

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.