

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

PRODUCT NAME ORAL SYRUP™ SF (Sugar-Free Flavored Syrup Vehicle)

PRODUCT CODE 2599

SUPPLIER MEDISCA Inc.

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MEDISCA Pharmaceutique Inc.

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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)

May be harmful if swallowed in large quantities.

May cause eye irritation.

ADVERSE PHYSIOCHEMICAL, HUMAN

HEALTH AND ENVIRONMENTAL

**EFFECTS** 

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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 Not applicable

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
SACCHARIN SODIUM	6155-57-3	612-173-5	*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 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.

spray. Do not get water inside containers.

#### **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 and carbon oxides will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

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Small fire: dry chemical, CO2 or water spray. Large fire: dry chemical, CO2, alcohol resistant foam or water

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

**CLEANUP PROCEDURE** 

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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.

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 (Not applicable) CAS #: Not applicable

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

PHYSICAL STATE

(AIR = 1)

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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

Liquid

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

**DESCRIPTION** Clear to slightly hazy, cherry flavored liquid. SOLUBILITY Freely miscible in water. **ODOR** Sweet fruity odor **FLAMMABILITY** This product is an aqueous mixture which will not burn. **BOILING POINT** Not available DECOMPOSITION Not available **AUTO-IGNITION** Not available **TEMPERATURE TEMPERATURE EVAPORATION RATE** Not available EXPLOSIVE LIMIT Not available Not available **FLASH POINT** Not available LOWER FLAMMABLE/ Not available MELTING/FREEZING Not available (OCTANOL-WATER) EXPLOSIVE LIMIT(S) **POINT PARTICLE** Not available OXIDIZING PROPERTY Not available pΗ 4.0-5.0 (25.0°C) **CHARACTERISTICS** RELATIVE DENSITY Not available SPECIFIC GRAVITY 1.0300 - 1.0650 UPPER FLAMMABLE/ Not available (WATER = 1) (25.0°C) EXPLOSIVE LIMIT(S) Not available 250 - 450 cPs VAPOR DENSITY Not available VAPOR PRESSURE VISCOSITY

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

#### **SECTION 10: STABILITY AND REACTIVITY**

(25.0°C)



REACTIVITY Not established

Stable under recommended storage conditions. CHEMICAL STABILITY

**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.

POSSIBLITY OF HAZARDOUS

REACTION

CONDITIONS TO AVOID Moisture, sunlight and extreme temperatures.

Not established

#### 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

**IRRITATION** 

Due to lack of data the classification is not possible.

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** No component of this product, present at ≥0.1%, is listed.

> NTP No component of this product, present at ≥0.1%, is listed.

**IARC** SACCHARIN SODIUM is listed in group 3 (not classifiable as to its carcinogenicity to

humans).

No other 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.

REPRODUCTIVE TOXICITY Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY -

SINGLE EXPOSURE

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Due to lack of data the classification is not possible.

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY -

REPEATED EXPOSURE

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

SIGNS AND SYMPTOMS OF

**EXPOSURE** 

**ROUTES OF EXPOSURE:** Oral

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Inhalation POTENTIAL HEALTH EFFECTS 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

cause skin irritation.

**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 Not available

MOBILITY IN SOIL Freely miscible in 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

<u>AUSTRALIA</u>

HAZCHEM Not Applicable

<u>EU</u>

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

Not Listed

IBC CODE

ENVIRONMENTAL HAZARDS Not available SPECIAL SHIPPING INFORMATION Not applicable

#### **SECTION 15: REGULATORY INFORMATION**

**UNITED STATES REGULATIONS** 

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Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	California Prop 65		
SACCHARIN SODIUM,	N/L	N/L	N/L	N/L	X	N/L	X	N/L
6155-57-3								
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	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
Ī	SACCHARIN SODIUM,	N/L	N/L	N/L	N/L	N/L	N/L
L	6155-57-3						
	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
SACCHARIN SODIUM, 6155-57-3	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**

ABBREVIATIONS AND ACRONYMS

#### Available upon request

01/2023

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

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SUPERSEDES 04/2021



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

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