hazard 1 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 Not applicable

CAS NUMBER Not applicable

ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT Not applicable

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
GLYCERIN	56-81-5	200-289-5	*Proprietary
SACCHARIN SODIUM	128-44-9	204-886-1	*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.

\*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

ade 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 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

COMPOSITION

**NOTES** 

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

Get emergency medical help.

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

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Water spray, CO<sub>2</sub>, 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

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. 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. 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.

If the product gets frozen by accident or during shipment, let it thaw to room temperature or use a warm water

bath for faster results.

#### **SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

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

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	Country	Limit valu	Limit value-8 hours		hours 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	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	Germany (AGS)	N/L	200(1)	400(1)(2)	N/L	N/L	N/L	N/A	(1) Inhalable fraction (2) 15 minutes average value	
GESTIS	Germany (DFG)	N/L	200(1)	400(1)(2)	N/L	N/L	N/L	N/A	(1) Inhalable fraction (2) 15 minutes average value	
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	N/L	100	N/L	N/L	N/A	Inhalable aerosol	

Chemical Name: SACCHARIN SODIUM CAS #: 128-44-9

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

raction: 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. Not available

BIOLOGICAL MONITORING
CONTROL BANDING

Not available

NOTES

METHYLPARABEN: Perrigo OEL: 500 microgram/m³

#### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

PHYSICAL STATE

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Liquid



**DESCRIPTION** Clear, syrupy liquid with a sweet fruity odor

**SOLUBILITY** Freely miscible with 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 - 4.4					
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.053 - 1.075	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available					
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available					

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

PRODUCTS
HAZARDOUS POLYMERIZATION Wi

HAZARDOUS POLYMERIZATION Will not occur
POSSIBLITY OF HAZARDOUS Not established

REACTION

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 Due to lack of data the classification is not possible.

SERIOUS EYE DAMAGE/EYE

Due to lack of data the classification is not possible.

IRRITATION

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RESPIRATORY SENSITIZATION Due to lack of data the classification is not possible.

SKIN SENSITIZATION Due to lack of data the classification is not possible.

**GERM CELL MUTAGENICITY** Due to lack of data the classification is not possible.

CARCINOGENICITY **OSHA** Based on the compositional information available from the supplier, no component of this

product is listed.

NTP Based on the compositional information available from the supplier, no component of this

product is listed.

**IARC** Based on the compositional information available from the supplier, no component of this

California Based on the compositional information available from the supplier, no component of this

**Proposition 65** product is listed.

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 -Due to lack of data the classification is not possible.

SINGLE EXPOSURE

SPECIFIC TARGET ORGAN TOXICITY -

REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

SIGNS AND SYMPTOMS OF

**EXPOSURE** 

ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

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

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Long-term usage may cause possible hypersensitization in susceptible individuals.

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

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 In its final form, this product is not expected to be a skin hazard.

Eyes May cause 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** 

OTHER ADVERSE EFFECTS

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Freely miscible with water. MOBILITY IN SOIL

Not available This product is not intended to be released into the environment

Not available



### **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

<u>EU</u>

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 CF Appendix A	FR Part 355 Appendix B	Pennsylvania	California Prop 65		
GLYCERIN, 56-81-5	N/L	N/L	N/L	N/L	X	X	X	N/L
SACCHARIN SODIUM	N/L	N/L	N/L	N/L	X	N/L	X	N/L
128-44-9								

N/L = Not Listed; X = Listed

### **AUSTRALIAN REGULATIONS**

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	
GLYCERIN, 56-81-5	N/L	N/L	N/L	N/L	N/L	N/L	ĺ
SACCHARIN SODIUM	N/L	N/L	N/L	N/L	N/L	N/L	
128-44-9							

N/L = Not Listed

#### **EU REGULATIONS**

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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
GLYCERIN, 56-81-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L
SACCHARIN SODIUM 128-44-9	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

Not applicable

AGREEMENT

### **SECTION 16: OTHER INFORMATION**

**REFERENCES** 

ABBREVIATIONS AND ACRONYMS

Available upon request

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 SUPERSEDES 11/2023

01/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at <a href="https://www.medisca.com">www.medisca.com</a>

**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

Last Revision: 11/2023

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