

according to Regulation (EC) No. 1907/2006 (REACH), Article 31

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Profisep Clean**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Commercial product name: Profisep Clean

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

No further relevant information available.

Use of the substance / the mixture: Auxiliary agent in dentistry

1.3 Details of the supplier of the safety data sheet

Company / Manufacturer: SILADENT Dr. Böhme & Schöps GmbH
 Street / mailbox: Im Klei 26
 Country code. / postal code / city: D - 38644 Goslar
 Phone: +49 (0) 53 21 / 37 79 – 0
 Fax: +49 (0) 53 21 / 38 96 32
 E-mail / Website: info@siladent.de / www.siladent.de
 Further information obtainable from: SILADENT Dr. Böhme & Schöps GmbH

1.4 Emergency telephone number:

SILADENT Dr. Böhme & Schöps GmbH: +49 (0) 53 21 / 37 79 - 0 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture:** Classification according to Regulation (EC) No 1272/2008GHS02 flame
Aerosol 1

H222-H229 Extremely flammable aerosol. Pressurised container: may burst if heated.

GHS07
Skin Irrit. 2
Eye Irrit. 2
STOT SE 3

H315 Causes skin irritation
 H319 Causes serious eye irritation.
 H336 May cause drowsiness or dizziness.

2.2 Label elements**Labelling according to Regulation (EC) 1272/2008:**

The product is classified and labelled according to the CLP Regulation.

Hazard pictograms

GHS02 GHS07

Signal word:

Hazard

Hazard-determining components of labelling:

Propan-2-ol

Hazard statements:

H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.
 H315 Causes skin irritation
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Profisep Clean**Precautionary statements:**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251	Do not pierce or burn, even after use.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:






Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking. Keep out of the reach of children

2.3 Other hazards:**Results of PBT and vPvB assessment**

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterization:	Mixtures	
Description:	Mixture of substances listed below with non-hazardous additions.	
3.2 Dangerous components:		
CAS: 29387-86-8	Dowanol PnB	25-50%
EINECS: 249-598-7	 Skin Irrit. 2, H315; Eye Irrit. 2, H319	
Index no.: 603-402-00-8		
CAS: 67-63-0	Propan-2-ol	25-50%
EINECS: 200-661-7	 Flam. Liq. 2, H225;  Eye Irrit. 2, H319; STOT SE 3, H336	
Index no.: 603-117-00-0		
CAS: 74-98-6	Propane	10-25%
EINECS: 200-827-9	 Flam. Gas 1, H220; Press. Gas, H280	
Index no.: 601-003-00-5		
CAS: 106-97-8	Butane	2.5-10%
EINECS: 203-448-7	 Flam. Gas 1, H220; Press. Gas, H280	
Index no.: 601-004-00-0		

Additional information: For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures:	
If inhaled:	In case of unconsciousness place and transport in a stable lateral position.
Following skin contact:	Wash off immediately with soap and water and rinse thoroughly.
Following eye contact:	Rinse eyes under running water for several minutes with the eyelid open. If symptoms persist, consult a physician.
If swallowed:	If symptoms persist, consult a physician. Rinse mouth and drink copious amounts of water.

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- 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:** CO₂, extinguishing powder or water spray.
Fight larger fires with water spray or alcohol-resistant foam.
- For safety reasons unsuitable extinguishing agents:** Full water jet
- 5.2 Special hazards arising from the substance or mixture:** No further relevant information available.
- 5.3 Advice for firefighters**
- Special protective equipment:** No special measures required.

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:** Do not allow to enter sewers / surface or ground water.
- 6.3 Methods and material for containment and cleaning up:** Ensure adequate ventilation.
- 6.4 Reference to other sections:** For information on safe handling: see Section 7.
For information on personal protective equipment: see Section 8.
For information on disposal: see Section 13.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling:** Ensure good ventilation/extraction at the workplace.
Open and handle container with care.
- Notes on fire and explosion protection:** Keep sources of ignition away - no smoking.
Take measures against electrostatic charging.
Pressurised container. Protect from sunlight and temperatures exceeding 50°C (e.g. due to light bulbs).
Do not open by force or burn, even after use.
Do not spray into flames or red-hot objects.
- Conditions for safe storage, including any incompatibilities**
- 7.2 Storage:**
- Requirements to be met by storerooms and receptacles:** Store in a cool place.
The official regulations for the storage of pressurised aerosol packaging must be observed.
- Information about storing in one common storage facility:** Not required.

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Profisep Clean**Further information about storage conditions:**

Keep containers tightly closed.
Do not close the container gas-tight.
Store in cool and dry place in tightly closed containers.
Protect from heat and direct sunlight.

Storage class:

2B

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 information, see Section 7.

8.1 Control parameters**Components with limit values that require monitoring at the workplace:****67-63-0 Propan-2-ol**

OEL: long-term value: 500 mg/m³, 200 ml/m³
2(II);DFG, Y

74-98-6 Propane

OEL: long-term value: 1800 mg/m³, 1000 ml/m³
4(II);DFG

106-97-8 Butane

OEL: long-term value: 2400 mg/m³, 1000 ml/m³
4(II);DFG

DNEL-VALUES

CAS: 67-63-0 Propan-2-ol
Dermal DNE: 888 mg / kg / bw / day
long term exposure-systemic effects
Inhalative DENEL: 500 mg / m³
long term exposure-systemic effects

PNEC values:

CAS: 67-63-0 Propan-2-ol
PNEC- aqua: 140.9 mg / l (fresh water)
140.9 mg / l (marine water)
PNEC sediment: 552 mg / kg (fresh water)
552 mg / kg (marine water)
Soil: 28 mg / kg

Components with biological limit values:**67-63-0 Propan-2-ol**

BLV 25 mg/l Sample material: Whole blood
Sampling time: end of exposure or shift
Parameter: Acetone
25 mg/l
Sample material: Urine
Sampling time: end of exposure or shift
Parameter: Acetone

Additional information:

The lists valid during the making were used as basis.

8.2 Exposure controls:

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General protective and hygienic measures: Keep away from food, drink and animal feed.
Take off contaminated, soaked clothing immediately.
Wash hands prior to breaks and at the end of work.
Do not inhale gases/vapours/aerosols.
Avoid contact with eyes and skin.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

Hand protection:



Protective gloves: The glove material must be impermeable and resistant to the product / substance / preparation. Selection of the glove material taking into account breakthrough times, permeation rates and degradation.

Glove material The selection of a suitable glove depends not only on the material but also on other quality characteristics and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of glove materials cannot be calculated in advance and must therefore be checked before use.

Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Gloves made of the following materials are suitable as splash protection: Nitrile rubber, NBR
Butyl rubber, BR
Fluorocarbon rubber (Viton)

Eye protection:



Tightly sealing safety goggles.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****General information:****Appearance:****Form:**

Aerosol

Colour:

Colourless

Odour:

Characteristic

Change in condition:**Melting point / melting range:**

Not determined.

Boiling point / boiling range:

-44°C

Flash point:

-97°C

Ignition temperature:

260°C

Auto-ignition:

Product is not self-igniting.

Explosion hazard:

The product is not explosive; however, the formation of explosive vapour/air mixtures is possible.

Explosion limits:**Lower:**

1,1 Vol %

Upper:

12,0 Vol %

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Vapour pressure at 20°C:	4000 hPa
Density at 20°C:	0,727 g/cm ³
Solubility in / miscibility with water:	Partially miscible.
Viscosity	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
VOC (EC):	67,0 %
Solids content:	0 %

9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity:	Thermal decomposition
10.2 Chemical stability	No decomposition if used as intended.
10.3 Possibility of hazardous reactions	No hazardous reactions known.
10.4 Conditions to avoid	No further relevant information available.
10.5 Incompatible material	No further relevant information available.
10.6 Hazardous decomposition products	No hazardous decomposition products known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity:****Classification-relevant LD/LC50 values:****29387-86-8 Dowanol PnB**

Oral	LD50	>3300 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)

67-63-0 Propan-2-ol

Oral	LD50	5045 mg/kg (rat)
Dermal	LD50	12800 mg/kg (rabbit)
Inhalative	LC50/4 h	30 mg/l (rat)

106-97-8 Butane

Inhalative	LC50/4 h	658 mg/l (rat)
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Primary irritant effect:

On the skin: Irritates the skin and mucous membranes.

In the eye: Causes serious eye irritation.

Sensitisation: No sensitizing effects known.

Additional toxicological information:

Based on the calculation method of the General Classification Guideline of the EU for preparations in the last amended version, the product exhibits the following hazards: irritant

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Profisep Clean**SECTION 12: Ecological information**

12.1 Toxicity	
Aquatic toxicity:	No further relevant information available.
12.2 Persistence and degradability:	No further relevant information available.
Behaviour in environmental systems:	No further relevant information available.
12.3 Bioaccumulative potential:	No further relevant information available.
12.4 Mobility in soil:	No further relevant information available.
Further ecological information:	
General notes:	Water hazard class 1 (self-classification): slightly hazardous to water Do not allow to enter groundwater, waters or the sewage system undiluted or in larger amounts.
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 of together with household waste. Do not allow to enter the sewage system.
European Waste Directory	
16 00 00	WASTE NOT LISTED ELSEWHERE IN THE DIRECTORY
16 05 00	Gases in pressure vessels and spent chemicals
16 05 04	gases in pressure vessels containing dangerous substances (including halons)
Uncleaned packaging – Recommendation:	Disposal in accordance with official regulations.

SECTION 14: Transport information

14.1 UN-Number	
ADR, IMDG, IATA	UN1950
14.2 UN proper shipping name	
ADR	1950 PRESSURISED GAS PACKAGING
IMDG	AEROSOLS
IATA	AEROSOLS, flammable
14.3 Transport hazard class(es)	
ADR	
	
Class	2.5F Gases.
Hazard label	2.1
IMDG, IATA	

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Class
Label

2.1

2.1

14.4 Packing group
ADR, IMDG, IATA

not applicable

14.5 Environmental hazards
Marine pollutant:

No

14.6 Special precautions for user**Attention:**

gases

Kemler number:

-

EMS Number:

F-D,S-U

14.7 Transport in bulk according to Annex II of
MARPOL73/78 and the IBC Code:

Not applicable

Transport/Additional information**ADR****Excepted quantities (EQ):**

E0

Limited quantities (LQ)

1L

Transport category

2

Tunnel restriction code

D

Notes:

Limited quantity:

Maximum 30 kg per package (carton), apply "diamond with black corners label" to the carton.

UN „Model Regulation“:

UN1950, PRESSURISED GAS PACKAGING, 2.1

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Guideline 2012/18/EU

Named hazardous substances - ANNEX I None of the constituents are contained.

Seveso category P3a FLAMMABLE AEROSOLS

Threshold quantity (in tonnes) for use in lower classified operations 150 t

Threshold quantity (in tonnes) for use in higher classified operations 500 t

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of limitation: 3

Directive 2011/65/EU on the restriction of
the use of certain hazardous substances in
electrical and electronic equipment - Annex
II:

None of the constituents are contained.

REGULATION (EU) 2019/1148
Annex I - RESTRICTED EXPLOSIVES
PRECURSORS (Upper limit concentration
for a licence under Article 5(3)):

None of the constituents are contained.

Annex II - REPORTABLE EXPLOSIVES
PRECURSORS:

None of the constituents are contained.

National regulations:

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Profisep Clean**Technical instructions air:**

Class:NK

Proportion in %: 85.0

Water hazard class:

WGK 1 (self-classification): slightly hazardous to water.

15.2 Chemical safety assessment:

A chemical safety assessment has not been conducted.

SECTION 16: Other information

The information contained in this safety data sheet is based to the best of our knowledge and belief on currently available information regarding the correct handling of the product under normal conditions. Any other use of this product in combination with other processes not included in this data sheet is the sole responsibility of the user. This document does not constitute an express or implied warranty as to product quality or suitability for a particular purpose.

Relevant phrases:

H220:	Extremely flammable gas.
H225:	Highly flammable liquid and vapour.
H280:	Contains gas under pressure; may explode if heated.
H315:	Causes skin irritation.
H319:	Causes serious eye irritation.
H331:	Toxic if inhaled.
H336:	May cause drowsiness or dizziness.

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 Organization
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (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 Harmonized 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