

# **Allergens Statement**

## **Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20**

We declare that,

None of 26 allergens listed in 1223/2009 Regulation has been added to the abovementioned product

FRAGRANCE ALLERGENS (as of EU Regulation 1223/2009 Annex III, No. 67-92, are not present

FOOD ALLERGENS (as of EU Directive 2000/13/EC – as amended -, Annex IIIa, and EU Regulation 1169/2011, Annex II, are not present

This declaration is based to the best of our knowledge about raw materials, process of synthesis and equipment used. We do not perform analysis to evaluate the possible presence of these contaminants in each production lot.

13/12/2022



## **CMR Statement**

# **Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20**

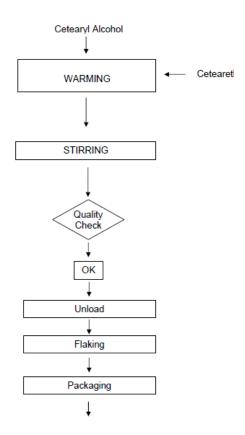
We hereby confirm that Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20 does not contain any Dioxanes or CMR (Carcinogenic, Mutagenic, Toxic to Reproduction) substances as listed according to Regulation (EC) No 1907/2006 of The European Parliament.

13/12/2022



# **Manufacturing Flow Chart**

# **CETEARYL ALCOHOL and CETEARETH-20**



**Primesurf CAC20** 



## **GMO Free Statement**

# **Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20**

Wecan declare and certify that Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20 (INCI: Cetearyl alcohol, Ceteareth-20 is not GMO (Genetically modified organisms) or derivatives of GMO's are not used in the manufacturing process.

13/12/2022



## **INCI & REACH Statement**

# **Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20**

To the best of our knowledge, the components of Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20 are as follows in the table below.

## **INCI Composition**

| INCI             | CAS No     | Composition | REACH Registration |
|------------------|------------|-------------|--------------------|
| Cetearyl Alcohol | 67762-27-0 | ≥ 50%       | 01-2120092297-47-  |
|                  |            |             | XXXX               |
| Ceteareth-20     | 68439-49-6 | ≥10% ≤25 %  | Polymer            |

26/04/2022

#### Revision: 7 June 2021

## SAFETY DATA SHEET

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

#### 1.1 Product identifier

Product Name: Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20
 Chemical Name: Alcohols, C16-18, ethoxylated (>=15 <=25 EO)</li>
 INCI Name: CETEARYL ALCOHOL and CETEARETH - 20

- CAS Number: 68439-49-6

- EC Number:

- REACH Registration Number:

- Synonyms:

- Chemical Description: Cetearyl alcohol (and) Ceteareth-20

## 1.2 Relevant identified uses of the substance or mixture and uses advised against

- Use of the substance/mixture: Industrial auxiliary, For cosmetics and toiletry.

#### 1.3 Details of the supplier of the safety data sheet

Ekokoza s.r.o. Fryčovice 297 73945, Fryčovice eshop@ekokoza.cz +420605779993 IČ:07508247

#### **Emergency telephone number**

Nouzové telefonní číslo: +420224919293 , +420224915402 (telefon 24hod/denně) Toxikologické informační středisko, Na Bojišti 1, 128 08 Praha2)

#### **SECTION 2:** Hazards identification

#### 2.1 Classification of the substance or mixture

- CLP:
- Classification according to EC Regulation Criteria 1272/2008 (CLP)

Eye Irrit. 2

H319 - Causes serious eye irritation.

Adverse physiochemical, human health and environmental effects: No other hazards

#### 2.2 Label elements



- Signal Word: Warning

## **SECTION 2:** Hazards identification (....)

#### 2.2.1 Hazard statements

H319 - Causes serious eye irritation.

## 2.2.2 Precautionary statements

P264 - Wash thoroughly after handling.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P337+P313 - If eye irritation persists: Get medical advice/attention.

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3 Other hazards

- vPvB Substances: None

- PBT Substances: None

## **SECTION 3:** Composition/information on ingredients

#### 3.1 Substances

- Not applicable

#### 3.2 Mixtures

## 3.2.1 Alcohols, C16-18, ethoxylated (>=15<=25 EO)

>= 20% - Alcohols, C16-18, CAS: 68439-49-6 3.3/2 Eye Irrit. 2 H319

#### SECTION 4: First aid measures

## 4.1 Description of first aid measures

#### 4.1.1 Contact with eyes

Wash immediately and thoroughly with running water, keeping eyelids raised, for at least 10 minutes.

Following this: Protect the eyes with a sterile gauze or a clean, dry hankerchief

**OBTAIN A MEDICAL EXAMINATION** 

Protect uninjured eye.

## 4.1.2 Contact with skin

After contact with skin, wash immediately with plenty of soap and water

Wash thoroughly the body (shower or bath)

Remove contaminated clothing immediately and dispose of safely.

## 4.1.3 Ingestion

## **SECTION 4:** First aid measures (....)

Do not induce vomiting. SEEK A MEDICAL EXAMINATION IMMEDIATELY and present the safety-data sheet

Give nothing to eat or drink

#### 4.1.4 Inhalation

Remove casualty to fresh air and keep warm and at rest.

In case of inhalation, consult a doctor immediately and show packaging or label.

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

- None

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

- In case of accident or un-wellness, seek medical advice immediately (show directions for use and safety data sheet if possible).

## **SECTION 5:** Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media: Water, Carbon dioxide (CO2).
- Unsuitable extinguishing media: None in particular

## 5.2 Special hazards arising from the substance or mixture

- Do not inhale explosion and combustion gases. Burning produces heavy smoke.

## 5.3 Advice for firefighters

- Use suitable breathing apparatus
- Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
- Move undamaged containers from immediate hazard area if it can be done safely.

## **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures

- Wear personal protection equipment
- Remove persons to safety
- See protective measures under point 7 and 8

#### 6.2 Environmental precautions

- Do not allow to enter into soil/subsoil.
- Do not allow to enter into surface water or drains
- Retain contaminated washing water and dispose of it.
- In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
- Suitable material for taking up: absorbing material, organic, sand

## SECTION 6: Accidental release measures (....)

#### 6.3 Methods and material for containment and cleaning up

- Wash with plenty of water.

#### 6.4 Reference to other sections

- See also section 8 and 13

## **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

- Avoid contact with skin and eyes, inhalation of vapours and mists.
- Don't use empty container before they have been cleaned.
- Before making transfer operation, assure that there aren't any incompatible material residuals in the containers.
- Contaminated clothing should be changed before entering eating areas.
- Do not eat or drink while working.
- See also section 8 for recommended protective equipment

## 7.2 Conditions for safe storage, including any incompatibilities

- Compatible Materials: Stainless steel, poliethlene, paper
- Avoid temperatures: >70°C °C (melted substance)
- Incompatible materials; None in particular.
- Instructions as regards storage premises: Adequately ventilated premises.

#### 7.3 Specific end use(s)

- See Section 1.2
- None in particular
- See Section 1

## **SECTION 8:** Exposure controls/personal protection

## 8.1 Control parameters

- None

8.1.1 DNEL/DMEL

8.1.2 PNEC

#### 8.2 Exposure controls







## SECTION 8: Exposure controls/personal protection (....)

Eye protection: Eye glassesProtection for skin: Overall

Protection for hands:

Chemicals resistant gloves (EN 374)

The choice of glove material depends not only on the chemical nature of the substance being handled,

but also on the type of exposure and the permeation time of the substance itself.

Chemical resistant and waterproofing gloves compliant with approved standards should always be used when chemicals are handled if the risk assessment indicates the need.

The glove material must be impermeable and resistant to the product / substance / formulation. Ask the supplier for information on the quality of the material and the precise transit time, which must be respected.

Please note that the choice of gloves also depends on quality characteristics that vary from one manufacturer to another.

- Respiratory protection: Not needed for normal use
- Thermal Hazards: None
- Environmental exposure controls: None. Use according to good practises of work
- Appropriate Engineering Controls: None

#### 8.3 Environmental exposure controls

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Appearance: Flakes
Colour: White
Odour: Typical
pH: 6 - 8 sol. 1%
Melting point/Range: C.a 50°C
Boiling Point/Range: >250°C
Flash Point: >125°C
Solubility in water: Dispersible

- Realtive density Not determined
- Decomposition temperature > 200°C

Flammability: N/aRelative Density: N/a

- Upper/lower flammable or explosive limits N/a
- Vapour Pressure: Not applicable

- Vapour Density: N/a

- Partition Coefficient (n-Octanol/Water): N.a

- Auto-Ignition Temperature: N.a

#### 9.2 Other information

- Not determined

## **SECTION 10:** Stability and reactivity

## SECTION 10: Stability and reactivity (....)

#### 10.1 Reactivity

- Stable under normal conditions

#### 10.2 Chemical stability

- Stable under normal conditions

#### 10.3 Possibility of hazardous reactions

- None

#### 10.4 Conditions to avoid

- Stable under normal conditions

#### 10.5 Incompatible materials

- Avoid the contact with powerful oxidising agents

#### 10.6 Hazardous decomposition products

- It may generate irritant/toxic mists/gases

## **SECTION 11:** Toxicological information

## 11.1 Information on toxicological effects

If not differently specified, the information required in Regulation (EU)2015/830 listed below must be considered as N.A.:

Toxicological information of the product:

Primesurf CAC20

**Acute Toxicity** 

Not classified

Based on available data, the classification criteria are not met

## 11.2 Serious eye damage/irritation

serious eye damage/irritation:

The product is classified: Eye Irrit. 2 H319

#### 11.3 Skin corrosion/irritation

Not classified

Based on available data, the classification criteria are not met

#### 11.4 Ingestion

Not classified

Based on available data, the classification criteria are not met

#### 11.5 Inhalation

respiratory or skin sensitisation:

Not classified

Based on available data, the classification criteria are not met

## 11.6 Carcinogenicity

- Not Classified
- Based on available data, the classification criteria are not met.

## **SECTION 11:** Toxicological information (....)

#### 11.7 Germ cell mutagenicity

- Not Classified
- Based on available data, the classification criteria are not met.

#### 11.8 Teratogenicity

- Not Classified
- Based on available data, the classification criteria are not met.

## **SECTION 12:** Ecological information

#### 12.1 Toxicity

Degradability : The product is biodegradable according to OECD methodas to be used in cleaning products as required by Regulation EC N° 648/2004

COD: n.d. CL50 - see below EC50 - see below

- AOX: None
- Heavy Metals: None

Primesurf CAC20

Not classified for environmental hazards

Based on available data, the classification criteria are not met

Alcohols, C16-18, ethoxylated (> = 15 - < = 25 EO) - CAS: 68439-49-6

a) Aquatic acute toxicity:

- LC50 (Carassius Auratus) (96h) 100 mg/l
- EC50 (Daphnia) (48h) (100mg/l)

#### 12.2 Persistence and degradability

Biodegradability: Readily biodegradable - Test: Method OECD 301 - Duration: 28d > - %: 60 -

Notes: Read Across

Alcohols, C16-18, ethoxylated (> = 15 - < = 25 EO) - CAS: 68439-49-6

Biodegradability: Not persistent and Biodegradable - Test: N.A. - Duration: 28d > - %: 60 -

Notes: Easily biodegradable

#### 12.3 Bioaccumulative potential

- Not determined

#### 12.4 Mobility in soil

- Not determined

#### 12.5 Results of PBT and vPvB assessment

- No data

#### 12.6 Other adverse effects

- None

#### **SECTION 13:** Disposal considerations

#### 13.1 Waste treatment methods

- Avoid release to the environment. Refer to special instructions/Safety data sheets
- Disposal should be in accordance with local, state or national legislation
- Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

#### **SECTION 14:** Transport information

#### 14.1 UN number or ID number

- UN No.: Not classified as dangerous in the meaning of transport regulations.

#### 14.2 UN proper shipping name

- Proper Shipping Name: Not applicable

#### 14.3 Transport hazard class(es)

- Hazard Class: Not applicable

#### 14.4 Packing group

- Packing Group: Not applicable

#### 14.5 Environmental hazards

- Not applicable

#### 14.6 Special precautions for user

- Not applicable

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- Not applicable

## **SECTION 15:** Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) 2015/830

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC)

## **SECTION 15:** Regulatory information (....)

1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions:

Directive 2012/18/EU (Seveso III)

Regulation (EC) nr 648/2004 (detergents).

Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

#### 15.2 Chemical safety assessment

- No

#### **SECTION 16:** Other information

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. The data do not describe the product's properties (product specification). Neither should any agreed property nor the suitability of the product for any specific purpose be deduced from the data contained in the safety data sheet. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

--- end of safety datasheet ---

## **Product Specification**

## **CETEARYL ALCOHOL and CETEARETH-20**

INCI: CETEARYL ALCOHOL and CETEARETH-20

Description: Blend of fatty alcohol C 16-C 18 and fatty alcohol

ethoxylated CAS number: 67762-27-0 and 68439-49-6

EC number: 267-008-6 and Polymer

| INCI             | Composition | CAS number | EC number |
|------------------|-------------|------------|-----------|
| CETEARYL ALCOHOL | ≥ 50%       | 67762-27-0 | 267-008-6 |
| CETEARETH-20     | ≥10% ≤25 %  | 68439-49-6 | Polymer   |

| Test parameter       | Unit     | Specification |
|----------------------|----------|---------------|
| Appearance at 25°C   |          | flakes        |
| Colour               |          | white         |
| Water (K.F)          | %        | 1 max         |
| Amine value          | mg KOH/g | 0.5 max       |
| Acid number          | mg KOH/g | 0.5 max       |
| Hydroxyl number      | mg KOH/g | 170 – 185     |
| Saponification value |          | 1 max         |
| PH water sol. 5%     |          | 5-7           |

## **Additional information**

Dropping point 48 - 53°C

Raw material basis Vegetable (coconut/palm kernel/palm oil)

Petrochemical (ethylene oxide)

Self-emulsifying base for cosmetic

preparations

Issue: 4 HL ISSUE DATE: 08/02/2023

## Storage, packaging and handling

## **Storage temperature**

0 - +30 °C, in original sealed packing and protect from moisture

## **Shelf life**

24 months

## **Additional Notes**

| Note                    | Information   |
|-------------------------|---|
| Allergens               | None of 26 allergens listed in 1223/2009 Regulation has   |
| _                       | been added to above mentioned product   |
| Animal testing          | Following Art. 18 of Cosmetic Regulation (EC) N°  |
|                         | 1223/2009 indication, the product has never been  |
|                         | tested by the product has never been tested by Prime  |
|                         | Surfactants Ltd on animal nor has anyone been   |
|                         | Commissioned by Prime Surfactants Ltd to test this  |
|                         | product on animals  |
| Antioxidants            | Not present   |
| BSE                     | Free  |
| CMR                     | The product contains CMR substances, categories 1 A, 1 B or 2 as defined in Regulation (EC) N° 1272/2008 part 3, Annex VI and in Cosmetic Regulation (EC) N° 1223/2009. Standard values: Ethylene Oxide < 1 ppm 1,4 Dioxane < 5 |
|                         | ppm (not checked on each product lots)  |
|                         | Technically unavoidable CMR impurities resulting from   |
|                         | our qualified manufacturing process (alkoxylation)  |
| Ethanol                 | Free  |
| Microplastic            | Free  |
| GMO                     | Free  |
| Heavy metals            | Meets the legal requirement Max 10 ppm  |
| Lactose, latex & gluten | Free  |
| Nano material           | The product is free from Nano material as defined in Art. 2 (K) and Art. 16 of Cosmetic Regulation (EC) N° 1223/2009  |
| Pesticides              | Based on our actual knowledge we do not expect  |
|                         | pesticides to be present  |
| Phthalates              | Based on our actual knowledge we do not expect phthalates to be present   |
| Polycyclic aromatic     | Based on our actual knowledge we do not expect  |
| hydrocarbons            | polycyclic aromatic hydrocarbons to be present  |
| Preservatives           | Not present   |
| Solvents                | Not present   |
| SVHC                    | Not present not present above 0,1% concentration limit  |

# **Vegan and Vegetarian Statement**

# **Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20**

We declare and certify that Emulsifying Wax Cetearyl Alcohol/ Ceteareth 20 product is derived from vegetal and petrochemical and is free from animal, animal part or derivatives, therefore our product is suitable for vegan-vegetarians.

26/03/2022