

Safety data sheet in accordance with regulation (EC) no. 1907/2006 (amended by regulation (EU) Nr. 453/2010)

Date of issue: 23.04.2015
Date of revision: 29.12.20
Valid from: 29.12.20
Version: 5

Aqua Spacer – water removable die spacer
- CAD/CAM spacer

Replaces version: 4 „A“, „B“
03-4110, 03-4120

Section 1: Identification of the substance/mixture and of the company

1.1 Product Identifier

Substances: ethanol
Index-no.: 603-002-00-5
EG-no.: 200-578-6
CAS-no.: 64-17-5
REACH-registration no.: void

Other means or identification: not determined

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

Relevant identified uses:

SU 20 health care. Water removable spacer for pressable ceramics/CAD-CAM - for use in dental labs

Uses advised against:

Should not be used outside a dental lab.

1.3 Details of the supplier of the safety data sheet

Supplier:

al dente Dentalprodukte GmbH

Street:

Borsigstr. 1

Address / zip-code / town:

D-38644 Goslar

Information contact:

+49 (0) 5321-80031

Phone / Fax / Email:

+49 (0)5321-80031 / +49 (0)5321-50881 / E-Mail: info@aldente.de

1.4 Emergency Telephone Number:

+49 (0) 171 8637790

Section 2: Hazards identification:

2.1 Classification of the substance or mixture:

Classification according to regulation (EC) no. 1272/2008 (CLP)
Flammable liquids (chapter 2.6), category 2 (Flam. Liq. 2), H225,
Eye irritation (chapter 3.3), category 2 (Eye Irrit. 2), H319,
For the full text of the H-statements mentioned in this section, see section 16.

2.2 Label Elements

Labelling according to regulation (EC) no. 1272/2008 (CLP/GHS)

Hazard pictograms:



Signal word / hazard designation: danger (Flam.Liq. 2), warning (Skin Irrit. 2)

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Hazardous component(s) for labelling: contains ethanol

Reduced labelling (≤ 125 ml) (according to exemptions from the packaging and labelling regulations according to EC-CLP-

regulation) Signal word: danger hazard pictograms:



Hazard statements:

H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H336: May cause drowsiness and dizziness

Precautionary statements:

P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P233: Keep container tightly closed.
P102: Keep out of reach of children.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P261: Avoid breathing dust / fume.

Supplemental Hazard information (EU):

EUH066: Repeated exposure may cause skin dryness or cracking.

2.3 Other Hazards:

No supplementary information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Principal component of the substance:

Substance name: Ethanol This substance does not meet the PBT or vPvB criteria according to the regulation (EC) no. 1907/2006, annex XIII.
Index-no.: 603-002-00-5
EG-no.: 200-578-6
CAS-no.: 64-17-5

Impurities, stabilizers:

Substance name: Isopropyl (0-7%) This substance does not meet the PBT or vPvB criteria according to the regulation (EC) no. 1907/2006, annex XIII.
Index-no.: 603-117-00-0
EG-no.: 200-661-7
CAS-no.: 67-63-0
Classification according to 1272/2008 (CLP):
Flammable liquids (chapter 2.6), category 2 (Flam. Liq. 2), H225,
Eye irritation (chapter 3.3), category 2 (Eye Irrit. 2), H319,
May cause drowsiness or dizziness (chapter 3.8), category 3 (STOT SE3), H336

3.2 Mixtures not applicable

Description of the mixture:

EG-no.: CAS-no.: Index-Nno.: REACH-registration no.:
Content ration: %
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(Full text of H- and EUH-phrases: see SECTION 16)

Section 4: First aid measures

4.1 Description of first aid measures:

In general: take off contaminated clothing

Following inhalation:

In case of dizziness after inhalation of vapors, take the person concerned to fresh air.

Following skin contact:

Wash affected skin thoroughly with water and soap.

Following eye contact:

Rinse eyes with current water for at least 10 minutes. If eye irritation persists consult a doctor.

Following ingestion:

Rinse mouth. If discomfort persist consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Irritant effects, drowsiness, nausea, vomiting, headache, doziness.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: not determined

Special treatment: not determined

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable: dry powder, foam, sand

Unsuitable: water

5.2 Special hazards arising from the substance or mixture

Flammable. An incomplete combustion may result in toxic components within the flue gas. In case of fire a respiratory equipment working independently from its ambient environment is recommended for the fire fighters.

5.3 Advice for fire-fighters

In case of fire a respiratory equipment working independently from its ambient environment is recommended for the fire fighters.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove all sources of ignition immediately. Ensure good ventilation. Do not inhale fume or spray.

For emergency responders

Personal protective equipment:

respiratory equipment working independently from its ambient environment

6.2 Environmental precautions

Prevent the liquids from ingressing into surface water or drains.

6.3 Methods and material for containment and cleaning up

Wear safety equipment, absorb with liquid binding material (sand, universal binding material) and dispose of as hazardous material.

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6.4 Reference to other sections

Dangerous combustion products: see section 5. Personal protective equipment: see section 8.

Section 7: Handling and storage

7.1 Precautions for safe handling

Fire preventions:

Provide adequate ventilation. Keep away from sources of ignition – don't smoke!



Aerosol and dust generation preventions:

Not determined

Environmental precautions:

Do not allow to reach the drain system

Advice on general occupational hygiene:

Follow the advice on general occupational hygiene, when dealing with chemicals, keep away from food, don't smoke.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Store under 30°C, tightly closed. Keep away from food.

Requirements for storage rooms and vessels

According to TRGS 510, annex 9, regulation for small quantities

Storage class: (LGK) (VCI) 3

7.3 Specific end uses

Sector specific guidelines: dental laboratories

Except for the applications mentioned in section 1.2 there are no other specific end applications provided.

Section 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limits

Substance: Ethanol ; CAS-no. : 64-17-5

Spezifizierung : TRGS 905/TRGS 900

Limit value type (country of origin) : (AGW): 960 mg/m³ bzw. 500 ml/m³ (ppm)

Peak limitation: Exceedance factor (ÜF) 2, category for short term values II

Toxic to reproduction: A risk of foetal damage is ceased to fear when observing the MAK / BAT values.

Source (TRGS) Not determined

8.2 Exposure controls

Appropriate engineering controls

Personal protective equipment

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Eye / face protection



Wear tight fitting goggles

Skin protection

Hand protection

The glove material has to be impermeable and resistant to the product.

Full contact:

Gloves made of butyl rubber.

Layer thickness: $\geq 0,7$ mm

Penetration time: ≥ 60 min



Splash contact:

Gloves made of nitrile rubber

Layer thickness: 0,40 mm

Penetration time: < 120 min.

Body protection

Wear adequate working clothes.

Respiratory protection

Generally there are no special measures to be taken. In case of release of a more important quantity (drained off bottle) provide for sufficient ventilation.

Thermal hazards

Not applicable if not stored over 45°C for a longer space of time.

Environmental exposure controls

Not determined

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state:	
- Aggregate state:	Liquid
- colour :	Tooth-coloured
Odour :	Characteristic (like alcohol)
Odour threshold :	No data available
pH-value:	n.b.
Melting point / freezing point :	-114,5 °C
Initial boiling point/boiling range :	78 °C
Flash point:	17 °C
Evaporation rate :	No data available
Flammability:	n.b.
Upper/lower explosive limits	15,0 Vol% // 3,4 Vol%

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Vapour pressure :	59 hPa when 20 °C
Vapour density:	No data available
Relative density:	n.b.
Solubility:	Unlimited miscibility
Partition coefficient: n-octanol/water:	n.b.
Auto-ignition temperature:	425 °C
Decomposition temperature:	No data available
Viscosity:	n.b.
explosive properties:	Not classified as explosive
Oxidising properties:	none

9.2 Other information

Physical hazards

Explosives There are no further data available

Section 10: Stability and reactivity

10.1 Reactivity:

Risk of ignition

10.2 Chemical stability:

Under standard ambient conditions the material is chemically stable.

10.3 Possibility of hazardous reactions:

n.b.

10.4 Conditions to avoid:

Storing for a longer space of time over 45°C.

10.5 Incompatible materials:

Strong oxidants

10.6 Hazardous decomposition products:

None when storing at room temperature.

Section 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 rat: 10.470 mg/kg

OECD test guideline 401

Symptoms: slight irritation of mucous membrane

Skin irritation

Result rabbit: no skin irritation

OECD test guideline 404

Repeated or prolonged exposure may cause skin irritation and dermatitis due to degreasing properties of the product (EUH066)

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Eye irritation

Result rabbit: eye irritation
OECD test guideline 405
Causes serious eye irritation (H319)

Sensitisation to the respiratory tract / skin

Test on sensitisation (Magnusson und Kligman):

Result: negative

Germ cell mutagenicity

Genotoxicity in vitro

Ames test Salmonella typhimurium

Result: negative

Method: OECD test guideline 471

Carcinogenicity

No information available

Reproductive toxicity

No information available

Specific target organ toxicity (single exposure)

No information available

Specific target organ toxicity (repeated exposure)

No information available

Aspiration hazard

No information available

Symptoms related to the physical, chemical and toxicological characteristics:

In case of ingestion: after a resorption of immense quantities: dizziness, rapture, anesthesia.

In case of skin contact: dryness

In case of inhalation: euphoria

In case of eye contact: irritation

Systemische Wirkung: Euphorie

Follow the usual instructions when dealing with chemicals.

Section 12: Ecological information

12.1 Toxicity

The product is slightly hazardous to water (water pollution class I). The hazard presented by this product in a container of 20 ml can be neglected.

12.2 Persistence and degradability

Biodegradability 94 %

OECD test guideline 301E

Easily biodegradable.

12.3 Bioaccumulative potential

Bioaccumulation is not to be expected.

12.4 Mobility in soil

No information available

12.5 Results of PBT- and vPvB assessment

This substance does not meet the PBT or vPvB criteria according to the regulation (EC) no. 1907/2006, annex XIII.

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12.6 Other adverse effects

No environmental problems can be expected when handled and used properly. Leakage into the environment is to be prevented.

Section 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging disposal

Containers are to be treated as the product itself. 150110 (AVV)

Waste codes / waste designations according to EWC / AVV:

160506 (AVV)

Special precautions

none

Other relevant provisions for waste treatment national or EC

Waste directive 2008/98/EC has to be observed.

Section 14: Transport information

14.1 UN-no.

UN 1170

14.2 UN proper shipping name

ADR/RID

Ethanol

IMDG-Code / ICAO-TI / IATA-DGR

Ethanol
EmS F-E S-D

14.3 Transport hazard class(es) / hazard labels

Class 3

14.4 Packing group

II

14.5 Environmental hazards

Environmentally hazardous substance marking

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / XXX no

Marine Pollutant: yes / XXX no

14.6 Special precautions for user

Do not expose to sources of ignition. Beware of inflammable materials.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Pollution category (X, Y or Z) :

Type of ship (1, 2 or 3) : not relevant

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Section 15: Regulatory information

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

EU-regulations, e.g.:

Directive /EC) no. 2037/2000 (substances that deplete the ozone layer):
Not regulated

Directive (EC) no. 850/2004 (persistent organic pollutants):
Not regulated

Directive (EC) no. 689/2008 (export and import of dangerous chemicals):
Not regulated

Directive (EC) no. 648/2004 (detergent regulation):
Not regulated

Restrictions in accordance with title VIII of the regulation (EC) no. 1907/2006:
This product does not contain any ingredients of very high concern according to REACH EC no. 1907/2006, Art. 57 low concentration limit of $\geq 0,1$ % (w/w).

National regulations, e.g.:

Water hazard class: 1

Technical instructions on Air Quality Control (TA-Luft)
Not regulated

Other relevant regulations

Leaflet BG-Chemie

M004 irritant materials

M050 tasks with hazardous materials

TRGS 900 Ethanol (64-17-5) AGW: 500 ppm 960 mg/m³ peak limit value 2 if one meets the AGW- und BGW values no risk of reproductional damage is to be expected (see no. 8.1).

15.2 Chemical safety assessment

No chemical safety assessment has been performed on this substance.

Section 16: Other information

Indication of changes

Adaption to the classification and labelling according to directive (EC) no. 1272/2008
Section 1: Erreichbarkeit der Notrufnummer.

Abbreviations and acronyms

n.a. Not applicable

Key literature references and sources for data

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Gestis substance data base - <http://gestis.itrust.de/>
Federal Agency for Industrial Health and Safety – www.baua.de

Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

Relevant R-, H- and EUH-phrases (number and full text):

Hazard statements:

H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H336: May cause drowsiness and dizziness

Precautionary statements:

P210: Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P233: Keep container tightly closed.
P102: Keep out of reach of children.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P261: Avoid breathing dust / fume.

Supplemental Hazard information (EU):

EUH066: Repeated exposure may cause skin dryness or cracking.

Training advice

Provide adequate information, instruction and training for operators / technicians using this product.

Further information

This information is based on our present state of knowledge. It should therefore not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. We do not take any responsibility for possible sources of errors or sufficiency of this document. The user of the product accepts the sole responsibility to adhere to all herein mentioned regulations. It is the user's obligation to read this document carefully.