

Material Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier:** Burn Gel/burn gel dressing/burn gel spray
- 1.2. Relevant identified uses of the substance or mixture and uses advised against:**
Uses: Adults and paediatric patients with burns, scalds and sunburn.
Uses advised against: Do not use on serious burns, mucous membranes or the eyes.
- 1.3. Details of the supplier of the safety data sheet:**
Manufacturer: RFX+CARE Manufacturing Co.,Ltd.
Address: No. 599 Wuxie Road Yuecheng District, Shaoxing, Zhejiang, China 312000
- 1.4. Emergency telephone number:** 0575-88681702
- 1.5. Details of the distributor:**
Distributor: GPBM Nordic AB
Address: Sörredsvägen 113,SE-41878 Göteborg,Sweden

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
According to the classification of Regulation (EC) No.1272/2008, this product is not classified as a hazardous chemical.
- 2.2. Label elements**
As it is not classified as a hazardous chemical according to Regulation (EC) No.1272/2008, there is no relevant hazard label element.
- 2.3. Other hazards**
None

SECTION 3: Composition/information on ingredients

Composition information: mixture

Ingredients	CAS No	Concentration %	CLP classification
Water	7732-18-5	90%	No Hazard classification
Silicone emulsion	59227-89-3	3%	No Hazard classification
Glycerin	56-81-5	3%	No Hazard classification
Carbomer	9007-20-9	2%	No Hazard classification
Propylene glycol	57-55-6	2%	No Hazard classification

SECTION 4: First aid measures

- 4.1. Description of first aid measures**
Skin contact: This product is intended to be in contact with the skin when used as directed in the instructions for use. No harm
Eye contact: If misuse causes contact with eyes, Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Inhalation: Not relevant.
Ingestion: If misuse leads to ingestion. Rinse out mouth with water. Never give anything by mouth to an unconscious person. If symptoms persist consult doctor.
- 4.2. Most important symptoms and effects, both acute and delayed**
Not relevant.
- 4.3. Indication of any immediate medical attention and special treatment needed**
If misuse causes contact with eyes or ingestion, symptoms persist, please consult a doctor.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

All common extinguishing agents are suitable

5.2. Special hazards arising from the substance or mixture

Smoke, soot, CO/CO₂, and other toxic fumes.

5.3. Advice for firefighters

Keep unnecessary personnel away.

Wear full protective clothing.

Wear self-contained breathing apparatus

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No specific measures.

6.2. Environmental precautions

keeping away from drains, surface and ground water

6.3. Methods and material for containment and cleaning up

No specific measures.

6.4. Reference to other sections

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Keep packages tightly sealed

Keep away from heat and direct sunlight.

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with eyes.

7.2. Conditions for safe storage, including any incompatibilities

Keep dry.

Keep away from light and heat.

Store 0-30°C.

7.3. Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

8.2. Exposure controls

Eye protection: Wear protective glasses

Skin protection: None required

Respiratory protection: None required

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Gel	Colour:	white
Melting point:	No information found.	Boiling point:	No information found.

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Flammability:	Non-Flammable	Lower and upper explosion limit:	No information found.
Decomposition temperature:	No information found.	Auto-ignition temperature:	No information found.
pH:	5-7	Flash point:	No information found.
Kinematic viscosity:	No information found.	Vapour pressure:	No information found.
Solubility:	Soluble in water	Density:	No information found.

9.2. Other information

None

SECTION 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

Not expected under prescribed storage and handling conditions.

10.4. Conditions to avoid

dust generation.

10.5. Incompatible materials

No further relevant information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known

SECTION 11: Toxicological information

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

Toxicological data: There is no available data for the product itself, only for the ingredients, Refer to below excel for individual ingredient LD50's

Ingredients	CAS No	LD50		
		oral	inhalation	dermal
Purified Water	7732-18-5	NA	NA	NA
Emulsifier	9007-20-9	NA	NA	NA
Glycerol	56-81-5	27200mg/kg	there were no mortalities at the highest tested concentration (5.85 mg/L)	45 ml/kg
Surfactant	59227-89-3	NA	NA	NA
Propylene glycol	57-55-6	22000mg/kg	> 317 042mg/m³ air	> 2 000mg/kg

Skin corrosion/irritation: The main component is water, which has no effect, and other trace components may cause irritation.

Serious eye damage/irritation: The main component is water, which has no effect, and other trace components may cause irritation..

Respiratory or skin sensitization: The main component is water, which has no effect, and other trace components may cause irritation.

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.

11.2. Information on other hazards

No information found.

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SECTION 12: Ecological information**12.1. Toxicity**

Acute/Chronic Toxicity: Not available

12.2. Persistence and degradability

Not available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

There is no such influence.

12.6. Endocrine disrupting properties

There is no such influence.

12.7. Other adverse effects

None

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Recommendation: Smaller quantities can be disposed of with household waste.

SECTION 14: Transport information**14.1. UN number or ID number**

Not applicable.

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es)

Non-hazardous for Transport

14.4. Packing group

Not applicable

14.5. Environmental hazards

Refer to section 12.1.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

(EU)2017/745 medical device regulation

Regulation (EC) No 1272/2008

COMMISSION REGULATION (EU) 2020/878

Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

supplier has carried out a chemical safety assessment for the mixture

SECTION 16: Other information

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this product.

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This bulletin cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers. It is your responsibility to develop appropriate work practice guidelines and employee instructional programs for your operation

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