



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

Printing date 04.02.2020

Version number 5

Revision: 04.02.2020

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

- **1.1 Product identifier**
- **Trade name: OtoVita Cleaning Spray**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
For the external care and disinfection of earmoulds and hearing aids
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dreve Otoplastik GmbH  
Max-Planck-Straße 31  
59423 Unna / Germany  
Tel.: ++49 2303 / 8807-0  
Fax.: ++49 2303 / 8807-29
- **Further information obtainable from:**  
Department Research & Development  
Fax: ++49 2303 / 8807-562  
Email: sicherheitsdatenblatt@dreve.de
- **1.4 Emergency telephone number:**  
Tel.: ++ 49 211 / 797-3350  
Plant Fire Department Henkel

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements**  
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
P101 If medical advice is needed, have product container or label at hand.  
P102 Keep out of reach of children.  
P103 Read label before use.  
P273 Avoid release to the environment.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
According to Regulation (EC) No 648/2004 on detergents the following substances have to be listed:  
Flavour / Perfume oil (< 0,1%)  
Nonionic Tenside (≤ 0,2%)
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 7173-51-5 EINECS: 230-525-2	didecyldimethylammonium chloride ⚠ Flam. Liq. 3, H226; ⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≤1%
CAS: 2372-82-9 EINECS: 219-145-8	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine ⚠ Acute Tox. 3, H301; ⚠ STOT RE 2, H373; ⚠ Skin Corr. 1A, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≤1%
CAS: 98246-84-5	Guanidin, N,N"-1,3-Propandiylbis-, N-Kokos-alkylderivat ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302	≤1%

- **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:** Generally the product does not irritate the skin.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Do not induce vomiting.  
Call a doctor immediately.
- **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:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid contact with skin and eyes.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Dilute with plenty of water.

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- Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**  
No dangerous substances are released.  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Avoid contact with skin and eyes.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Keep container tightly sealed.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves** Not applicable.
- **Penetration time of glove material** Not applicable.
- **Eye protection:** Goggles recommended during refilling
- **Body protection:** Protective work clothing

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Fluid
Colour:	Colourless
Odour:	Fruity-fresh
Odour threshold:	Not determined.
- **pH-value:** Not determined.

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· <b>Change in condition</b> Melting point/freezing point: Undetermined. Initial boiling point and boiling range: 100 °C	
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b> Lower: Not determined. Upper: Not determined.	
· <b>Oxidising properties</b>	Not determined Not applicable.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density at 20 °C:</b>	1.0 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b> Dynamic: Not determined. Kinematic: Not determined.	
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No dangerous reactions if used according to specifications.
- **10.2 Chemical stability** Stable if used according to specifications.
- **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** No further relevant information available.
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.

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- **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.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
Harmful to aquatic organisms
- **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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
Disposal must be made according to official regulations.
- |                                   |          |
|-----------------------------------|----------|
| · <b>European waste catalogue</b> |          |
| HP14                              | Ecotoxic |
- **Uncleaned packaging:**
  - **Recommendation:** Disposal must be made according to official regulations.
  - **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

- |                                       |      |
|---------------------------------------|------|
| · <b>14.1 UN-Number</b>               | Void |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |
| · <b>14.2 UN proper shipping name</b> | Void |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void |

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- |  |                 |
|--|-----------------|
| <b>· 14.3 Transport hazard class(es)</b>   |                 |
| <b>· ADR, ADN, IMDG, IATA</b>  |                 |
| <b>· Class</b>   | Void            |
| <b>· 14.4 Packing group</b>  |                 |
| <b>· ADR, IMDG, IATA</b>   | Void            |
| <b>· 14.5 Environmental hazards:</b>   |                 |
| <b>· Marine pollutant:</b>   | No              |
| <b>· 14.6 Special precautions for user</b>                                       | Not applicable. |
| <b>· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| <b>· UN "Model Regulation":</b>  | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
- **Labelling according to Regulation (EC) No 1272/2008 GHS label elements**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

<b>· Regulation (EU) No 649/2012</b>		
7173-51-5	didecyldimethylammonium chloride	Annex I Part 1

- **National regulations:**
- **Technical instructions (air):**

Class	Share in %
NK	≤2.5

- **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.

- **Relevant phrases**  
H226 Flammable liquid and vapour.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.
- **Department issuing SDS:** Department Research & Development
- **Contact:** Dr. Thomas Veit, Lothar Sutor, Susanne Langesberg

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• **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 4: Acute toxicity - oral – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

• **\* Data compared to the previous version altered.**

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