



Sterile Sucrose 24% Solution

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 0

Chemwatch: 26-8231

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Safety Data Sheet according to WHS and ADG requirements

S.GHS.AUS.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

| | |
|-------------------------------|------------------------------|
| Product name | Sterile Sucrose 24% Solution |
| Synonyms | Not Available |
| Other means of identification | Not Available |

Relevant identified uses of the substance or mixture and uses advised against

| | |
|--------------------------|--|
| Relevant identified uses | Sterile Sucrose 24% Solution is intended for administration in infants below the age of three months during minor surgical procedures. |
|--------------------------|--|

Details of the supplier of the safety data sheet

| | |
|-------------------------|---|
| Registered company name | Phebra |
| Address | 19 Orion Road Lane Cove West NSW 2066 Australia |
| Telephone | +61 2 9420 9199 1800 720 020 |
| Fax | +61 2 9420 9177 |
| Website | www.phebra.com |
| Email | info@phebra.com |

Emergency telephone number

| | |
|-----------------------------------|-----------------|
| Association / Organisation | Not Available |
| Emergency telephone numbers | +61 401 264 004 |
| Other emergency telephone numbers | N/A |

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

| | |
|------------------|----------------|
| Poisons Schedule | Not Applicable |
| Classification | Not Applicable |

Label elements

| | |
|---------------------|----------------|
| Hazard pictogram(s) | Not Applicable |
|---------------------|----------------|

SIGNAL WORD **NOT APPLICABLE**

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Substances

See section below for composition of Mixtures

Continued...

Mixtures

| CAS No | %[weight] | Name |
|-----------|-----------|----------------|
| 57-50-1 | 24 | <u>Sucrose</u> |
| 7732-18-5 | 76 | <u>water</u> |

SECTION 4 FIRST AID MEASURES**Description of first aid measures**

| | |
|---------------------|--|
| Eye Contact | <p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin Contact | <p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation. |
| Inhalation | <ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary. |
| Ingestion | <ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES**Extinguishing media**

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- ▶ foam.
- ▶ dry chemical powder.
- ▶ carbon dioxide.

Special hazards arising from the substrate or mixture

| | |
|-----------------------------|-------------|
| Fire Incompatibility | None known. |
|-----------------------------|-------------|

Advice for firefighters

| | |
|------------------------------|---|
| Fire Fighting | <ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use. |
| Fire/Explosion Hazard | <ul style="list-style-type: none"> ▶ The material is not readily combustible under normal conditions. ▶ However, it will break down under fire conditions and the organic component may burn. ▶ Not considered to be a significant fire risk. ▶ Heat may cause expansion or decomposition with violent rupture of containers. ▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). ▶ May emit acrid smoke. <p>Decomposes on heating and produces toxic fumes of:</p> <ul style="list-style-type: none"> · carbon dioxide (CO₂) · other pyrolysis products typical of burning organic material. |
| HAZCHEM | Not Applicable |

SECTION 6 ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

| | |
|---------------------|---|
| Minor Spills | <ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. |
|---------------------|---|

| | |
|---------------------|--|
| | <ul style="list-style-type: none"> ▶ Place in a suitable, labelled container for waste disposal. |
| Major Spills | <p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment as required. ▶ Prevent spillage from entering drains or water ways. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. |

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

| | |
|--------------------------|---|
| Safe handling | <ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. |
| Other information | <ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers. ▶ Protect containers against physical damage and check regularly for leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. |

Conditions for safe storage, including any incompatibilities

| | |
|--------------------------------|--|
| Suitable container | <ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks. ▶ Glass container is suitable for laboratory quantities |
| Storage incompatibility | Avoid contamination of water, foodstuffs, feed or seed. None known |

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA


| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|------------------------------|------------|---------------|----------------------|---------------|---------------|---------------|
| Australia Exposure Standards | Sucrose | Sucrose | 10 mg/m ³ | Not Available | Not Available | Not Available |

EMERGENCY LIMITS

| Ingredient | Material name | TEEL-1 | TEEL-2 | TEEL-3 |
|------------------------------|---------------|---------------|---------------|---------------|
| Sterile Sucrose 24% Solution | Not Available | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|------------|---------------|---------------|
| Sucrose | Not Available | Not Available |
| water | Not Available | Not Available |

Exposure controls

| | |
|---|---|
| Appropriate engineering controls | <p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions.</p> |
| Personal protection |  |
| Eye and face protection | <ul style="list-style-type: none"> ▶ Safety glasses with side shields ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment |

Sterile Sucrose 24% Solution

| | |
|------------------------------|---|
| | <ul style="list-style-type: none"> ▶ should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent] |
| Skin protection | See Hand protection below |
| Hands/feet protection | Wear general protective gloves, eg. light weight rubber gloves. Suitability and durability of glove type is dependent on usage. |
| Body protection | See Other protection below |
| Other protection | No special equipment needed when handling small quantities. OTHERWISE: <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit. |

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

Sterile Sucrose 24% Solution

| Material | CPI |
|----------------|-----|
| BUTYL | C |
| NATURAL RUBBER | C |
| NEOPRENE | C |
| PVA | C |
| VITON | C |

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| | | | |
|---|--|--|----------------|
| Appearance | Sterile Sucrose 24% Solution is a clear, colourless to yellow solution; mixes with water. Sterile Sucrose 24% Solution is an aqueous solution. | | |
| Physical state | Liquid | Relative density (Water = 1) | 1.10 |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | 6-8 | Decomposition temperature | Not Available |
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | Not Available | Molecular weight (g/mol) | Not Applicable |
| Flash point (°C) | Not Available | Taste | Not Available |
| Evaporation rate | Not Available | Explosive properties | Not Available |
| Flammability | Not Available | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | Not Available | Surface Tension (dyn/cm or mN/m) | Not Available |
| Lower Explosive Limit (%) | Not Available | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | Not Available | Gas group | Not Available |
| Solubility in water (g/L) | Miscible | pH as a solution (1%) | Not Available |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |

SECTION 10 STABILITY AND REACTIVITY

| | |
|---|---|
| Reactivity | See section 7 |
| Chemical stability | Product is considered stable and hazardous polymerisation will not occur. |
| Possibility of hazardous reactions | See section 7 |
| Conditions to avoid | See section 7 |
| Incompatible materials | See section 7 |

Hazardous decomposition products

See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

| | |
|--------------|---|
| Inhaled | The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product |
| Ingestion | The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. |
| Skin Contact | The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. |
| Eye | Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn). |
| Chronic | Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. |

| | | |
|------------------------------|---|---------------|
| Sterile Sucrose 24% Solution | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| Sucrose | TOXICITY | IRRITATION |
| | Oral (rat) LD50: 29700 mg/kg ^[2] | Not Available |
| water | TOXICITY | IRRITATION |
| | Not Available | Not Available |

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

| | |
|--------------------------------------|--|
| SUCROSE | Oral (Human) TDLo: 9.6E-5 mg/kg |
| Sterile Sucrose 24% Solution & WATER | No significant acute toxicological data identified in literature search. |

| | | | |
|-----------------------------------|---|--------------------------|---|
| Acute Toxicity | ☉ | Carcinogenicity | ☉ |
| Skin Irritation/Corrosion | ☉ | Reproductivity | ☉ |
| Serious Eye Damage/Irritation | ☉ | STOT - Single Exposure | ☉ |
| Respiratory or Skin sensitisation | ☉ | STOT - Repeated Exposure | ☉ |
| Mutagenicity | ☉ | Aspiration Hazard | ☉ |

Legend: ✘ – Data available but does not fill the criteria for classification
✔ – Data available to make classification
☉ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

| | ENDPOINT | TEST DURATION (HR) | SPECIES | VALUE | SOURCE |
|------------------------------|---------------|--------------------|---------------|---------------|---------------|
| Sterile Sucrose 24% Solution | Not Available | Not Available | Not Available | Not Available | Not Available |
| | | | | | |
| Sucrose | Not Available | Not Available | Not Available | Not Available | Not Available |
| | | | | | |
| water | Not Available | Not Available | Not Available | Not Available | Not Available |
| | | | | | |

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|-------------------------|------------------|
| Sucrose | LOW | LOW |
| water | LOW | LOW |

Continued...

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|------------|----------------------|
| Sucrose | LOW (LogKOW = -3.7) |
| water | LOW (LogKOW = -1.38) |

Mobility in soil

| Ingredient | Mobility |
|------------|------------------|
| Sucrose | LOW (KOC = 10) |
| water | LOW (KOC = 14.3) |

SECTION 13 DISPOSAL CONSIDERATIONS**Waste treatment methods**

| | |
|-------------------------------------|--|
| Product / Packaging disposal | <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. |
|-------------------------------------|--|

SECTION 14 TRANSPORT INFORMATION**Labels Required**

| | |
|-------------------------|----------------|
| Marine Pollutant | NO |
| HAZCHEM | Not Applicable |

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION**Safety, health and environmental regulations / legislation specific for the substance or mixture****SUCROSE(57-50-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

WATER(7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

| National Inventory | Status |
|-------------------------------|--------------------|
| Australia - AICS | Y |
| Canada - DSL | Y |
| Canada - NDSL | N (Sucrose; water) |
| China - IECSC | Y |
| Europe - EINEC / ELINCS / NLP | Y |
| Japan - ENCS | N (Sucrose) |
| Korea - KECI | Y |
| New Zealand - NZIoC | Y |
| Philippines - PICCS | Y |
| USA - TSCA | Y |

Legend:

Y = All ingredients are on the inventory

N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

| | |
|----------------------|---------------|
| Revision Date | 27/06/2017 |
| Initial Date | Not Available |

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL: No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

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