

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 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 | 1 | 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 |
|------------------|------------|-----------|--------------|
| 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.

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.

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 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

| | 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 | 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/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 | 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 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

NOTES

METHYLPARABEN: Perrigo OEL: 500 microgram/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | | | | |
|-------------------------------------|---|---|---------------|---|---------------|
| PHYSICAL STATE | 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 | pH | 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 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

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 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 product is listed.

California Proposition Based on the compositional information available from the supplier, no component of this product is listed.

Due to lack of data the classification is not possible.

ADDITIONAL CARCINOGENICITY INFORMATION
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

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
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

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

Not available

MOBILITY IN SOIL

Freely miscible with 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 | EPA 40 CFR Part 355 Appendix B | Pennsylvania | Right-to-know New Jersey | Massachusetts | California Prop 65 |
|---------------------------|--------------------------|-------------------------|--------------------------------|--------------------------------|--------------|--------------------------|---------------|--------------------|
| GLYCERIN, 56-81-5 | N/L | N/L | N/L | N/L | X | X | X | N/L |
| SACCHARIN SODIUM 128-44-9 | N/L | N/L | N/L | N/L | X | N/L | 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 | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|------------------------------|-------------------------------|-----------------------|----------------------------------|------------------|------------------------------------|-----------------------------------|
| GLYCERIN, 56-81-5 | 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 = 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 |
|------------------------------|------------------|-----------------|--------------|-------------|--------------|---|------------|
| 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 AGREEMENT

Not applicable

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** – 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

11/2023

SUPERSEDES

01/2023

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.