

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 20.11.2017

Version 2.2

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Catalogue No. 137041

Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

REACH Registration Number This product is a mixture. REACH Registration Number see section 3.

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

Identified uses Pharmaceutical production
In compliance with the conditions described in the annex to this safety data sheet.

1.3 Details of the supplier of the safety data sheet

Company Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0

Responsible Department LS-QHC * e-mail: prodsafe@merckgroup.com

1.4 Emergency telephone number Please contact the regional company representation in your country.

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

Corrosive to metals, Category 1, H290

Skin corrosion, Category 1A, H314

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Danger

Hazard statements

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Precautionary statements

Prevention

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

Response

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

Reduced labelling (≤ 125 ml)

Hazard pictograms



Signal word

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Danger

Hazard statements

H314 Causes severe skin burns and eye damage.

Precautionary statements

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

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Aqueous solution

3.1 Substance

Not applicable

3.2 Mixture

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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sodium hydroxide ($\geq 10\%$ - $< 20\%$)		
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PBT/vPvB: Not applicable for inorganic substances

1310-73-2	01-2119457892-27-	
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		Corrosive to metals, Category 1, H290
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		Skin corrosion, Category 1A, H314
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For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. First aid measures

4.1 Description of first aid measures

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General advice

First aider needs to protect himself.

After inhalation: fresh air. Call in physician.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower. Call a physician immediately.

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist. Remove contact lenses.

After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.

4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion, Cough, Shortness of breath, collapse, death

Risk of blindness!

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Not combustible.

Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

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Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Suppress (knock down) gases/vapours/mists with a water spray jet.

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Do not breathe vapours, aerosols. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® OH -, Merck Art. No. 101596). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

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Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

No aluminium, tin, or zinc containers.

Storage conditions

Tightly closed.

Recommended storage temperature see product label.

7.3 Specific end use(s)

See exposure scenario in the Annex to this MSDS.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

sodium hydroxide (1310-73-2)

Worker DNEL, longterm	Local effects	inhalation	1 mg/m ³
Consumer DNEL, longterm	Local effects	inhalation	1 mg/m ³

Predicted No Effect Concentration (PNEC)

sodium hydroxide (1310-73-2)

PNEC no data available

8.2 Exposure controls

Engineering measures

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Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Tightly fitting safety goggles

Hand protection

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

This recommendation applies only to the product stated in the safety data sheet(>,<)> supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment

protective clothing

Respiratory protection

required when vapours/aerosols are generated.

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Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful substances

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	colourless
Odour	odourless
Odour Threshold	Not applicable
pH	ca. 14 at 20 °C
Melting point	No information available.
Boiling point	No information available.
Flash point	Not applicable
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.

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Lower explosion limit	Not applicable
Upper explosion limit	Not applicable
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	ca. 1,185 g/cm ³ at 20 °C
Relative density	No information available.
Water solubility	at 20 °C soluble
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

Corrosion	May be corrosive to metals.
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SECTION 10. Stability and reactivity

10.1 Reactivity

The life science business of Merck operates as MilliporeSigma in the US and Canada

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See section 10.3

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Risk of ignition or formation of inflammable gases or vapours with:

Metals, Light metals

Possible formation of:

Hydrogen

Violent reactions possible with:

ammonium compounds, Cyanides, organic nitro compounds, organic combustible substances, phenols, powdered alkaline earth metals, acids, Nitriles, magnesium

10.4 Conditions to avoid

no information available

10.5 Incompatible materials

Aluminium, various plastics, brass, Metals, metal alloys, Zinc, Tin, Light metals, glass, quartzes/silicate ceramics, animal/vegetable tissues

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

Acute inhalation toxicity

Symptoms: mucosal irritations, Cough, Shortness of breath, Possible damages: damage of respiratory tract

Acute dermal toxicity

This information is not available.

Skin irritation

Necrosis

Mixture causes severe burns.

Eye irritation

Mixture causes serious eye damage. Risk of blindness! Necrosis

Sensitisation

This information is not available.

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

Systemic effects:

collapse, death

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Components

sodium hydroxide

Skin irritation

Rabbit

Result: Causes burns.

(External MSDS)

Eye irritation

Rabbit

Result: Irreversible effects on the eye

(ECHA)

Sensitisation

Patch test: human

Result: negative

(ECHA)

Germ cell mutagenicity

Genotoxicity in vitro

Mutagenicity (mammal cell test): micronucleus.

Result: negative

(Lit.)

Ames test

Result: negative

(IUCLID)

SECTION 12. Ecological information

Mixture

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

12.1 Toxicity

No information available.

12.2 Persistence and degradability

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Additional ecological information

Harmful effect due to pH shift. Death of fish possible. Does not cause biological oxygen deficit.

Neutralisation possible in waste water treatment plants.

Discharge into the environment must be avoided.

Components

sodium hydroxide

Toxicity to fish

LC50 *Gambusia affinis* (Mosquito fish): 125 mg/l; 96 h

(External MSDS)

Toxicity to daphnia and other aquatic invertebrates

EC50 *Ceriodaphnia* (water flea): 40,4 mg/l; 48 h

(ECHA)

Toxicity to bacteria

EC50 *Photobacterium phosphoreum*: 22 mg/l; 15 min

(External MSDS)

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances.

PBT/vPvB: Not applicable for inorganic substances

SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 UN number	UN 1824
14.2 Proper shipping name	SODIUM HYDROXIDE SOLUTION
14.3 Class	8
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
Tunnel restriction code	E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number	UN 1824
14.2 Proper shipping name	SODIUM HYDROXIDE SOLUTION
14.3 Class	8
14.4 Packing group	II
14.5 Environmentally hazardous	--

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Catalogue No. 137041
Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

14.6 Special precautions for user no

Sea transport (IMDG)

14.1 UN number UN 1824
14.2 Proper shipping name SODIUM HYDROXIDE SOLUTION
14.3 Class 8
14.4 Packing group II
14.5 Environmentally hazardous --
14.6 Special precautions for user yes
EmS F-A S-B

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard SEVESO III
Legislation Not applicable

Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at work.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

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Substances of very high concern (SVHC)

This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of $\geq 0.1\%$ (w/w).

National legislation

Storage class 8B

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

Hazard statements

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

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Product name Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

Precautionary statements

Prevention

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

Response

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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

P308 + P310 IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.

Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

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EXPOSURE SCENARIO 1 (Industrial use)

1. Industrial use (Pharmaceutical production)

Sectors of end-use

SU 3 Industrial uses: Uses of substances as such or in preparations at industrial sites
SU 10 Formulation [mixing] of preparations and/ or re-packaging (excluding alloys)

Chemical product category

PC19 Intermediate

Process categories

PROC1 Use in closed process, no likelihood of exposure
PROC2 Use in closed, continuous process with occasional controlled exposure
PROC3 Use in closed batch process (synthesis or formulation)
PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)
PROC8a Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
PROC8b Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at dedicated facilities
PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC14 Production of preparations or articles by tableting, compression, extrusion, pelletisation
PROC15 Use as laboratory reagent

Environmental Release Categories

ERC1 Manufacture of substances
ERC2 Formulation of preparations
ERC4 Industrial use of processing aids in processes and products, not becoming part of articles
ERC6a Industrial use resulting in manufacture of another substance (use of intermediates)
ERC6b Industrial use of reactive processing aids

2. Contributing scenarios: Operational conditions and risk management measures

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2.1 Contributing scenario controlling environmental exposure for: ERC1, ERC2, ERC4, ERC6a, ERC6b

Technical conditions and measures / Organizational measures

Water	Solutions with high pH-value must be neutralized before discharge.
Remarks	Do not allow uncontrolled discharge of product into the environment.

2.2 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC14, PROC15

Product characteristics

Concentration of the Substance in Mixture/Article	Covers the percentage of the substance in the product up to 100 %.
Physical Form (at time of use)	Aqueous solution

Frequency and duration of use

Frequency of use	600 minutes/day
Frequency of use	200 days/year

Other operational conditions affecting workers exposure

Outdoor / Indoor	Indoor without local exhaust ventilation (LEV)
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Technical conditions and measures

Good work practice required. Ensure adequate ventilation, especially in confined areas.

Conditions and measures related to personal protection, hygiene and health evaluation

Wear suitable gloves (tested to EN374), coverall and eye protection. Breathing apparatus only if aerosol or dust is formed.

3. Exposure estimation and reference to its source

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Catalogue No.	137041
Product name	Sodium hydroxide solution 5 mol/L EMPROVE® EXPERT

For (other) local effects risk management measures are based on qualitative risk characterisation.

4. Guidance to Downstream User to evaluate whether he works inside the boundaries set by the Exposure Scenario

Please refer to the following documents: ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system; ECHA Guidance for downstream users; ECHA Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building, Part E: Risk Characterisation and Part G: Extending the SDS; VCI/Cefic REACH Practical Guides on Exposure Assessment and Communications in the Supply Chain; CEFIC Guidance Specific Environmental Release Categories (SPERCs).