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

- · 1.1 Product identifier
- · Trade name: AH Plus Cleaner
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Cleaning material/ Detergent
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Dentsply DeTrey GmbH

De-Trey-Str. 1 D-78467 Konstanz **GERMANY** 

Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsplysirona.com

- · Further information obtainable from:
- Departement Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- $\cdot$  1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

#### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Eye Irrit. 2 H319 Causes serious eye irritation.

- · 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





GHS02

GHS07

- · Signal word Danger
- · Hazard statements

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking.

P241 *Use explosion-proof [electrical/ventilating/lighting] equipment.* 

Wear protective gloves/protective clothing/eye protection/face protection. P280

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing. Dispose of contents/container in accordance with local/regional/national/international

P501 regulations.

#### · Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

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

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· 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: 64-17-5	ethanol	50 – 100%
EINECS: 200-578-6	Flam. Liq. 2, H225; Eye Irrit. 2, H319	
CAS: 75-65-0	tert-butyl alcohol	2.5-10%
EINECS: 200-889-7	Flam. Liq. 2, H225; Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	

<sup>·</sup> 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 Immediately wash with water and soap and rinse thoroughly.
- · After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Information for doctor 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

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · 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: Self-contained respiratory protective device.
- · Additional information Cool endangered receptacles with water spray.

### SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· 6.2 Environmental precautions:

Dilute with plenty of water.

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). Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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#### **SECTION 7: Handling and storage**

- · 7.1 Precautions for safe handling Observe normal care for working with chemicals.
- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- ·Storage
- · Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- · 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:

CAS: 64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

CAS: 75-65-0 tert-butyl alcohol

WEL Short-term value: 462 mg/m³, 150 ppm Long-term value: 308 mg/m³, 100 ppm

- · Regulatory information WEL: EH40/2011
- · 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.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not necessary if room is well-ventilated.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

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 preparation 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.

Butyl rubber, BR

Recommended thickness of the material:  $\geq 0.7 \text{ mm}$ 

*Permeation: Level ≥6* 

· Penetration time of glove material

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

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

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· Eye protection:



Tightly sealed goggles.

· 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: Alcohol-like
Odour threshold: Not determined.

pH-value: Not determined.

· Change in condition

Melting point/freezing point: undetermined

*Initial boiling point and boiling range:* 80 °C (ASTM D1120-72)

Flash point: 18 °C (Abel c.c.)
 Flammability (solid, gaseous) Not applicable.

· Ignition temperature: 425 °C (Ethanol)

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of explosive air/

vapour mixtures are possible.

· Explosion limits:

 Lower:
 2,4 Vol %

 Upper:
 15 Vol %

· Vapour pressure at 20 °C: 59 hPa

Density at 20 °C: 0,84 g/cm³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

Water: Fully miscible

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

dynamic: Not determined. kinematic: Not determined.

· Solvent content:

 Organic solvents:
 80,0 %

 Water:
 20,0 %

• 9.2 Other information No further relevant information available.

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#### 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 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.

· LD/LC50 values relevant for classification:		
ATE (Acut	te Toxicity	Estimate)
Inhalative	LC50/4 h	110 mg/l
CAS: 64-1	7-5 ethano	ol .
Oral	LD50	6,200 mg/kg (rat)
Inhalative	LC50/4 h	95.6 mg/l (rat)
CAS: 75-6	CAS: 75-65-0 tert-butyl alcohol	
Oral	LD50	2,743 mg/kg (rat)
Dermal	LD50	> 2,000 mg/kg (rabbit)
Inhalative		11 mg/l (ATE)

- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation

Causes serious eye irritation.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, 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 to.	xicity:
CAS: 64-1	7-5 ethanol
LC50/48h	8,140 mg/l (Fish acute toxicity study)
EC50/48h	9,268 mg/L (daphnia magna)
CAS: 75-6	5-0 tert-butyl alcohol
LC50/96h	6,140 mg/l (Fish acute toxicity study)
EC50/48h	933 mg/L (daphnia magna)

- 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.

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- · Additional ecological information:
- · General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 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.

· European waste catalogue	
18 01 06*	chemicals consisting of or containing hazardous substances
HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage

- · 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

· 14.1 UN-Number · ADR, IMDG, IATA	UN1987
· 14.2 UN proper shipping name · ADR	1987 ALCOHOLS, N.O.S. (ETHANOL (ETHYL ALCOHOL), BUTANOLS)
· IMDG	ALCOHOLS, N.O.S. (ETHANOL (ETHYL ALCOHOL), BUTANOLS)
· IATA	ALCOHOLS, N.O.S. (ETHANOL, BUTANOLS)

- · 14.3 Transport hazard class(es)
- $\cdot ADR$



· Class
· Label
3 (F1) Flammable liquids.
3

· IMDG, IATA



· Class 3 Flammable liquids.

· Label

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14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
EMS Number:	F- $E$ , $S$ - $D$
Stowage Category	$B$ $\overline{}$
14.7 Transport in bulk according to An	nex II of
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	1L
Excepted quantities $(EQ)$	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E
<i>IMDG</i>	
Limited quantities (LQ)	1L
Excepted quantities $(EQ)$	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN "Model Regulation":	UN 1987 ALCOHOLS, N.O.S. (ETHANOL (ETHY
Ü	ALCOHOL), BUTANOLS), 3, II

#### **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 P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 40
- · 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 attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

#### · Relevant phrases

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

· Department issuing SDS: Research & Development

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· Contact: HotLine for urgent technical support: +49-7531-583-350

· 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 Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 4: Acute toxicity – Category 4

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

\* Data compared to the previous version altered.

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