

Product Name:
Issued:

Freestyle Control Solution
Mar-10-2020



SAFETY DATA SHEET

Version: 5
Previous Version: 4
Supersedes the SDS dated: Sep-17-2019

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

1.1 Product Identifier

Product Name: Freestyle 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)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System. EU notification not required.

2.2 Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System. EU notification not required.

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

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Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Compound 1	80-90	Present		Not Hazardous*	No data available
Compound 2	10-15	NA		Not Hazardous*	No data available
HEPES 7365-45-9	0-1	Present		Acute Tox. 4 (H302)	No data available
Compound 3	0-1	Present		Not Hazardous*	No data available
Compound 4	0-3	Present		Not Hazardous*	No data available
Amaranth Dye 915-67-3	0-0.1	Present		Eye Corr. 2 (H319)	No data available
Sodium Hydroxide 1310-73-2	0-0.1	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
Proclin 300 55965-84-9	0-0.1	NA		Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Skin Corr. 1B (H314) Skin Sens. 1 (H317) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	No data available
Compound 5	0-0.01	Present		Not Hazardous*	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.

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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: None known from occupational exposure.

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: Avoid inhalation of combustion products.

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.

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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 1	Not Applicable	None
Compound 2	Not Applicable	None
HEPES 7365-45-9	Not Applicable	None
Compound 3	Not Applicable	None
Compound 4	Not Applicable	None
Amaranth Dye 915-67-3	Not Applicable	None
Sodium Hydroxide 1310-73-2	Not Applicable	None
Proclin 300 55965-84-9	Not Applicable	None
Compound 5	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Compound 2	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Sodium Hydroxide 1310-73-2	2 mg/m ³ Ceiling	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.

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Respiratory Protection:	An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
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:	Liquid
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
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):	Not determined.
Partition coefficient:	Not determined.
n-octanol/water	
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

Product Name: Freestyle Control Solution
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Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Not determined

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely
Dermal: Unlikely
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Compound 2	LD50 >	40,000	mg/kg	Rats Mice
HEPES 7365-45-9	LD50 >	316	mg/kg	Animals
Compound 3	LD50 =	3550	mg/kg	Rats
Compound 4	LD50 >=	8000 25800	mg/kg	Dogs Rats
Sodium Hydroxide 1310-73-2	LD50 =	325	mg/kg	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: Not determined.

Dermal Irritation: Not determined.

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Eye Irritation: A minor ingredient is an eye irritant.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: None

Carcinogenicity: Not carcinogenic in humans.

Mutagenicity: None expected from normal clinical use of this product.

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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)/NOEC	Species	Duration
Compound 3	0-1	1295	Fathead Minnow	96 Hours

Chemical Name	Percent	48h EC50 (mg/l)	Species	Duration
Compound 3	0-1	1661	Daphnia magna	48 Hours
Sodium Hydroxide 1310-73-2	0-0.1	40	Daphnia	48 Hours

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

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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 1	Present	X	X	Not listed.	X
Compound 2	-	X	X	Not listed.	X
HEPES 7365-45-9	Present	X	X	Not listed.	X
Compound 3	Present	X	X	Not listed.	X
Compound 4	Present	X	X	Not listed.	X

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Amaranth Dye 915-67-3	Present	X	X	Not listed.	X
Sodium Hydroxide 1310-73-2	Present	X	X	Not listed.	X
Proclin 300 55965-84-9	-	-	X	Not listed.	X
Compound 5	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Compound 1	-	-	X	X	Present	
Compound 2	Present	-	X	X	Present	
HEPES 7365-45-9	-	-	X	X	-	
Compound 3	Present	-	X	X	Present	HSR002722
Compound 4	Present	-	X	X	Present	
Amaranth Dye 915-67-3	Present	-	X	X	Present	
Sodium Hydroxide 1310-73-2	Present	-	X	X	Present	HSR001547
Proclin 300 55965-84-9	Present	-	X	-	Present	
Compound 5	-	Present	X	X	-	

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 1	80-90	Not Listed	Not Listed	Not Listed
Compound 2	10-15	Not Listed	Not Listed	Not Listed
HEPES 7365-45-9	0-1	Not Listed	Not Listed	Not Listed
Compound 3	0-1	Not Listed	Not Listed	Not Listed
Compound 4	0-3	Not Listed	Not Listed	Not Listed
Amaranth Dye 915-67-3	0-0.1	Not Listed	Not Listed	Not Listed
Sodium Hydroxide 1310-73-2	0-0.1	Not Listed	Not Listed	Not Listed
Proclin 300 55965-84-9	0-0.1	Not Listed	Not Listed	Not Listed
Compound 5	0-0.01	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 1	80-90	No	Not Applicable	Not applicable
Compound 2	10-15	No	Not Applicable	Not applicable
HEPES 7365-45-9	0-1	No	Not Applicable	Not applicable
Compound 3	0-1	No	Not Applicable	Not applicable
Compound 4	0-3	No	Not Applicable	Not applicable
Amaranth Dye 915-67-3	0-0.1	No	Not Applicable	Not applicable
Sodium Hydroxide 1310-73-2	0-0.1	No	1000 lb 454 kg	Not applicable
Proclin 300 55965-84-9	0-0.1	No	Not Applicable	Not applicable
Compound 5	0-0.01	No	Not Applicable	Not applicable

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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
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
H315 - Causes skin irritation
H319 - Causes serious eye irritation

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Component
Amaranth Dye 915-67-3
(0-0.1)

Reason for Revision
(M)SDS sections updated 3

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