

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 12.08.2019

Version number 2

Revision: 12.08.2019

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

- **1.1 Product identifier**
- **Trade name:** Weleda WHITE MALLOW Nappy Change Cream
- **Article number:**
00966500 Weiße Malve Babycreme
009665CH Weiße Malve Babycreme
009665EN Weiße Malve Babycreme
009665F0 Weiße Malve Babycreme
009665SI Weiße Malve Babycreme
009665UE Weiße Malve Babycreme
009665US Weiße Malve Babycreme
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No data available.
- **Application of the substance / the mixture** Cosmetic Product
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Weleda AG, Schwäbisch Gmünd,
Zweigniederlassung der Weleda A.G. Arlesheim/Schweiz
Möhlerstraße 3
73525 Schwäbisch Gmünd
- **Telefon:** ++49 7171 919 0
Internet: www.weleda.de
- **Further information obtainable from:**
Gefahrstoffmanagement D; E-mail: MSDS@weleda.de; Telefon: ++49 71719198148
- **1.4 Emergency telephone number:**
Poisoning information head office Freiburg tel: +49 (0) 761/19240

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements** The finished product is exempted from the CLP labeling requirement.
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS09

- **Signal word** Void
- **Hazard statements**
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
P391 Collect spillage.
- **Additional information:**
When used as intended, the product is safe and compatible in accordance with the legal requirements (Article 3 of the EC Cosmetics Regulation). The following information is in case of misuse or accident or, if required, for commercial use.

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1314-13-2	zinc oxide	≥10-<25%
EINECS: 215-222-5	⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
Index number: 030-013-00-7		

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Rinse with warm water.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
 - Do not induce vomiting
 - Rinse mouth.
 - possibly consult poison center or a physician.
 - In case of babies/infants always consult a poison center or a physician.
- **4.2 Most important symptoms and effects, both acute and delayed**
 - No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
 - No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
 - Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
 - Hazardous vapours may form during fires.
- **5.3 Advice for firefighters**
 - Do not allow water used to extinguish fire to enter surface or ground water.
 - The product is combustible.
- **Protective equipment:** Wear protective equipment. Keep unprotected persons away.
- **Additional information**
 - The hazards caused by the preparation related to the bulk. In the dosage form the deal and the dosage should be noted, according to leaflet.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
 - Particular danger of slipping on leaked/spilled product.
 - The danger zones must be cordoned off and marked with appropriate warning and safety signs.
 - Vacating danger area.
 - Adhering to specifications of the emergency plan.

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- Well-informed contact.
- **6.2 Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
Avoid release to the environment
 - **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Do not flush with water or aqueous cleansing agents
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 - **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.
The hazards caused by the preparation related to the bulk. In the dosage form the deal and the dosage should be noted, according to leaflet.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
No special precautions are necessary if used correctly.
It's essential to apply the instructions of the manufacturer.
- **Information about fire - and explosion protection:** The product is combustible.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
The basic requirements for the storage of hazardous materials are observed.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
The hazards caused by the preparation related to the bulk. In the dosage form the deal and the dosage should be noted, according to leaflet.
Store in a well-ventilated place. Keep container tightly closed.
- **Storage class:** 11
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
Limiting exposure must be done in the following gradation: substitution > technical / organizational measures > personal protective equipment.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

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Due to missing tests no recommendation to the glove material can be given for the product/ the mixture/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• **Material of gloves**

The protective gloves to be used must represent the specifications of following prescriptions:

- EC guideline 89/686/ EEC
- norm EN374

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

• **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• **Eye protection:** Goggles recommended during refilling

• **Body protection:**

Body protective substances are and-mix job specifically to select in her execution into dependence of hazardous materials concentrations. The chemical resistance of the protective substances should be clarified with the supplier.

SECTION 9: Physical and chemical properties

• **9.1 Information on basic physical and chemical properties**

• **General Information**

• **Appearance:**

Form:	Pasty
Colour:	Yellowish-white
Odour:	like honey
Odour threshold:	Not determined.

• **pH-value:** Not applicable.

• **Change in condition**

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.

• **Flash point:** Not applicable.

• **Flammability (solid, gas):** Not determined.

• **Decomposition temperature:** Not determined.

• **Auto-ignition temperature:** Product is not selfigniting.

• **Explosive properties:** Product does not present an explosion hazard.

• **Explosion limits:**

Lower:	Not applicable.
Upper:	Not applicable.

• **Vapour pressure:** Not applicable.

Density at 20 °C:	1.021 g/cm ³
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

• **Solubility in / Miscibility with water:** Insoluble.

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- **Partition coefficient: n-octanol/water:** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Heating up strongly.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** See chapter 5.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
The classification was carried out for tested properties according to legal classifications Anh VI Tables 3.1 and 3.2 of the CLP Regulation ("EC-List"), otherwise according to the regulation (EC) No. 1272/2008.

1314-13-2 zinc oxide

Oral LD50 >2,000 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Other information (about experimental toxicology):**
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.
- **Additional toxicological information:**
The hazards caused by the preparation related to the bulk. In the dosage form the deal and the dosage should be noted, according to leaflet.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.

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- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
The hazards caused by the preparation related to the bulk. In the dosage form the deal and the dosage should be noted, according to leaflet.
Toxic to aquatic life with long lasting effects.
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Dispose of waste according to applicable legislation.
The product must be disposed of according to Waste Directive 2008/98/EC, as well as national and regional regulations.
Disposal instructions refer to the Bulk. Common household quantities can be disposed together with household garbage.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|---------------------------------------|
| · 14.1 UN-Number | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | ENVIRONMENTALLY HAZARDOUS |
| · ADR | SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| · ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 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. |

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- | | |
|--|--|
| · Transport/Additional information: | Exemption of dangerous goods by implementation of the following special provisions: ADR: 375
IMDG-Code: 969 IATA-DGR A197 |
| · UN "Model Regulation": | UN 3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9,
III |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** E2 Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The finished product is subject to the legislation for cosmetics in the EU. Warnings and application conditions are observed. Regulation (EC) No 1907/2006 is not applicable to the finished product intended for consumers. All figures relate to the professional user of the product unwrapped and used for distribution of information under Article 32.

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- **Relevant phrases**
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **Department issuing SDS:**
WELEDA management of hazardous substances | Tel. +49 (0)7171/919231| e-mail: MSDS@weleda.de
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- **Sources**
The classification was carried out for tested properties according to legal classifications Anh VI Tables 3.1 and 3.2 of the CLP Regulation ("EC-List"), otherwise according to the regulation (EC) No. 1272/2008.
- *** Data compared to the previous version altered.**