

Product Name:
Issued:

Medisense Brand Glucose & Ketone Control Solutions HI / MID / LO
Oct-28-2016



SAFETY DATA SHEET

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
1360 South Loop Road
Alameda, CA 94502

Manufactured by:
Bionostics Inc.
7 Jackson Road
Devens, MA 01434-4026
USA

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)

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 Category 2

irritation

None

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2 Label elements

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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 | EEC Classification | 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% Skin Corr. 1B (H314) 2% = C < 5% Skin Irrit. 2 (H315)0,5% = C < 2% 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 |

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| | | | | | |
|------------------------|-------|----|--|--|-------------------|
| Proclin 300 55965-84-9 | 0-0.1 | NA | | Acute Tox. 3 (H311) Acute Tox. 3 (H331) Acute Tox. 3 (H301) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) Skin Corr. 1B (H314) Skin Sens. 1 (H317) | 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 R-phrases mentioned in this Section, see Section 16
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

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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.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

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 |

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| | | |
|----------------------------|----------------|------|
| 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/m ³ for nuisance dust; 3 mg/m ³ respirable particulate | | | | |
| Sodium Hydroxide 1310-73-2 | | TWA: 2 mg/m ³ | | 2 mg/m ³ (STEL) | |

| Chemical Name | The Netherlands | Spain | Switzerland | UK OEL/MEL |
|----------------------------|-----------------|----------------------------|---|----------------------------|
| Sodium Hydroxide 1310-73-2 | | 2 mg/m ³ (STEL) | 2 mg/m ³ (TWA) 2 mg/m ³ (STEL) | 2 mg/m ³ (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: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Not determined
Odor: Not determined.
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.

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Partition coefficient: Not determined.
n-octanol/water

Autoignition Temp. (°C): Not determined.
Decomposition temperature Not determined.
(°C):

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

Not determined.

10.5 Incompatible materials

Strong bases, Water-reactive materials

10.6 Hazardous decomposition products

May emit toxic fumes under fire conditions, Carbon monoxide (CO), Carbon dioxide (CO₂)

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 |

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| | | | | |
|------------------------|------------------|---------------|-------|--------------|
| Compound 4 | LD50 >= | 8000 25800 | mg/kg | Dogs Rats |
| Proclin 300 55965-84-9 | LD50 = LD50 = | 60 53 | mg/kg | Mice 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) = LD50 (ip) = | 9000 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

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Not determined.

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

| Chemical Name | Percent | 48h EC50 (daphnia - mg/l) (48HLCD) | 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

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14.6. Special Provisions: Not applicable

14.7. Transport in bulk Not applicable

**according to Annex II of
 MARPOL 73/78 and the IBC**

Code:

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:

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| 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 | Not Applicable | 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.

WHMIS Hazard Class: Not determined.

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

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Supersedes the SDS dated: Aug-19-2008 Page 10 of 11

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| Custom Config Fields | |
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Synonyms:

Solartek Glucose & Ketone Control Solution