

Safety Data Sheet

according to Regulation (EC) No 1907/2006

VITA OPAQUE FLUID

Revision date:

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

+49-(0)761-19240

number:**Further Information**

medical device

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Skin corrosion/irritation: Skin Corr. 1

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes severe skin burns and eye damage.

Causes serious eye damage.

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

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- P303+P361+P353 protection.
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.

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	
	GHS Classification			
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.

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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**

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 measures**

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.

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 exhaustion at critical locations.

Hints on joint storage

No special measures are necessary.

7.3. Specific end use(s)

Use as laboratory reagent

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters**Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
1310-73-2	Sodium hydroxide	-	2		STEL (15 min)	WEL

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.

Protective and hygiene measures

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.

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, Dermatril 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
pH-Value:	12,7

Changes in the physical state

Melting 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

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Explosive properties

The product is not: Explosive.

Lower explosion limits: not determined

Upper explosion limits: not determined

Self-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure:
(at 50 °C) <=1100 hPaDensity: 1,00000 g/cm³**Solubility in other solvents**

not determined

Partition coefficient n-octanol/water: not determined

Relative vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: 0,4 %

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 product has not been tested.

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:	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:	8

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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: 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: 8



Classification code: C5
 Limited quantity: 5 L
 Excepted quantity: E1

Marine transport (IMDG)

14.1. UN 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: 8



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: 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: 8



Special Provisions: A3 A803
 Limited quantity Passenger: 1 L
 Passenger LQ: Y841
 Excepted quantity: E1

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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

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**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

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

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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.)