



Trade name: OtoVita OtoVita Cleaning Tissues

Substance number: 71201

Version: 1 / GB

Date revised: 31.07.2023

Replaces Version: - / GB

Print date: 31.07.2023

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

1.1. Product identifier

OtoVita OtoVita Cleaning Tissues

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

Use of the substance/preparation

Disinfectant of earmolds

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Dreve Otoplastik GmbH

Max-Planck-Straße 31

59423 Unna

Telephone no. +49 2303 8807-0

Fax no. +49 2303 8807-29

Information provided by / telephone Department Research & Development: Fax: +49 2303 8807-562

E-mail address of person responsible sicherheitsdatenblatt@dreve.de

for this SDS

1.4. Emergency telephone number

Henkel Fire Department / 24h-Emergency-Contact-No.: +49 211 797-3350

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Aquatic Chronic 3 H412

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008

For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P501.1 Dispose of contents/container to industrial incineration plant.

2.3. Other hazards

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product



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does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients

Didecyldimethylammonium chloride

CAS No. 7173-51-5
 EINECS no. 230-525-2
 Registration no. 01-2119945987-15
 Concentration $\geq 0,1$ < 1 %
 Classification (Regulation (EC) No. 1272/2008)
 Acute Tox. 3 H301
 Skin Corr. 1B H314
 Aquatic Acute 1 H400
 Aquatic Chronic 2 H411

Concentration limits (Regulation (EC) No. 1272/2008)
 Aquatic Acute 1 H400 M = 10
 ATE oral 238 mg/kg

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

CAS No. 2372-82-9
 EINECS no. 219-145-8
 Registration no. 01-2119980592-29
 Concentration $\geq 0,1$ < 0,25 %
 Classification (Regulation (EC) No. 1272/2008)
 Acute Tox. 3 H301
 Skin Corr. 1B H314
 STOT RE 2 H373
 Aquatic Acute 1 H400
 Aquatic Chronic 1 H410
 Route of exposure: oral

Concentration limits (Regulation (EC) No. 1272/2008)
 Aquatic Acute 1 H400 M = 10
 Aquatic Chronic 1 H410 M = 1
 1
 ATE oral 261 mg/kg

Guanidine, N,N''-1,3-Propanediylbis-, N-cocos alkyl derivatives

CAS No. 98246-84-5
 EINECS no. 308-757-1
 Registration no. 01-2120761537-47
 Concentration $\geq 0,1$ < 0,25 %
 Classification (Regulation (EC) No. 1272/2008)
 Skin Corr. 1C H314
 Eye Dam. 1 H318
 Aquatic Acute 1 H400
 Aquatic Chronic 1 H410
 Acute Tox. 4 H302

Other information

Accordinging Regulation on detergents (EC) No 648/2004 following substances shall be listed: non-ionic



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surfactants, perfumes: < 5,0%

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of persistent symptoms consult doctor.

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Do not induce vomiting. Summon a doctor immediately.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

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

Until now no symptoms known so far.

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

Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up



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Pick up with absorbent material. Clean contaminated floors and objects thoroughly, observing environmental regulations. Dispose of as prescribed.

6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation if necessary).

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Further information on storage conditions

Keep container tightly closed and dry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Other information

Contains no substances with occupational exposure limit values.

Derived No/Minimal Effect Levels (DNEL/DMEL)

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0,91	mg/kg

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	2,35	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Route of exposure	dermal	
Concentration	0,54	mg/kg

Type of value	Derived No Effect Level (DNEL)	
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Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	0,7	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Concentration	0,2	mg/kg

Didcyldimethylammonium chloride

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	5,39	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	5,39	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	1,55	mg/kg

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Acute	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	1,55	mg/kg

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivates

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	0,88	mg/m ³

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	1	mg/kg

Predicted No Effect Concentration (PNEC)

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N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

Type of value	PNEC		
Type	Freshwater		
Concentration	0,001		mg/l
Type of value	PNEC		
Type	Soil		
Concentration	45,34		mg/kg
Type of value	PNEC		
Type	Marine sediment		
Concentration	0,85		mg/kg
Type of value	PNEC		
Type	Freshwater sediment		
Concentration	8,5		mg/kg
Type of value	PNEC		
Type	Sewage treatment plant (STP)		
Concentration	1,33		mg/l
Type of value	PNEC		
Type	Water (intermittent release)		
Concentration	0		mg/l
Type of value	PNEC		
Type	Marine		
Concentration	0		mg/l

Didecyldimethylammonium chloride

Type of value	PNEC		
Type	Freshwater		
Concentration	0,002		mg/l
Type of value	PNEC		
Type	Marine		
Concentration	0,0002		mg/l
Type of value	PNEC		
Type	Freshwater sediment		
Concentration	2,82		mg/kg
Type of value	PNEC		
Type	Marine sediment		
Concentration	0,28		mg/kg
Type of value	PNEC		
Type	Sewage treatment plant (STP)		
Concentration	0,595		mg/l
Type of value	PNEC		
Type	Soil		
Concentration	1,4		mg/kg

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivates

Type of value PNEC



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Type	Freshwater	
Concentration	0,0004	mg/l
Type of value	PNEC	
Type	Saltwater	
Concentration	0,00004	mg/l
Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	1	mg/l
Type of value	PNEC	
Type	Sediment	
Concentration	10	mg/kg
Type of value	PNEC	
Type	Marine sediment	
Concentration	1	mg/kg
Type of value	PNEC	
Type	Soil	
Concentration	3,7	mg/kg

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals.

Respiratory protection

Not necessary, but do not inhale vapours.

Hand protection

Not necessary.

Eye protection

Safety glasses

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid on inert carrier material	
Colour	colourless	
Odour	fruity	
Melting point		
Remarks	not determined	
Freezing point		
Remarks	not determined	
Boiling point or initial boiling point and boiling range		
Value	100	°C
Flammability		
evaluation	not determined	



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Upper and lower explosive limits

Remarks not determined

Flash point

Remarks Not applicable

Ignition temperature

Remarks not determined

Decomposition temperature

Remarks not determined

pH valueValue 9,34
Temperature 20 °C**Viscosity**

Remarks not determined

Solubility(ies)

Remarks not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure

Remarks not determined

Density and/or relative densityValue 1,0 g/cm³
Temperature 20 °C**Relative vapour density**

Remarks not determined

9.2. Other information**Odour threshold**

Remarks not determined

Evaporation rate (ether = 1) :

Remarks not determined

Solubility in water

Remarks Completely miscible

Explosive properties

evaluation not determined

Oxidising properties

Remarks not determined

Other information

None known

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

No hazardous reactions known.

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10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**Acute oral toxicity**

ATE	>	10.000	mg/kg
Method	calculated value (Regulation (EC) No. 1272/2008)		

Acute oral toxicity (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine**

Species	rat		
LD50	261		mg/kg
Method	OECD 401		

Didecyldimethylammonium chloride

Species	rat		
LD50	238		mg/kg
Method	OECD 401		
Source	Manufacturer's data		

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivates

Species	rat		
LD50	500	to	2000 mg/kg
Method	OECD 401		

Acute dermal toxicity

Remarks Based on available data, the classification criteria are not met.

Acute dermal toxicity (Components)**Didecyldimethylammonium chloride**

Species	rabbit		
LD50	>	3342	mg/kg
Source	Manufacturer's data		

Acute inhalational toxicity

Remarks Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Remarks Based on available data, the classification criteria are not met.

Skin corrosion/irritation (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine**

Species	rabbit		
evaluation	corrosive		
Method	OECD 404		

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

Species	Human		
evaluation	corrosive		



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Didecyldimethylammonium chloride

Species	rabbit
evaluation	corrosive
Method	OECD 404

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivatives

Species	rabbit
evaluation	corrosive
Method	OECD 404

Serious eye damage/irritation

Remarks	Based on available data, the classification criteria are not met.
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Serious eye damage/irritation (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine**

evaluation	corrosive
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Didecyldimethylammonium chloride

Species	rabbit
evaluation	corrosive

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivatives

Species	rabbit
evaluation	strongly irritant
Method	OECD 405

Sensitization

Remarks	Based on available data, the classification criteria are not met.
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Subacute, subchronic, chronic toxicity

Remarks	not determined
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Mutagenicity

Remarks	Based on available data, the classification criteria are not met.
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Reproductive toxicity

Remarks	Based on available data, the classification criteria are not met.
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Carcinogenicity

Remarks	Based on available data, the classification criteria are not met.
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Specific Target Organ Toxicity (STOT)**Single exposure**

Remarks	Based on available data, the classification criteria are not met.
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Repeated exposure

Remarks	Based on available data, the classification criteria are not met.
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Specific Target Organ Toxicity (STOT) (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine****Repeated exposure**

evaluation	May cause damage to organs through prolonged or repeated exposure
	Route of exposure oral

Species	rat
NOAEL	4 mg/kg

Aspiration hazard

Remarks	Based on available data, the classification criteria are not met.
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11.2 Information on other hazards**Endocrine disrupting properties with respect to humans**

Remarks	The product does not contain a substance that has endocrine disrupting properties with respect to
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humans.

Other information

No toxicological data are available.

SECTION 12: Ecological information

12.1. Toxicity**General information**

not determined

Fish toxicity (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine**

Species	zebra fish (Brachydanio rerio)	
LC50	0,431	mg/l
Method	OECD 203	

Didecyldimethylammonium chloride

LC50	0,49		mg/l
Duration of exposure	96	h	
Method	OECD 203		

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivatives

Species	Zebrabaerbling	
LC50	0,707	mg/l
Duration of exposure	96	h
Method	OECD 203	

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivatives

Species	Zebrabaerbling	
NOEC	0,125	mg/l
Duration of exposure	9	d
Method	OECD 212	

Daphnia toxicity (Components)**N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine**

Species	Daphnia magna	
EC50	0,077	mg/l
Duration of exposure	48	h
Method	OECD 202	

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

Species	Daphnia magna	
NOEC	0,024	mg/l
Duration of exposure	21	d
Method	OECD 211	

Didecyldimethylammonium chloride

LC50	0,029		mg/l
Duration of exposure	48	h	
Method	OECD 211		

Didecyldimethylammonium chloride

NOEC	0,021		mg/l
Method	OECD 211		

Guanidine, N,N"-1,3-Propanediylbis-, N-cocos alkyl derivatives

Species	Daphnia magna	
EC50	0,058	mg/l
Duration of exposure	48	h

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Method	OECD 202	
Guanidine, N,N''-1,3-Propanediylbis-, N-cocos alkyl derivatives		
Species	Daphnia magna	
NOEC	0,025	mg/l
Duration of exposure	21 d	

Algae toxicity (Components)

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine		
Species	Scenedesmus subspicatus	
EC10	0,012	mg/l
Duration of exposure	72 h	
Method	OECD 201	

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine		
Species	Pseudokirchneriella subcapitata	
ErC50	0,015	mg/l
Duration of exposure	72 h	
Method	OECD 201	

Didecyldimethylammonium chloride		
Species	Pseudokirchneriella subcapitata	
EC50	0,062	mg/l
Duration of exposure	72 h	

Guanidine, N,N''-1,3-Propanediylbis-, N-cocos alkyl derivatives		
Species	Scenedesmus subspicatus	
EC50	0,0197	mg/l
Duration of exposure	72 h	
Method	OECD 201	

Bacteria toxicity (Components)

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine		
Species	activated sludge	
EC50	18	mg/l
Duration of exposure	3 h	
Method	OECD 209	

Didecyldimethylammonium chloride		
Species	activated sludge	
NOEC	5,95	mg/l
Method	OECD 209	

Guanidine, N,N''-1,3-Propanediylbis-, N-cocos alkyl derivatives		
Species	activated sludge	
EC50	28,4	mg/l
Method	OECD 209	

12.2. Persistence and degradability**General information**

not determined

Ready degradability (Components)

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine		
Value	79	%
Duration of test	28 d	
Method	Sewage water systeme	

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine		
Value	68	%
Duration of test	28 d	

Didecyldimethylammonium chloride



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12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Octanol/water partition coefficient (log Pow) (Components)

N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine

log Pow 4,46

Guanidine, N,N''-1,3-Propanediylbis-, N-cocos alkyl derivates

log Pow 3,6

Temperature 20 °C

Method Regulation (EC) No. 440/2008, Annex, A.8

12.4. Mobility in soil

General information

not determined

12.5. Results of PBT and vPvB assessment

General information

not determined

Results of PBT and vPvB assessment

The product contains no PBT substances

The product contains no vPvB substances.

12.6 Endocrine disrupting properties

Endocrine disrupting properties with respect to the environment

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects

General information

not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

Must not be disposed together with household garbage.

Dispose of waste according to applicable legislation.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

SECTION 14: Transport information



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	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper shipping name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-

SECTION 15: Regulatory information

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification (Regulation (EC) No. 1272/2008)

Aquatic Chronic 3

H412

Calculation method

Hazard statements listed in Chapter 2/3

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious 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.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

CLP categories listed in Chapter 2/3

Acute Tox. 3	Acute toxicity, Category 3
Acute Tox. 4	Acute toxicity, Category 4
Aquatic Acute 1	Hazardous to the aquatic environment, acute, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic, Category 3
Eye Dam. 1	Serious eye damage, Category 1
Skin Corr. 1B	Skin corrosion, Category 1B
Skin Corr. 1C	Skin corrosion, Category 1C
STOT RE 2	Specific target organ toxicity - repeated exposure, Category 2

Supplemental information



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Relevant changes compared with the previous version of the safety data sheet are marked with: ***
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.