

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- **PRODUCT IDENTIFIER:** Medical device/Incontinence products
PRODUCT NAME: ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Wash Gloves With Barrier Cream
Washcap – Shampoo Cap
- **NAME OF SUPPLIER, ADDRESS AND TELEPHONE NUMBER**
SUPPLIER: KAF GRUP SAĞLIK HİZMETLERİ
ADDRESS: Atakent Mah. 221 Sk. No:3/A Rota Office A Blok Kat:14 D:83 K.ÇEKMECE / İSTANBUL
TEL: +90 212 471 42 00
FAX: +90 212 471 42 01
Web: www.kafgrup.com
- **NAME OF MANUFACTURER, ADDRESS**
MANUFACTURER: KAF GRUP SAĞLIK HİZMETLERİ
ADDRESS: Hadımköy atatürk San Bölgesi Denizkızı sok. No:4/5 Arnavutköy / İSTANBUL
- **WHO GAVE INFORMATION ABOUT SECURITY:** Filiz KAYMAZ
- **EMERGENCY TELEPHONE NUMBER:** In case of poisoning if it is necessary, call the national poison centre **114 (UZEM)**.
EMERGENCY FIRST AID CENTRE: 112
FIRE DEPARTMENT:110

2. HAZARDS IDENTIFICATION

2.1 Physical Hazards: No physical hazards.

Health Hazards: No health hazards.

Environmental Hazards: No environmental hazards.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

2.2 Label Elements:

According to SEA Regulation;

Hazard Pictograms: Not classified.

Signal Word: Not classified.

Hazard Statements: Not classified.

Precautionary Statements:

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P501: Dispose of contents/container in accordance with national regulations.

Additional Warnings: The relevant risk safety phrases together with hazard and precautionary statements are given in section 16.

3. COMPOSITION/INFORMATION ON INGREDIENTS OF MIXTURE

Chemical Definition: Mixture

• Dangerous Substances It Contains:

| Substance or Compound | EC NO | CAS NO | Content % | Classification (SEA Regulations) |
|----------------------------|-----------|-------------|-----------|--|
| Cocamidopropyl betaine | 604-575-4 | 147170-44-3 | <0,18 | Eye Dam.1 H318 Aquatic Chronic 3 H412 |
| Ethylhexylglycerin | 408-080-2 | 70445-33-9 | ≤0,1 | Eye Dam.1 H318 Aquatic Chronic 3 H412 |
| CITRIC ACID MONOHYDRATE | 691-328-9 | 5949-29-1 | <1 | Skin Irrit.2 H315 Eye Irrit.2 H319 |
| Tetrasodium Edla | 200-573-9 | 64-02-8 | <0,3 | Eye Dam.1 H318 Acute Tox.4 H302 |

Notes: The full text of the H-codes is given in Section 16.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

4. FIRST AID MEASURES

General Recommendation: If symptoms persist, consult a doctor. When you contact your doctor, show this safety data sheet.

In The Event of Inhalation: Move the exposed person to fresh air immediately. If any discomfort continues, consult a doctor.

If Swallowed: Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical advice immediately.

In Case of Skin Contact: Wash contaminated clothing before reuse. If any discomfort continues, consult a doctor.

Eye Contact: If there are contact lenses, it should be removed before rinsing. Rinse eyes immediately with plenty of water by opening the eyelids. Continue to rinse for at least 15 minutes and call a healthcare professional.

Antidote: Apply treat symptomatically.

5. FIRE – FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Fire Extinguishers: Water spray, fine spray, foam, dry chemical powder or foam, carbon dioxide fire extinguishers in accordance with the surrounding material.

Unsuitable Extinguishers: No data available.

5.2 Special Hazards Arising from the Substance or Mixture: In case of fire, toxic gases may be formed.

5.3 Advice for firefighters

Personnel in charge should use breathing apparatus and chemical protective clothing during fire fighting. Move personnel to a safe area. Use fire-fighting methods appropriate to the local conditions and environment. Take the wind behind you. Cool undamaged packages with water spray. Avoid polluting the environment by using more fire extinguishers than necessary. Firefighting residues

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

should not be allowed to reach sewers, water pipes, surface and underground waters. Fire residues and contaminated fire extinguishing water should be disposed of in accordance with local regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions

Use your personal protective equipment. Make sure you have good ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Direct personnel to a safe area.

6.2 Environmental Precautions

Prevent it from entering drains / surface water / groundwater. If it contaminates water or sewage, inform the competent authorities. If there is no safety hazard, prevent further leakage and spillage.

6.3 Methods and Material for Containment and Cleaning Up

Provide adequate ventilation. Dispose of the collected material according to the regulations.

6.4 Reference to Other Sections

For personal protection see section 8.
For waste disposal, see Section 13.

7. HANDLING AND STORAGE

7.1 Handling

Protective Precautions for Safe Handling of The Substance/Preparation:

Please read the user manual carefully before using. Do not buy torn packages. It should not be used in individuals known to be hypersensitive to any of the substances it contains.

Technical Precautions for Protection of Environmental:

Prevent it from entering drains / surface water / groundwater. In case of contamination with water or sewage, inform the competent authorities and inform the authorities. Make sure that the environment is well ventilated. Keep away from sources of ignition and heat. Keep fire fighting equipment ready.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

7.2 Conditions For Safe Storage, Including Any Incompatibilities:

Store in a cool and dry place with minimal risk of damage. Observe the storage conditions in accordance with the information on the packaging. Keep container tightly closed. Store without freezing. Store at temperatures between 0 ° C and + 40 ° C.

7.3 Specific end uses

Use the product in accordance with the instructions for use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No Information available.

8.2 Exposure Controls

DNEL Exposure Limit Values: No data available.

PNEC Exposure Limit Values: No data available.

8.2.1 Engineering Precautions

The equipment and appropriate protection methods to be used in places where personal protection is required are defined in accordance with the "Personal Protective Equipment Regulation" dated 9.2.2004 and numbered 25368. When using personal protective equipment in accordance with the relevant regulation, ensure that there is good and proper ventilation (especially in closed areas).

8.2.2 Personal Protective Equipment

See the label for details when using this product. In all other cases, use the following Personal Protective Equipment.

Respiratory Protection: Does not require special precaution. In case of any discomfort, seek medical advice immediately.

Eye / Face Protection: Does not require special precaution. In case of any discomfort, rinse immediately with plenty of water and seek medical advice.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

Skin Protection: Does not require special precaution. In case of any discomfort, seek medical advice immediately.

Protection of Hands: Does not require special precaution. In case of any discomfort, seek medical advice immediately.

Thermal Damages: No data available.

8.2.3 Environmental Exposure Controls

Please comply with the instructions to avoid effects on people and the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

| 9.1 Information On Basic Physical And Chemical Properties | |
|---|---------------------------------------|
| Appearance | Liquid |
| Odour | Unique |
| Colour | White |
| 9.2 Other Information | |
| Density | 0,950 -1,050 g/cm ³ (20°C) |
| Flash Point | Not available. |
| Boiling Point | Not available. |
| Explosion Hazard | Not available. |
| Viscosity | Not available. |
| Solubility (in Water/Alcohol/Oil) | Soluble in water. |
| Vapor Pressure | Not available. |
| Partition Coefficient (n-octanol/water) | Not available. |
| pH Value | 5,5-6,5 |
| Melting Point | Not available. |
| Flammability | Not available. |

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

10. STABILITY AND REACTIVITY

- 10.1 Reactivity:** No hazardous reactions in storage and handling, if applicable.
- 10.2 Chemical stability:** Stable under normal temperature conditions and recommended usage conditions and under stipulated storage conditions.
- 10.3 Possibility of hazardous reactions:** No data available.
- 10.4 Conditions to avoid:** No data available.
- 10.5 Incompatible materials:** Strong alkali and strong oxidizing agents.
- 10.6 Hazardous decomposition products:** No data available.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

- Acute toxicity**

| Substance | LD50 Oral values | LD50 dermal | LC 50 Inhalation (4hours) |
|------------------------|------------------------------|--------------|---------------------------|
| Cocamidopropyl betaine | 2335 mg/kg (rat-female male) | > 2000 mg/kg | - |

- Eye Irritation:** There is no irritating effect.
- Skin Irritation:** There is no irritating effect.
- Sensitizing effect:** Not classified as sensitizing.
- Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

Aşağıdaki grupların potansiyel etkilerine dair bilgiler:

- Toxicity in repeated ingestion:** No further relevant information available.
- CMR-effects (cancer-producing, transgender and reproductive-threatening effect)**

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

- **Germ cell mutagenicity:** Based on available data, it does not meet the classification criteria.
- **Carcinogenicity:** Based on available data, it does not meet the classification criteria.
- **Reproductive toxicity:** Based on available data, it does not meet the classification criteria.
- **Specific Target Organ Toxicity - single exposure**
Based on available information, it does not meet the classification criteria.
- **Specific Target Organ Toxicity - repeated exposure**
Based on available information, it does not meet the classification criteria.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Cocamidopropyl betaine

| Species | Time Criterion | Last Value | Toxicity |
|--|----------------|------------|-----------|
| Fish (fresh water) | 96 hours | LC50 | 1.11 mg/L |
| Fish (marine) | 96 hours | LC50 | 1.1 mg/L |
| Invertebrate animal (Daphnia magna) | 48 hours | EC50 | 1.9 mg/L |
| Alga (Monoraphidium griffithii) | 10 days | EC50 | 1.5 mg/L |

- 12.2 Persistence and degradability:** There are no short term hazardous decomposition products. The product itself and its decomposition products are not toxic.
- 12.3 Bioaccumulative potential:** No bioaccumulative potential.
- 12.4 Mobility in Soil:** No information available.
- 12.5 Results of PBT and vPvB assessment:** No information available.
- 12.6 Other adverse effects:** None.

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

In line with the regulation on the general principles of proper disposal/product waste management and the regulation on the control of hazardous wastes, waste identification numbers/waste descriptions should be collected specifically for each industry class and process in accordance with local legislation.

The Ministry of Environment and Urbanization must be disposed of in line with the WASTE MANAGEMENT REGULATION published in the Official Gazette dated 02.04.2015 and numbered 29314.

14. TRANSPORT INFORMATION

ADR

- 14.1 UN Number:** Not classified as dangerous.
- 14.2 UN Proper Shipping Name:** Not classified as dangerous.
- 14.3 Transport Hazard Class(es):** Not classified as dangerous.
- 14.4 Packing Group:** Not classified as dangerous.

IMDG

- 14.1 UN Number:** Not classified as dangerous.
- 14.2 UN Proper Shipping Name:** Not classified as dangerous.
- 14.3 Transport Hazard Class(es):** Not classified as dangerous.
- 14.4 Packing Group:** Not classified as dangerous.

ICAO/IATA

- 14.1 UN Number:** Not classified as dangerous.
- 14.2 UN Proper Shipping Name:** Not classified as dangerous.
- 14.3 Transport Hazard Class(es):** Not classified as dangerous.
- 14.4 Packing Group:** Not classified as dangerous.
- 14.5 Environmental Hazards:** No data available.
- 14.6 Special Precautions For User:** No data available.
- 14.7 Transport In Bulk According To Annex II Of MARPOL And The IBC Code:** No data available.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

15. REGULATORY INFORMATION

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

Related regulations;

- Regulation on Registration, Evaluation, Authorization, and Restriction of Chemicals 23.06.2017- Official Gazette No. 30105)
- REGULATION ON CLASSIFICATION, LABELING AND PACKAGING OF SUBSTANCES AND MIXTURES (11 December 2013, WEDNESDAY and Official Gazette No. 28848)
- Regulation on Transport of Dangerous Goods by Road (O.G.24 / 10 / 2013-28801)

15.2 Chemical Safety Assessment: A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

16.1 Explanation on Revision: First edition

Revision Date: -

16.2 Abbreviations:

SDS: Safety Data Sheet

CAS: Service registration number of chemical substances

EINECS: European Inventory of chemical substances

SEA: Regulation on Classification, Labeling, and Packaging of Substances and Mixtures published RG.- 11/12 / 2013-28848

CLP: Directive No. 1272/2008 <Classification, Labeling, and Packaging of Substances and Mixtures> published in the EU

TWA: time-weighted average measured or calculated for a specified reference period of 8 hours

STEL: Unless another time is specified, the exposure upper limit value that must not be exceeded for a period of 15 minutes.

Mg / m³: at a temperature of 20 oC and 101.3 KPa. The amount in milligrams of the substance in 1 m³ of air at a pressure (760 mm mercury pressure)

ppm: The amount of matter in 1 m³ of air in milliliters (ml / m³)

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

NIOSH: The National Institute for Occupational Safety and Health / US National Institute for Occupational Safety and Health CEN: Comite Europeen de Normalization / European Standardization Committee

NTP: (National Toxicology Program) National Toxicology Program

IARC: (The International Agency for Research on Cancer) International Agency for Research on Cancer

OSHA: (Occupational Safety and Health Association) Worker health and safety association

EWC: (European Waste Catalog) European Union Waste Catalog

ADR: Transport of Dangerous Goods

RID: Transport of dangerous goods by rail

ADNR: Regulation on Dangerous Goods Transport in Rivers

IMDG: Training and authorization regulation within the scope of the international code for dangerous goods transported by sea

ICAO: International Civil Aviation Organization

IATA: International Air Transport

16.3 Literature References And Sources Of Information:

- ☐ Key information sources used in the preparation of this safety data sheet are as follows.
- ☐ Datasheets for raw materials and product components
- ☐ Regulation and annexes on the preparation and distribution of safety data sheets for dangerous substances and preparations
- ☐ Regulation on Preparation of Safety Data Sheets Regarding Hazardous Substances and Mixtures (13.12.2014- Official Gazette No. 29204) and its annexes
- ☐ UN ADR, IMDG, IATA LISTS
- ☐ ECHA and relevant EU directives, IUCLID (INTERNATIONAL CHEMICAL DATA INFORMATION LEGISLATION), HSDB (DANGEROUS MATERIAL DATA BANK)

16.4 Method/procedure used for categorization and classification of mixtures: Not classified in accordance with Regulation on Classification, Labeling and Packaging of Substances and Mixtures(Official Gazette: 11.12.2013, 28848)

16.5 Full text of H-phrases as mentioned in section 2 and 3:

H319: Causes serious eye irritation.

H318: Causes serious eye damage.

H412: Harmful to aquatic life with long lasting effects.

H315: Causes skin irritation.

H302: Harmful if swallowed.

Safety Data Sheet

Prepared According to Regulation About Preparation of Safety Data Sheet for Hazardous Substance and Mixtures (Official Gazette No. 13.12.2014- 29204)



ONECARE
Barrier Cream Incontinence Wipes
Barrier Cream Incontinence Perineal Cloths
Washcap – Shampoo Cap
Wash Gloves With Barrier Cream

Preparation Date: 23.07.2020
New Issue Date: First Edition
Edition: -

MSDS No:ZD.GBF:699

16.5 Other Informations:

This document has been prepared by the person (s) certified in accordance with the regulation, using the safety data sheets provided by the manufacturer.

Prepared by

Name and Surname: Zeynep DİLEK
Contact Information: zeynep-dilek@outlook.com
Document No: TÜV/11.14.02 - Chemical Assessment Expert

Other informations

Usage and application information are given in the technical prospectus of the products. Details are based on the information we have today and do not express any assurance about the product quality, and any action related to the subject cannot be justified. This Safety Data Sheet prepared for ONECARE Barrier Cream Incontinence Wipes , Barrier Cream Incontinence Perineal Cloths, Wash Gloves with Barrier Cream, Washcap – Shampoo cap product has been prepared on behalf of KAF GRUP SAĞLIK HİZMETLERİ.

Zeynep DİLEK
Sertifika No: 01.85.05