

1. Identification of the Substance / Mixture and of the Company / Undertaking

Product name:	HypaSoothe Burn Dressing & Emergency Burn Gel
Product code(s):	D8160, D8161, D8163 & D8164
SDS reference:	0001 v2
Supplier's name and address:	
Name:	Safety First Aid Group Ltd
Address:	Avenue One Letchworth Garden City Hertfordshire SG6 2WW
Contact phone:	44(0)208 202 7447
Contact email:	quality@sfag.co.uk

Recommended use: wound /burn gel

Used to create a moist wound environment for the treatment of minor conditions such as minor burns, superficial lacerations, cuts and abrasions (partial thickness wounds) and skin tears.

Restrictions on use:

Use only once. Re-use could result in risk of cross-infection and reduced product performance.

2. Hazards Identification

2.1. Classification of the mixture

The mixture does not meet the criteria for classification in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements in accordance with CLP Regulation of (EC No 1272/2008)

Signal word: N.A

Hazard Pictograms: N.A

Hazard statement Parts: N.A

Precautionary statement: N.A

Supplemental Hazard information (EU)54: N.A

2.3. Other hazards

This mixture does not contain any substances that are assessed to be persistent, bio accumulative and toxic (PBT) or very persistent and very bio accumulative (vPvB), according to the criteria given in Annex XIII of Regulation (EC) No. 1907/2006.

This mixture does not contain substances included in the list established in accordance with Article 59(1) for having endocrine disrupting properties.

Other hazards which do not result in classification.

No Known hazard may contribute to the overall hazards of the mixture.

3. Composition / Information on Ingredients

Substance name	CAS No	EC No	Percentage by descending order by mass or volume	Classification according to Regulation (EC) No 1278/2008 (CLP).
Purified water	7732-18-5	NA	50-70	Not Classified
Polyol	9003-11-6	NA	5-20	Not Classified
Carbomer	9003-01-4	NA	0.5-5	Not Classified
Cross linked CMC	74811-65-7	NA	1-5	Not Classified
Substrate in case of burn dressing	Not applicable for mixture	NA	5-10	Not Classified
Calcium Alginate	9005-35-0	NA	1-5	Not Classified
Neutralizer	NA	NA	0.1-1	Not Classified
Silver complex	7440-22-4	NA	0.1-5	Not Classified

4. First Aid Measures

4.1. Description of first aid measures

4.1.1. First aid instructions provided by relevant routes of exposure

Inhalation: Not usually relevant, unless it gets too hot and breaks down. If any decomposition fumes are inhaled, remove to fresh air.

Skin contact: Not hazardous under normal conditions of use. Like all Mixtures, has a possibility of causing skin irritation or sensitization in susceptible individuals.

Eye contact: Rinse eyes thoroughly with water, obtain medical attention if effects persist.

Ingestion (If swallowed): Obtain medical attention, do not induce vomiting. Give one or two glasses of water

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

Inhalation: Not a route of exposure for This mixture. If any decomposition fumes are inhaled, remove to fresh air.

Eyes: Not a route of exposure for This mixture: may cause temporary eye irritation if come in Contact.

Skin: If irritation occurs or sensitization develops, wash thoroughly with soap and water. Obtain medical attention if effects persist

Ingestion: Not a route of exposure for This mixture: slightly harmful if swallowed. May cause

gastrointestinal irritation.

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

Note to physicians: Treat symptomatically as above mentioned

5. Fire Fighting Measures

The requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

5.1. Extinguishing media

Suitable extinguishing media: The mixture is Non-Flammable.

In case of fire: Use a firefighting agent suitable for ordinary combustible material such as water or foam to extinguish.

Unsuitable extinguishing media: NA

5.2. Special hazards arising from the substance or mixture.

None inherent in this mixture

5.3. Advice for firefighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

No adverse effects on persons, property and the environment of spills, leaks, or releases.

6.1.1. For non-emergency personnel (NA)

Protective equipment:

Emergency procedures:

6.1.2. For emergency responders (NA)

6.2. Environmental precautions

No environmental issues expected.

6.3. Methods and material for containment and cleaning up. (NA)

6.4. Reference to other sections if applicable

See section 7 for information on safe handling.

See section 8 for information on personal protection equipment.

See section 13 for disposal information.

7. Handling and Storage

7.1. Precautions for safe handling

This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions.

7.2. Conditions for safe storage including any incompatibilities

In line with manufacturers storage precaution and conditions in the TD.

Technical measures and storage conditions: Store in cool, dry place, avoid direct sun light, moist sources, keep container tightly closed.

Packaging materials: primary (Heat sealable or cold seal liners)/secondary (paper carton) / tertiary (multilayers rigid paper carton)

Requirements for storage rooms and vessels: Cool-Dry-away from sunlight-at T between 0° C and 40°C

Further information on storage conditions: No further relevant information available.

7.3. Specific end use (s) NA

8. Exposure Controls / Personal protection

8.1. Control parameters

Occupational exposure limits: No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

8.2. Exposure controls

8.2.1. Appropriate engineering controls: No engineering controls required.

8.2.2. Personal protection equipment:

8.2.2.1. Eye and face protection: Eye protection not required

8.2.2.2. Skin protection: No protective gloves required

Other skin protection: NA

8.2.2.3. Respiratory protection: Respiratory protection is not required.

8.2.2.4. Thermal hazards: No thermal Hazard expected so no thermal protection is not required under normal use

8.2.2.5. Environmental exposure controls: No hazard may expect so protection is not required.

9. Physical and Chemical Properties

Property Remarks/Guidance

(a) Physical state / Amorphous gel

(b) Colour /Various color

(c) Odour / Odorless

(d)Melting point/freezing point / Not applicable to the overall product.

(e) Boiling point or initial boiling point and boiling range / Not determined

(f) Flammability / Not determined

(g) Lower and upper explosion limit / Not applicable because do not apply to solids.

(h) Flash point / Not applicable.

(i) Auto-ignition temperature / Not determined.

(j) Decomposition temperature / Not applicable as the Mixtures will not decompose.

(k) pH / Not applicable for solid

(l) Kinematic viscosity / Not applicable

(m) Solubility / Insoluble in water.

- (n) Partition coefficient n-octanol/water (log value) / Not applicable because it does not generally, apply to mixtures
- (o) Vapour pressure / Not applicable
- p) Density and/or relative density / Not applicable
- (q) Relative vapour density / Not applicable
- (r) Particle characteristics / Not applicable

10. Stability and Reactivity

10.1. Reactivity

This material is considered to be non-reactive under normal use conditions.

10.2. Chemical stability

This material is considered to be Stable.

10.3. Possibility of hazardous reactions.

No hazardous reaction may possible

10.4. Conditions to avoid: No known conditions to be avoided

10.5. Incompatible materials: No known Incompatibility with other materials

10.6. Hazardous decomposition products: No known hazardous decomposition product under normal use

Under recommended usage conditions, hazardous decomposition products are not expected.

Unknown Hazardous decomposition products may occur as a result of oxidation, heating, or reaction with another material.

11. Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

The relevant hazard classes, for which information shall be provided, are:

- (a) Acute toxicity; Based on available data, the classification criteria are not met.
- (b) skin corrosion/irritation; Based on available data, the classification criteria are not met.
- (c) serious eye damage/irritation; Based on available data, the classification criteria are not met.
- (d) respiratory or skin sensitization; Based on available data, the classification criteria are not met.
- (e) germ cell mutagenicity; Based on available data, the classification criteria are not met.
- (f) carcinogenicity; ; Based on available data, the classification criteria are not met.
- (h) Specific Target Organ Toxicity STOT-single exposure: Based on available data, the classification criteria are not met.
- (i) Specific Target Organ Toxicity STOT-repeated exposure; Based on available data, the classification criteria are not met.
- (j) aspiration hazard. Based on available data, the classification criteria are not met.

Inhalation exposure: Not usually relevant, unless it gets too hot and breaks down. If any decomposition fumes are inhaled, remove to fresh air.

Skin exposure: Not hazardous under normal conditions of use. Like all Mixtures, has a possibility of causing skin irritation or sensitization in susceptible individuals .

Eye contact: Rinse eyes thoroughly with water, obtain medical attention if effects persist

Ingestion (If swallowed): Obtain medical attention, do not induce vomiting. Give one or two glasses of Water

11.2. Information on other hazards

This product, when used under reasonable conditions and in accordance with the directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

11.2.1. Endocrine disrupting properties

No adverse health effects caused by endocrine disrupting properties under corresponding Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605).

11.2.2. Other information

No Known hazard may contribute to the overall hazards of the mixture.

12. Ecological Information

The final product not considered as dangerous for the environment

12.1. Toxicity

Acute (short-term) toxicity: Not acutely toxic to aquatic life by GHS criteria.

Fish:

Crustacea:

Algae/aquatic plants:

Other organisms:

Chronic (long-term) toxicity: Not chronically toxic to aquatic life by GHS criteria.

Fish:

Crustacea:

Algae/aquatic plants:

Other organisms:

12.2 Persistence and degradability

Abiotic Degradation:

Physical- and photo-chemical elimination:

Biodegradation:

Where experimental data are not available, the supplier shall consider whether reliable and relevant information obtained from models can be provided.

12.3 Bio accumulative potential

Partition coefficient n-octanol /water (log K_{ow}):

Bioconcentration factor (BCF):

Where experimental data are not available, it shall be considered whether model predictions can be provided.

12.4 Mobility in soil:

This product is considered to be an article which does not release /distribute/mobile in soil.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB”

12.6 Endocrine disrupting properties

“This substance does not have endocrine disrupting properties with respect to non-target organisms as it does not meet the criteria set out in section B of Regulation (EU) No 2017/2100.”

Guidance on endocrine disruptors and their identification can be found at:

<https://echa.europa.eu/hot-topics/endocrine-disruptors>

12.7 Other adverse effects

No other adverse environmental effects (e.g., ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

13.1 Waste treatment methods.

Comply with all applicable local and federal laws. Wound care dressings can be disposed away with normal waste unless they are saturated or dripping with blood or other regulated bodily fluids from medical or nursing care; in that case, they must be disposed of as contaminated waste according to regulations and classified as hazardous waste. In order to minimize the risk of potential infection hazard or environmental pollution, disposing the medical device should follow disposal procedures according to applicable local laws”

14. Transport Information

In case of Final products:

No special transport requirements. Not a Dangerous Good or Workplace Hazardous Substance.

14.1 UN Number Not classified as dangerous goods according to transport regulations

14.2 UN Proper Shipping Name Not applicable

14.3 Transport Hazard Class Not applicable

14.4 Packing Group Not applicable

14.5 Environmental Hazard Not applicable

14.6 Special Precautions for User Not applicable

14.7 Hazchem Code Not applicable

15. Regulatory Information

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

Non-hazardous so no special, health and environmental regulations

15.2 Chemical Safety Assessment:

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

16. Other Information

Sources of data

Other suppliers' safety data sheets

The information contained in this data sheet is to the best of our knowledge and belief accurate and is based upon our supplier's technical knowledge of the product at the date of issue. However, no warranty or representation, expressed or implied, is made as to its accuracy, reliability or completeness of the foregoing data and safety information.

This data sheet and the health, safety and environmental information it contains are considered to be accurate as of the date specified above. We have reviewed any information contained herein which we received from sources outside Safety First Aid Group. However, no warranty or representation, express or implied, is made as to the accuracy or completeness of the data and information contained in this data sheet.

Health and safety precautions and environmental advice noted in this data sheet may not be accurate for all individuals and/or situations. It is the user's obligation to evaluate and use this material safely sheet and to comply with all applicable laws and regulations.

1. Identification of the Substance / Mixture and of the Company / Undertaking

Product name: Hypacool Instant Cold Pack
Product code(s): Q2281 & Q2281PK24
SDS reference: 0010
Supplier's name and address:
Name: Safety First Aid Group Ltd
Address: Avenue One
Letchworth Garden City
Hertfordshire
SG6 2WW
Contact phone: 44(0)208 202 7447
Contact email: quality@sfag.co.uk

Advised Uses:

Control and alleviate the gore and pain caused by strain, bruise, pull and burn, also can rapidly remove the pain and discomfort induced by fever, headache, toothache, mosquito bites.

Restrictions on use:

- (a) Anaesthetic skin
- (b) Cold allergy/cold-induced urticaria
- (c) Cold-induced myocardial ischemia (or other unstable heart or lung disease)
- (d) Diabetes mellitus (when complicated by vascular disease or sensory loss)
- (e) Peripheral vascular disease
- (f) Raynaud's phenomenon
- (g) Systemic lupus erythematosus
- (h) Uncovered open wounds

2. Hazards Identification

2.1 GHS Classification GHS Regulatory Status

This chemical is not considered hazardous by the UN GHS (GHS Rev.8(2019)).

2.2 GHS Label elements

1) **Signal word:** Not applicable.
 2) **Hazard class:** Not applicable.
 3) **Hazard pictograms:** Not applicable.
 4) **Hazard statements:** Not applicable.
 5) **Precautionary Statements - Prevention:** Not applicable.
 6) **Precautionary Statements - Response:** Not applicable.
 7) **Storage:** Not application.
 8) **Disposal:** Dispose of contents/container in accordance with local/regional/national/international regulations (to be specified).

2.3 Other hazards which do not result in classification. Not application.

3. Composition / Information on Ingredients

Ingredients	CAS #	%(weight)	ACGIH TLV		OSHA	
			TWA	STEL	PEL	STEL
Urea	57-13-6	34.3	5mg/m ₃	10mg/m ₃	N/Av	N/Av
Ammonium chloride	12125-02-9	13.1	10mg/m ₃	20mg/m ₃	N/Av	N/Av
Water	7732-18-5	52.6	N/Av	N/Av	N/Av	N/Av

4. First Aid Measures

4.1 Description of necessary first-aid measures

General Advice: Take proper precautions to ensure your own health and safety before attempting rescue and providing first aid. Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

Inhalation: Supply fresh air; consult doctor in case of complaints.

Skin Contact: Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

Eye Contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. **Ingestion:** Rinse out mouth with water. Never give anything by mouth to an unconscious person. If symptoms persist consult doctor.

Protection of first-aid: None.

4.2 Most important symptoms/effect, acute and delayed: See section 11.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

- 1) **Note to Physicians:** Treat symptomatically.
- 2) **Specific treatments :** No further relevant information available.

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: No further relevant information available.

5.2 Specific hazards arising from the mixture : No further relevant information available.

5.3 Special protective equipment and precautions for fire-fighters

Special protective equipment: No further relevant information available.

Special protective precautions: Fight fires from a safe distance. Evacuate personnel to safe area. Water spray may be useful in cooling equipment exposed to heat and flame.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency procedures:

- Ensure adequate ventilation.
- Use respiratory protective device against the effects of fumes/dust/aerosol.
- Avoid contact with eyes.

6.2 Environmental precautions

- Dilute with plenty of water.
- Do not allow to enter sewers/ surface or ground water.

6.3 Methods and materials for containment and cleaning up

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item13.

6.4 Reference to other sections:

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7. Handling and Storage

7.1 PRECAUTIONS FOR SAFEHANDLING. Handling:

- Keep receptacles tightly sealed.
- Keep away from heat and direct sunlight.
- Ensure good ventilation/exhaustion at the workplace.
- Prevent formation of aerosols.
- Avoid contact with eyes.

Information about fire - and explosion protection: Normal measures for preventive fire protection.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES Requirements to be met by storerooms and receptacles:

- Store in a cool location.
- Store in cool, dry conditions in well-sealed receptacles.
- Store away from foodstuffs.
- Store away from oxidizing agents.

Specific end use(s): No further relevant information available.

8. Exposure Controls / Personal protection

ADDITIONAL INFORMATION ABOUT DESIGN OF TECHNICAL FACILITIES: NO FURTHER DATA; SEE ITEM 7.

8.1 Exposure controls

Based on the composition shown in Section 3, the following measures are suggested for occupational safety measure.

8.2 Appropriate engineering controls

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.3 Personal protective equipment

8.3.1 Eye/face protection: Safety glasses.

8.3.2 Skin protection: Wear appropriate protective clothing, and gloves to prevent skin contact. The glove material has to be impermeable and resistant to the product/ the substance/ preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

8.3.3 Respiratory protection: Suitable respiratory protective device recommended.

8.3.4 Other Protection: Use good hygiene practices when handling this material including changing and laundering work clothing after use. Have a safety shower or eyewash fountain available. Wash hands thoroughly after handling material. Do not eat, drink, or smoke in work areas.

9. Physical and Chemical Properties

- (a) **Appearance (physical state, colour, etc.):** While solid.
- (b) **Odor:** Odourless
- (c) **Odor threshold:** No information found.
- (d) **pH:** No information found.
- (e) **Melting point/freezing point:** 132.7°C (270.9°F)
- (f) **Initial boiling point and boiling range:** No information found.
- (g) **Flash point:** No information found.
- (h) **Evaporation rate:** No information found.
- (i) **Flammability (solid, gas):** No information found.
- (j) **Upper/lower flammability or explosive limits:** No information found.
- (k) **Vapor pressure:** No information found.
- (l) **Vapor density:** 2.07(Air=1).
- (m) **Relative density:** No information found.
- (n) **Solubility(ies):** Easily soluble in cold water, hot water.
- (o) **Partition coefficient: n-octanol/water:** No information found.
- (p) **Auto-ignition temperature:** No information found.
- (q) **Decomposition temperature:** No information found.
- (r) **Viscosity:** No information found.

10. Stability and Reactivity

- 10.1 Reactivity:** No decomposition if used according to specifications.
- 10.2 Chemical Stability :** Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions**
Hazardous Polymerization: Not expected under prescribed storage and handling conditions.
- 10.4 Conditions to avoid:** Incompatible materials, dust generation.
- 10.5 Incompatible materials:** No further relevant information available.
- 10.6 Hazardous decomposition Products:** No dangerous decomposition products known.
- 10.7 Incompatibilities with Other Materials:** No further relevant information available.

11. Toxicological Information

11.1 Acute toxicity

Toxicological data: There is no available data for the product itself, only for the ingredients, Refer to Section 2 for individual ingredient LD50's and LC50's.

Ingredients	CAS No.	LC ₅₀	LD ₅₀	
		Inh, rat	oral	dermal
Urea	57-13-6	N/A	8741mg/kg	N/A
Ammonium chloride	12125-02-9	N/A	1650 mg/kg	N/A
Water	7732-18-5	N/A	N/A	N/A

11.2 Carcinogenic status:

No components are listed as carcinogens by ACGIH, IARC, OSHA or NTP.

11.3 Other information

Skin corrosion/irritation: Irritating effect possible.

Serious eye damage/irritation: Irritating effect possible.

Skin or skin sensitization: Sensitization possible.

Germ cell mutagenicity: No information found.

Reproductive toxicity: No information found.

STOT-single exposure: No information found.

STOT-repeated exposure: No information found.

Aspiration hazard: No information found.

12. Ecological Information

12.1 TOXICITY

Acute/Chronic Toxicity: Not available.

12.2 PERSISTENCE AND DEGRADABILITY Not available.

12.3 BIOACCUMULATIVE POTENTIAL

Bioaccumulation: No further relevant information available.

12.4 MOBILITY IN SOIL Not available.

12.5 OTHER ADVERSE EFFECTS Not available.

13. Disposal Considerations

13.1 Waste treatment methods Recommendation: Smaller quantities can be disposed of with household waste.

13.2 Contaminated packaging Recommendation: Disposal must be made according to official regulations.

13.3 Disposal recommendations Refer to section 13.1 and 13.2.

14. Transport Information

(a) **UN Number (TDG, ADR, IMDG, IATA):** Not applicable.

(b) **UN proper shipping name (TDG, ADR, IMDG, IATA):** Not applicable.

(c) **Transport hazard class (TDG, ADR, IMDG, IATA):** Non-hazardous for Transport.

(d) **Packing group (TDG, ADR, IMDG, IATA):** Not applicable.

- (e) **Environmental hazards (Marine pollutant):** Refer to section 12.1.
- (f) **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- (g) **Special precautions for user:** Not applicable.
- (h) The product is not subject to IMO/IMDG code.

15. Regulatory Information

Component	EINECS	TSCA	DSL	IECSC	NZIoC	PICCS	KECI	AICS
Urea	Listed	Listed	Not listed	Listed	Listed	Listed	Listed	Listed
Ammonium chloride	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed
Water	Listed	Listed	Listed	Listed	Listed	Listed	Listed	Listed

EINECS European Inventory of Existing Commercial Chemical Substances.

TSCA United States Toxic Substances Control Act Inventory.

DSL Canadian Domestic Substances List.

IECSC China Inventory of Existing Chemical Substances.

NZIoC New Zealand Inventory of Chemicals.

PICCS Philippines Inventory of Chemicals and Chemical Substances.

KECI Existing and Evaluated Chemical Substances.

AICS Australia Inventory of Chemical Substances.

16. Other Information

Sources of data Other suppliers' safety data sheets

The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

Recipients of our products must take on responsibility for observing existing laws and regulations