

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 1 of 9

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

GB CLP Regulation

Skin Corr. 1; H314

Eye Dam. 1; H318

Full text of hazard statements: see SECTION 16.

2.2. Label elements

GB CLP Regulation

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

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 2 of 9

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 (GB CLP Regulation)			
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

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 3 of 9

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 exhaustion at critical locations.

Hints on joint storage

No special measures are necessary.

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 4 of 9

7.3. Specific end use(s)

Use as laboratory reagent

SECTION 8: Exposure controls/personal protection

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.

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
---------------	----------------

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 5 of 9

Gas: not applicable

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

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/cm³

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 GB CLP Regulation

Acute toxicity

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

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 6 of 9

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

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 UK REACH.

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.

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 7 of 9

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
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
 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: 8



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: 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 or ID number: UN 1824
14.2. UN proper shipping name: SODIUM HYDROXIDE SOLUTION
14.3. Transport hazard class(es): 8

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 8 of 9

14.4. Packing group:

Hazard label:

III

8



Special Provisions:

A3 A803

Limited quantity Passenger:

1 L

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%

Safety Data Sheet

according to UK REACH Regulation

VITA OPAQUE FLUID

Revision date: 18.11.2022

Product code: 001

Page 9 of 9

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>

Classification for mixtures and used evaluation method according to GB CLP Regulation

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.)