# SAFETY DATA SHEET

Version: 5
Supersedes the SDS dated: Oct-29-2019

## Section 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product Identifier

**Product Name:** Medisense Brand Glucose & Ketone Control Solutions HI / MID / LO

**Synonyms:** Solartek Glucose & Ketone Control Solution

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

**Recommended use:** Reagent

### 1.3 Details of the supplier of the safety data sheet

**Supplier:** Abbott Diabetes Care Ltd
Range Road, Witney
Oxfordshire, OX29 0YL
UK

**E-mail Address:** Abbott.SDS@abbott.com

### 1.4 Emergency telephone number

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)
Ireland: +353-19014670 ; United Kingdom: + 44-870-8200418

## Section 2. Hazards identification

### 2.1 Classification of the substance or mixture

**Regulation (EC) No 1272/2008**

| | |
|---|---|
| **Skin corrosion/irritation** | Category 2 |
| **Serious eye damage/eye irritation** | Category 2 |

**None**

### 2.2 Label elements

**Product Name:** **Medisense Brand Glucose & Ketone Control Solutions HI / MID / LO**
**Issued:** **Oct-16-2020**

**Signal Word:** Warning

**Hazard Statements:**
H315 - Causes skin irritation
H319 - Causes serious eye irritation

**Precautionary Statements**
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

| Chemical Name | Percent | EINECS/ELINCS Number | EU - GHS Substance Classification | REACH No. |
|---|---|---|---|---|
| Compound 6 | na | Present | Not Hazardous* | No data available |
| Compound 1 | na | NA | Not Hazardous* | No data available |
| Compound 2 | na | Present | Not Hazardous* | No data available |
| Compound 3 | na | Present | Not Hazardous* | No data available |
| Sodium Hydroxide 1310-73-2 | 0-1 | Present | Skin Corr. 1A (H314)> 5%<br>Skin Corr. 1B (H314) 2% = C < 5%<br>Skin Irrit. 2 (H315)0,5% = C < 2%<br>Eye Irrit. 2 (H319)0,5% = C < 2% | No data available |
| Compound 4 | na | Present | Not Hazardous* | No data available |
| Compound 5 | na | Present | Not Hazardous* | No data available |

| | | | | |
|---|---|---|---|---|
| Proclin 300 55965-84-9 | 0-0.1 | NA | Acute Tox. 3 (H301)<br>Acute Tox. 3 (H311)<br>Acute Tox. 3 (H331)<br>Skin Corr. 1B (H314)<br>Skin Sens. 1 (H317)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 1 (H410) | No data available |

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the H-Statements mentioned in this Section, see Section 16**

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

### 4.2 Most important symptoms and effects, both acute and delayed

**Signs and Symptoms:** Available information support the following: vomiting, nausea.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Notes To Physician:** Treat symptomatically

## Section 5. Firefighting measures

### 5.1 Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

### 5.2 Special hazards arising from the substance or mixture

**Special Exposure Hazards:** Not determined

### 5.3 Advice for firefighters

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

## Section 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** For personal protection see section 8.

### 6.2. Environmental precautions

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

### 6.3. Methods and material for containment and cleaning up

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

### 6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

## Section 7. Handling and storage

### 7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wash thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions. Store in original container.

### 7.3. Specific end use(s)

**Recommended use:** Reagent

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

**Exposure limits:**

| Chemical Name | Employee Exposure Limit | Skin Notation |
|---|---|---|
| Compound 6 | Not Applicable | None |
| Compound 1 | Not Applicable | None |
| Compound 2 | Not Applicable | None |
| Compound 3 | Not Applicable | None |
| Sodium Hydroxide 1310-73-2 | Not Applicable | None |
| Compound 4 | Not Applicable | None |

| | | |
|---|---|---|
| Compound 5 | Not Applicable | None |
| Proclin 300 55965-84-9 | Not Applicable | None |

| Chemical Name | ACGIH TLV | France | German MAK | Ireland | Italy |
|---|---|---|---|---|---|
| Compound 1 | 10 mg/m³ for nuisance dust; 3 mg/m³ respirable particulate | | | | |
| Sodium Hydroxide 1310-73-2 | 2 mg/m³ Ceiling | TWA: 2 mg/m³ | | 2 mg/m³ (STEL) | |

| Chemical Name | The Netherlands | Spain | Switzerland | UK OEL/MEL |
|---|---|---|---|---|
| Sodium Hydroxide 1310-73-2 | | 2 mg/m³ (STEL) | 2 mg/m³ (TWA)<br>2 mg/m³ (STEL) | 2 mg/m³ (STEL) |

### 8.2. Exposure controls

**Engineering Controls:** No special provisions are required under normal product use conditions.

**Respiratory Protection:** Respiratory protection is not needed during normal product use.

**Eyes:** Wear eye protection appropriate to exposures when handling the product formulation.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Do not allow material to contaminate ground water system

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Appearance:** Clear/Colorless Liquid
**Odor:** Odorless.
**Odor Threshold:** Not determined
**pH:** Neutral
**Boiling Pt. @ 760 mm Hg (°C):** Not determined.
**Melting/Freezing Point (°C):** Not determined
**Flash Point (°C):** Not determined.
**Evaporation Rate at 20°C:** Not determined.
**Flammability (Solid):** Not determined.
**Lower Explosive Limit:** Not determined.
**Upper Explosive Limit:** Not determined.
**Vapor Pressure (mm Hg):** Not determined.
**Vapor Density (Air = 1):** Not determined.
**Specific Gravity:** Not determined.
**Solubility(ies):** Highly soluble in: water.
**Partition coefficient: n-octanol/water** Not determined.
**Autoignition Temp. (°C):** Not determined.
**Decomposition temperature (°C):** Not determined.

**Explosion Severity:** Not determined.
**Oxidizer Properties:** Not determined.

### 9.2. Other information

Not determined

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

### 10.4. Conditions to avoid

Heat, flames and sparks

### 10.5 Incompatible materials

Strong bases, Water-reactive materials

### 10.6 Hazardous decompostion products

May emit toxic fumes under fire conditions, Carbon monoxide (CO), Carbon dioxide ($CO_2$)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

**Routes of Exposure:**

**Oral:** Yes
**Dermal:** Yes
**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

| Chemical Name | Acute Test | Value | Units | Species |
|---|---|---|---|---|
| Compound 1 | LD50 > | 40,000 | mg/kg | Rats Mice |
| Compound 3 | LD50 = | 3550 | mg/kg | Rats |
| Sodium Hydroxide 1310-73-2 | LD50 = | 325 | mg/kg | Rats |
| Compound 4 | LD50 >= | 8000<br>25800 | mg/kg | Dogs<br>Rats |
| Proclin 300 55965-84-9 | LD50 =<br>LD50 = | 60<br>53 | mg/kg | Mice<br>Rats |

**Acute Toxicity - Dermal:** Data for component (s) given below.

| Chemical Name | Acute Test | Value | Units | Species |
|---|---|---|---|---|
| Compound 3 | LD50 > | 10,000 | mg/kg | Rabbits |

**Acute Toxicity - Inhalation:** Data for component (s) given below.

| Chemical Name | Test | Value | Units | Species |
|---|---|---|---|---|
| Compound 3 | LC 50 > | 42 | mg/L | Rats |

| Chemical Name | Test Type | Value | Units | Species | Comments |
|---|---|---|---|---|---|
| Compound 4 | LD50 (iv) =<br>LD50 (ip) = | 9000<br>18,000 | mg/kg | Mice | None. |

**Corrosivity:** A minor component was found to be corrosive to skin.

**Dermal Irritation:** A minor ingredient is a skin irritant.

**Eye Irritation:** A minor ingredient is an eye irritant.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Data for component (s) given below.

| Chemical Name | Micronucleus Assay | Ames Test: | Mouse Lymphoma Assay | Chromosomal Abbr. Assay |
|---|---|---|---|---|
| Compound 3 | No Data. | Negative | Negative without activation | No Data. |

**Aspiration hazard:** Not determined

**Notes:**
**1. ALD: Approximate lethal dosage**
**2. LC50: Concentration in air that produces 50% mortality**
**3. LD50: Oral or dermal dosage that produces 50% mortality**

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

| Chemical Name | Percent | LC 50 (mg/l)/NOEC | Species | Duration |
|---|---|---|---|---|
| Compound 3 | na | 1295 | Fathead Minnow | 96 Hours |

| Chemical Name | Percent | 48h EC50 (mg/l) | Species | Duration |
|---|---|---|---|---|
| Compound 3 | na | 1661 | Daphnia magna | 48 Hours |
| Sodium Hydroxide 1310-73-2 | 0-1 | 40 | Daphnia | 48 Hours |

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**
1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## Section 14. Transport information

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

**14.1. UN Number:** Not applicable
**14.2. Proper shipping name:** Not applicable
**14.3. Hazard class:** Not applicable
**14.4. Packing group:** Not applicable
**14.5. Environmental hazard:** Not applicable
**14.6. Special Provisions:** Not applicable
**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

# Section 15. Regulatory Information

## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### International Inventories

| Chemical Name | EINECS/ ELINCS | TSCA | DSL | NDSL | PICCS |
|---|---|---|---|---|---|
| Compound 6 | Present | X | X | Not listed. | X |
| Compound 1 | - | X | X | Not listed. | X |
| Compound 2 | Present | X | X | Not listed. | X |
| Compound 3 | Present | X | X | Not listed. | X |
| Sodium Hydroxide 1310-73-2 | Present | X | X | Not listed. | X |
| Compound 4 | Present | X | X | Not listed. | X |
| Compound 5 | Present | - | - | Not listed. | - |
| Proclin 300 55965-84-9 | - | - | X | Not listed. | X |

| Chemical Name | ENCS | ISHL | IECSC | AICS | KECL | New Zealand |
|---|---|---|---|---|---|---|
| Compound 6 | - | - | X | X | Present | |
| Compound 1 | Present | - | X | X | Present | |
| Compound 2 | Present | Present | X | X | - | |
| Compound 3 | Present | - | X | X | Present | HSR002722 |
| Sodium Hydroxide 1310-73-2 | Present | - | X | X | Present | HSR001547 |
| Compound 4 | Present | - | X | X | Present | |
| Compound 5 | - | - | - | X | Present | |
| Proclin 300 55965-84-9 | Present | - | X | - | Present | |

### Legend

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**ENCS** - Japan Existing and New Chemical Substances
**ISHL** - Japan Industrial Safety and Health Law
**IECSC** - China Inventory of Existing Chemical Substances
**AICS** - Australian Inventory of Chemical Substances
**KECL** - Korean Existing and Evaluated Chemical Substances

### Carcinogenicity Rating:

| Chemical Name | Percent | NTP: | IARC: | ACGIH: |
|---|---|---|---|---|
| Compound 6 | na | Not Listed | Not Listed | Not Listed |
| Compound 1 | na | Not Listed | Not Listed | Not Listed |
| Compound 2 | na | Not Listed | Not Listed | Not Listed |
| Compound 3 | na | Not Listed | Not Listed | Not Listed |
| Sodium Hydroxide 1310-73-2 | 0-1 | Not Listed | Not Listed | Not Listed |
| Compound 4 | na | Not Listed | Not Listed | Not Listed |
| Compound 5 | na | Not Listed | Not Listed | Not Listed |
| Proclin 300 55965-84-9 | 0-0.1 | Not Listed | Not Listed | Not Listed |

**SARA 313 Information**

| Chemical Name | Percent | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|---|---|---|---|---|
| Compound 6 | na | No | Not Applicable | Not applicable |
| Compound 1 | na | No | Not Applicable | Not applicable |
| Compound 2 | na | No | Not Applicable | Not applicable |
| Compound 3 | na | No | Not Applicable | Not applicable |
| Sodium Hydroxide 1310-73-2 | 0-1 | No | 1000 lb<br>454 kg | Not applicable |
| Compound 4 | na | No | Not Applicable | Not applicable |
| Compound 5 | na | No | Not Applicable | Not applicable |
| Proclin 300 55965-84-9 | 0-0.1 | No | Not Applicable | Not applicable |

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

### 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

## Section 16. Other information

**Full text of H-Statements referred to under sections 2 and 3**
H314 - Causes severe skin burns and eye damage
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H311 - Toxic in contact with skin
H331 - Toxic if inhaled
H301 - Toxic if swallowed
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
H317 - May cause an allergic skin reaction

**Document Authored By:** Global Occupational Toxicology

**Issued:** Oct-16-2020

**Supersedes the SDS dated:** Oct-29-2019

| Component | Reason for Revision |
|---|---|
| Compound 5 ( na ) | (M)SDS sections updated 1 |

**Product Name:** **Medisense Brand Glucose & Ketone Control Solutions HI / MID / LO**
**Issued:** **Oct-16-2020**

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