



according to Regulation (EC) No 1907/2006

VITA OPAQUE FLUID

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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

Post-office box: 1338

79704 Bad Säckingen

Telephone: +49(0)7761-562-0 Telefax: +49(0)7761-562-299

e-mail: info@vita-zahnfabrik.com Internet: www.vita-zahnfabrik.com 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.

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.



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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				
	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				
	215-185-5	011-002-00-6			
	Skin Corr. 1A; H314				

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

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

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.



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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

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

Absorb with liquid-binding material (e.g. 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

8.1. Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m³	fib/cm³	Category	Origin
64-17-5	Ethyl alcohol	1000	-		STEL (15 min)	
1310-73-2	Sodium hydroxide	-	2		STEL (15 min)	

8.2. Exposure controls







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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 (maximum wearing 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:

Initial boiling point and boiling range:

100 °C

Flash point:

not determined

not determined

Flammability

Solid: not applicable
Gas: not applicable

Explosive properties

The product is not: Explosive.

Lower explosion limits:

Upper explosion limits:

not determined

not determined

Auto-ignition temperature

Solid: not applicable
Gas: not applicable
Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure: <=1100 hPa

(at 50 °C)

Density: 1,00000 g/cm³



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Solubility in other solvents

not determined

Partition coefficient: not determined
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 toxicological effects

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 7060 mg/kg			

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.



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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.

12.6. 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:

Hazard label: 8



Classification code:

Limited quantity:

Excepted quantity:

Transport category:

Hazard No:

Tunnel restriction code:

C5

Limited quantity:

E2

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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



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14.4. Packing group:

Hazard label: 8

8

Classification code: C5
Limited quantity: 1 L
Excepted quantity: E2

Marine transport (IMDG)

14.1. UN number: UN 1824

14.2. UN proper shipping name: SODIUM HYDROXIDE SOLUTION

14.3. Transport hazard class(es):814.4. Packing group:IIHazard label:8



Special Provisions:

Limited quantity:

Excepted quantity:

E2

EmS:

F-A, S-B

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):814.4. Packing group:IIHazard label:8



Special Provisions:

Limited quantity Passenger:

Passenger LQ:

Excepted quantity:

A3 A803

0.5 L

Y840

Excepted quantity:

E2

IATA-packing instructions - Passenger: 851
IATA-max. quantity - Passenger: 1 L
IATA-packing instructions - Cargo: 855
IATA-max. quantity - Cargo: 30 L

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

Warning: strongly corrosive.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

SECTION 15: Regulatory information

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





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EU regulatory information

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

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



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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.)