

Glucose Control Solutions

Version 1.0

Issue Date 03/17/2017

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

1.1 Product Identifier

Trade Name

CONTOUR®NEXT control solutions (Level 1 and Level 2);
CONTOUR® control solutions (Normal, Low or High);
Breeze®2 normal control

Synonyms:

Glucose Control Solutions

SDS Date

March 17, 2017

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use:

In Vitro diagnostic reagent

Uses Advised Against:

All other uses

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer:

Ascensia Diabetes Care US, Inc.
5 Wood Hollow Rd
Parsippany, NJ 07054 USA
Tel: +1 973 560 6500

1.4 Emergency Telephone Number: Call Chemtrec (800) 424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

GHS Classification: Not a hazardous substance / mixture according to GHS.

2.2 Label Elements: None.

2.3 Other Hazards: None known.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

SECTION 4. FIRST-AID MEASURES

4.1 Description of First Aid Measures

General advice: Call a physician immediately. Arrange for transport to nearest emergency room.

If inhaled: Not an expected entry route.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. Take off contaminated clothing and shoes immediately. Wash contaminated clothing before re-use.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: Clean mouth with water and drink afterwards plenty of water. Take victim immediately to hospital.

Contact Number: Use the Ascensia Emergency Number in Section 1.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Suitable (or unsuitable) Extinguishing Media: Use any extinguisher that is suitable for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture This product is not flammable but will burn in a fire. Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO₂).

5.3 Advice for Fire-Fighters: In the event of fire, wear self-contained breathing apparatus.

5.4 Further information: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures: Use personal protective equipment.

6.2 Environmental Precautions: Avoid release to the environment.

6.3 Methods and Material for Containment and Cleaning Up: Cover spilt product with liquid-binding

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material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labelled, closable containers

6.4 Reference to Other Sections: Refer to Section 8 for personal protective equipment, and Section 13 for disposal information.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling: Avoid contact with skin, eyes and clothing. No special protective measures against fire required.

7.2 Conditions for Safe Storage, Including any Incompatibilities: Store at temperatures and conditions as indicated on the product label.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Exposure Controls:

Recommended Monitoring Procedures: None.

Appropriate Engineering Controls: Not required.

8.2 Personal Protective Measures

Eye/Face Protection: Safety glasses with side-shields.

Skin Protection: Not required.

Hands: Chemically resistant gloves.

Respiratory Protection: Not required.

Other protection: Please consult label for end-user requirements.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic Physical and Chemical Properties

Appearance: Red liquid	Odor: None
Odor Threshold: Not applicable	pH: Not applicable
Melting/Freezing Point: Not applicable	Boiling Point: Not applicable
Flash Point: Not applicable	Evaporation Rate: Not applicable
Lower Flammability Limit: Not applicable	Vapor Pressure: Not applicable

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Upper Flammability Limit: Not applicable	
Vapor Density(Air=1): Not applicable	Relative Density: 1.065
Solubility: Insoluble in water	Octanol/Water Partition Coefficient: Not applicable
Autoignition Temperature: Not established	Decomposition Temperature: Not established
Viscosity: Not applicable	Explosive Properties: None

Oxidizing Properties: None	Specific Gravity (H₂O= 1): Not established
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9.2 Other Information: None known.

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: The enclosed instructions for use should be consulted prior to use.

10.5 Incompatible Materials: Incompatible with strong oxidizing agents.

10.6 Hazardous Decomposition Products: Carbon dioxide, carbon monoxide.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

According to our experience and information the product has no harmful effects on health if properly handled.

Eye Contact: Slight irritation.

Skin contact: May cause skin irritation in susceptible persons.

Inhalation: No data is available on the product itself.

Ingestion: No data is available on the product itself.

Acute Toxicity: No data is available on the product itself.

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Skin corrosion/irritation: May cause skin irritation in susceptible persons.

Eye damage/ irritation: Slight irritation.

Respiratory Irritation: No data is available on the product itself.

Respiratory Sensitization: Relevant components are not sensitizers.

Skin Sensitization: Relevant components are not sensitizers.

Germ Cell Mutagenicity: Relevant components are not germ cell mutagens.

Carcinogenicity: Relevant components are not classified as carcinogens.

Reproductive Toxicity: Relevant components are not reproductive toxins.

Specific Target Organ Toxicity:

Single Exposure: No data available.

Repeat Exposure: No data available.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity: No data available.

12.2 Persistence and degradability: No data available.

12.3 Bioaccumulative Potential: No data available.

12.4 Mobility in Soil: No data available

12.5 Results of PBT and vPvB assessment: Components are not classified as PBT or vPvB.

12.6 Other Adverse Effects: No data available.

SECTION 13. DISPOSAL CONSIDERATIONS
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13.1 Waste Treatment Methods: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24).

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

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SECTION 14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
US DOT	Not applicable	Not regulated	Not applicable	Not applicable	Not applicable

EU ADR/RID	Not applicable	Not regulated	Not applicable	Not applicable	Not applicable
IMDG	Not applicable	Not regulated	Not applicable	Not applicable	Not applicable
IATA/ ICAO	Not applicable	Not regulated	Not applicable	Not applicable	Not applicable

14.6 Special Precautions for User: None.

SECTION 15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

US EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):

Components: None.

US EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required:

Components: None.

US EPA CERCLA Hazardous Substances (40 CFR 302):

Components: None.

California Prop. 65:

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating: Non-Hazardous.

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SECTION 16. OTHER INFORMATION

SDS Revision History: New SDS.
Date of preparation: March 17, 2017.
Date of last revision: New SDS.

HMIS Rating

Health	1
Flammability	0
Physical Hazard	0
Personal Protective Equipment (PPE)	B

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

* = Chronic Health Hazard

A = Safety Glasses

B = Safety Glasses, Gloves

C = Safety Glasses, Gloves, Apron

D = Face Shield, Gloves, Apron

E = Safety Glasses, Gloves, Dust Respirator

F = Safety Glasses, Gloves, Apron, Dust Respirator

G = Safety Glasses, Gloves, Vapor Respirator

H = Splash Goggles, Gloves, Apron, Vapor Respirator

Further information:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.