

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

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

##### 1.1. Product identifier

VITA OPAQUE FLUID

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

###### Use of the substance/mixture

Use as laboratory reagent

##### 1.3. Details of the supplier of the safety data sheet

Company name:	VITA Zahnfabrik H.Rauter GmbH & Co.KG	
Street:	Spitalgasse 3	
Place:	D-79713 Bad Säckingen	
Post-office box:	1338	
	D-79704 Bad Säckingen	
Telephone:	+49(0)7761-562-0	Telefax: +49(0)7761-562-299
e-mail:	info@vita-zahnfabrik.com	
Contact person:	regulatory affairs	
e-mail:	info@vita-zahnfabrik.com	
Internet:	www.vita-zahnfabrik.com	
Responsible Department:	Regulatory Affairs	

##### 1.4. Emergency telephone number:

+49-(0)761-19240

##### Further Information

medical device

#### SECTION 2: Hazards identification

##### 2.1. Classification of the substance or mixture

###### Regulation (EC) No 1272/2008

Skin Corr. 1; H314

Eye Dam. 1; H318

Full text of hazard statements: see SECTION 16.

##### 2.2. Label elements

###### Regulation (EC) No 1272/2008

###### Hazard components for labelling

ethyl alcohol

sodium hydroxide; caustic soda

Signal word: Danger

###### Pictograms:



###### Hazard statements

H314 Causes severe skin burns and eye damage.

###### Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

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

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

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P305+P351+P338 or shower.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

#### 2.3. Other hazards

No information available.

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
64-17-5	ethyl alcohol			1 - < 5 %
	200-578-6	603-002-00-5	01-2119457610-43	
	Flam. Liq. 2, Eye Irrit. 2; H225 H319			
1310-73-2	sodium hydroxide; caustic soda			< 1 %
	215-185-5	011-002-00-6		
	Skin Corr. 1A; H314			

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

##### Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
64-17-5	200-578-6	ethyl alcohol	1 - < 5 %
	dermal: LD50 = 7060 mg/kg		
1310-73-2	215-185-5	sodium hydroxide; caustic soda	< 1 %
	Skin Corr. 1A; H314: >= 5 - 100 Skin Corr. 1B; H314: >= 2 - < 5 Skin Irrit. 2; H315: >= 0.5 - < 2 Eye Irrit. 2; H319: >= 0.5 - < 2		

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

##### After inhalation

Provide fresh air. Medical treatment necessary.

##### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

##### After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

##### After ingestion

Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Adverse human health effects and symptoms: Gastric perforation. Call a physician immediately. Do not allow a neutralisation agent to be drunk.

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

No information available.

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

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Treat symptomatically.

#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

###### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

##### 5.2. Special hazards arising from the substance or mixture

Non-flammable.

##### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

###### **Additional information**

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

###### **General advice**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

##### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

##### 6.3. Methods and material for containment and cleaning up

###### **Other information**

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

##### 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

#### SECTION 7: Handling and storage

##### 7.1. Precautions for safe handling

###### **Advice on safe handling**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

###### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

###### **Advice on general occupational hygiene**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

##### 7.2. Conditions for safe storage, including any incompatibilities

###### **Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

###### **Hints on joint storage**

No special measures are necessary.

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#### 7.3. Specific end use(s)

Use as laboratory reagent

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

#### 8.2. Exposure controls



#### Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Suitable eye protection: goggles.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Recommended glove articles KCL, Dermatrill P NBR (Nitrile rubber) Breakthrough time: 480 min

##### Skin protection

Use of protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection. Technical ventilation of workplace Open windows to ensure natural ventilation.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	colourless
Odour:	characteristic

#### Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	100 °C
Flash point:	not determined

#### Flammability

Solid/liquid:	not applicable
Gas:	not applicable

#### Explosive properties

The product is not: Explosive.

Lower explosion limits:	not determined
Upper explosion limits:	not determined

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#### Self-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

pH-Value: 12,7

#### Solubility in other solvents

not determined

Partition coefficient n-octanol/water: not determined

Vapour pressure: <=1100 hPa

(at 50 °C)

Density: 1,00000 g/cm<sup>3</sup>

Relative vapour density: not determined

#### 9.2. Other information

##### Information with regard to physical hazard classes

Oxidizing properties

Not oxidising.

##### Other safety characteristics

Solid content: 0,4 %

Evaporation rate: not determined

##### Further Information

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Possibility of hazardous reactions.

#### 10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

#### 10.3. Possibility of hazardous reactions

Exothermic reaction with: Acid, Peroxides, Oxidizing agent.

#### 10.4. Conditions to avoid

none

#### 10.5. Incompatible materials

Keep away from: Acid, Oxidizing agent, Peroxides.

#### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

### SECTION 11: Toxicological information

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

##### Acute toxicity

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

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
64-17-5	ethyl alcohol				
	dermal	LD50 mg/kg	7060		

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#### Irritation and corrosivity

Causes severe skin burns and eye damage.  
Causes serious eye damage.

#### Sensitising effects

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

#### Carcinogenic/mutagenic/toxic effects for reproduction

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.

#### Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.  
The product has not been tested.

### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

### 12.7. Other adverse effects

No information available.

#### Further information

Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation. Handle contaminated packages in the same way as the substance itself.

#### Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

## SECTION 14: Transport information

#### Land transport (ADR/RID)

**14.1. UN number or ID number:** UN 1824

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**14.2. UN proper shipping name:**

SODIUM HYDROXIDE SOLUTION

**14.3. Transport hazard class(es):**

8

**14.4. Packing group:**

III

Hazard label:



Classification code:

C5

Limited quantity:

5 L

Excepted quantity:

E1

Transport category:

3

Hazard No:

80

Tunnel restriction code:

E

#### Inland waterways transport (ADN)

**14.1. UN number or ID number:**

UN 1824

**14.2. UN proper shipping name:**

SODIUM HYDROXIDE SOLUTION

**14.3. Transport hazard class(es):**

8

**14.4. Packing group:**

III

Hazard label:



Classification code:

C5

Limited quantity:

5 L

Excepted quantity:

E1

#### Marine transport (IMDG)

**14.1. UN number or ID number:**

UN 1824

**14.2. UN proper shipping name:**

SODIUM HYDROXIDE SOLUTION

**14.3. Transport hazard class(es):**

8

**14.4. Packing group:**

III

Hazard label:



Special Provisions:

223

Limited quantity:

5 L

Excepted quantity:

E1

EmS:

F-A, S-B

Segregation group:

18 - alkalis

#### Air transport (ICAO-TI/IATA-DGR)

**14.1. UN number or ID number:**

UN 1824

**14.2. UN proper shipping name:**

SODIUM HYDROXIDE SOLUTION

**14.3. Transport hazard class(es):**

8

**14.4. Packing group:**

III

Hazard label:



Special Provisions:

A3 A803

Limited quantity Passenger:

1 L

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Passenger LQ:	Y841	
Excepted quantity:	E1	
IATA-packing instructions - Passenger:		852
IATA-max. quantity - Passenger:		5 L
IATA-packing instructions - Cargo:		856
IATA-max. quantity - Cargo:		60 L

#### 14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

#### 14.6. Special precautions for user

Warning: strongly corrosive.

#### 14.7. Maritime transport in bulk according to IMO instruments

not applicable

### SECTION 15: Regulatory information

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

##### EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 75

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

##### National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

Water hazard class (D): 1 - slightly hazardous to water

#### 15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

### SECTION 16: Other information

#### Changes

This data sheet contains changes from the previous version in section(s): 14.

#### 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 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

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate



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LL50: Lethal loading, 50%  
 EL50: Effect loading, 50%  
 EC50: Effective Concentration 50%  
 ErC50: Effective Concentration 50%, growth rate  
 NOEC: No Observed Effect Concentration  
 BCF: Bio-concentration factor  
 PBT: persistent, bioaccumulative, toxic  
 vPvB: very persistent, very bioaccumulative  
 RID: Regulations concerning the international carriage of dangerous goods by rail  
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
 EmS: Emergency Schedules  
 MFAG: Medical First Aid Guide  
 ICAO: International Civil Aviation Organization  
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
 IBC: Intermediate Bulk Container  
 SVHC: Substance of Very High Concern  
 For abbreviations and acronyms, see table at <http://abbrev.esdscom.eu>

#### Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Corr. 1; H314	On basis of test data
Eye Dam. 1; H318	On basis of test data

#### Relevant H and EUH statements (number and full text)

H225 Highly flammable liquid and vapour.  
 H314 Causes severe skin burns and eye damage.  
 H318 Causes serious eye damage.  
 H319 Causes serious eye irritation.

#### Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*