

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Date of issue: 17.05.2023 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Product name : Kamistad Mouth Spray
Product code : 2069 SI 103

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

1.2.1. Relevant identified uses

Intended for general public
Main use category : Consumer use
Use of the substance/mixture : Cosmetic product for the gentle care of the oral mucosa and gums.

1.2.2. Uses advised against

Restrictions on use : Anything other than the above

1.3. Details of the supplier of the safety data sheet

STADA Arzneimittel AG
Stadastraße 2-18
61118 Bad Vilbel
Telephone: 06101 603-0
Email: info@stada.de

1.4. Emergency telephone number

Emergency number : +49 6101 603 153 - German and English language (9:00 – 16:00, Monday - Friday)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Eye Irrit. 2 H319
Full text of hazard classes, H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning
Hazard statements (CLP) : H319 - Causes serious eye irritation.
Precautionary statements (CLP) : P102 - Keep out of reach of children.
P264 - Wash hands thoroughly after handling.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P501 - Dispose of contents/container to an authorised waste collection point.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-	CAS-No.: 9002-92-0	1 - 2	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 Aquatic Chronic 3, H412

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Use personal protective equipment as required. If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Not expected to present a significant hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person.

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

Symptoms/effects after eye contact	: Causes eye irritation.
------------------------------------	--------------------------

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a water jet since it may cause the fire to spread.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not flammable.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂).

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Move containers from fire area if you can do it without risk. Exercise caution when fighting any chemical fire. Avoid fire-fighting water entering the environment.
- Protection during firefighting : As in any fire, wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate area. Avoid contact with eyes.

6.1.2. For emergency responders

- Emergency procedures : Ventilate area. Avoid contact with eyes.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Flush area with water. Absorb and/or contain spill with inert material, then place in suitable container.

6.4. Reference to other sections

SECTION 8: Exposure controls/personal protection. SECTION 13: Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Use good personal hygiene practices. Avoid contact with eyes.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep out of direct sunlight. Keep out of reach of children.
- Incompatible materials : Strong acids. Strong oxidising agents.

7.3. Specific end use(s)

Cosmetic product for the gentle care of the oral mucosa and gums.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

8.1.4. DNEL and PNEC

L-menthol (2216-51-5)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	10 mg/m ³
Long-term - systemic effects, dermal	19 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	132 mg/m ³
Long-term - local effects, inhalation	10 mg/m ³
DNEL/DMEL (General population)	
Long-term - systemic effects, oral	9,4 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	33 mg/m ³
Long-term - systemic effects, dermal	9,4 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	15,6 µg/l
PNEC aqua (marine water)	1,56 µg/l
PNEC aqua (intermittent, freshwater)	156 µg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	289 µg/kg dw
PNEC sediment (marine water)	28,9 µg/kg dw
PNEC (Soil)	
PNEC soil	48,4 µg/kg dw
PNEC (Oral)	
PNEC oral (secondary poisoning)	83,3 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	2,37 mg/l
Citric acid, monohydrate (5949-29-1)	
PNEC (Water)	
PNEC aqua (freshwater)	0,44 mg/l
PNEC aqua (marine water)	0,044 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	3,46 mg/kg dw
PNEC sediment (marine water)	34,6 mg/kg dw
PNEC (Soil)	
PNEC soil	33,1 mg/kg dw
PNEC (STP)	
PNEC sewage treatment plant	> 1000 mg/l

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No additional information available

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

8.2.2. Personal protection equipment

Personal protective equipment:

Not required for normal conditions of use.

8.2.2.1. Eye and face protection

Eye protection:

None under normal use

8.2.2.2. Skin protection

Skin and body protection:

None under normal use

Hand protection:

None under normal use

8.2.2.3. Respiratory protection

Respiratory protection:

None under normal use

8.2.2.4. Thermal hazards

Thermal hazard protection:

Not required for normal conditions of use.

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellow. Clear.
Odour	: Chamomile.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability (solid, gas)	: Not available
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 6,2 – 6,8
Viscosity, kinematic	: Not available
Solubility	: Not available
Log Kow	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: 1,01 – 1,04
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under recommended handling and storage conditions (see section 7).

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Keep away from heat. Direct sunlight.

10.5. Incompatible materials

Strong acids. Strong oxidising agents.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: 6,2 – 6,8
Serious eye damage/irritation	: Causes serious eye irritation. pH: 6,2 – 6,8
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %
--	--

11.2.2. Other information

Potential adverse human health effects and symptoms	: Causes eye irritation
---	-------------------------

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Kamistad Mouth Spray

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not regulated
UN-No. (IMDG) : Not regulated
UN-No. (IATA) : Not regulated
UN-No. (ADN) : Not regulated
UN-No. (RID) : Not regulated

14.2. UN proper shipping name

Proper Shipping Name : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
Proper Shipping Name (ADN) : Not regulated

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Proper Shipping Name (RID) : Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

ADN

Transport hazard class(es) (ADN) : Not regulated

RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

Packing group : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

Packing group (RID) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)

Reference code	Applicable on	Entry title or description
3(b)	Kamistad Mouth Spray	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	: Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	: WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Storage class (LGK, TRGS 510)	: LGK 12 - Non-combustible liquids.
Hazardous Incident Ordinance (12. BImSchV)	: Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

	ADR (Accord européen relatif au transport international des marchandises Dangereuses par Route)
	CAS (Chemical Abstracts Service) number
	CLP (Classification, Labeling and Packaging)
	DNEL (Derived No Effect Level)
	EC (European Community)

Kamistad Mouth Spray

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Abbreviations and acronyms:

	IATA (International Air Transport Association)
	IMDG (International Maritime Dangerous Goods Code)
	OEL (Occupational exposure limit)
	PBT (Persistent, Bioaccumulative and Toxic)
	PNEC (Predicted No Effect Concentration)
	REACH (Registration, Evaluation and Authorisation of Chemicals)
	UNxxxx (Number assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods)
	vPvB (very Persistent and very Bioaccumulative)

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier's safety documents. ECHA (European Chemicals Agency).
Other information	: Classification procedure according to Regulation (EC) No. 1272/2008 [CLP]: Physical hazards: On basis of test data. Health hazards: On basis of test data. Environmental hazards: On basis of test data.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.