



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 22.02.2013

Version 3.7

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

1.1 Product identifier

Catalogue No.	817073
Product name	Fumaric acid NF
REACH Registration Number	A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Identified uses	Pharmaceutical production For additional information on uses please refer to the Merck Chemicals portal (www.merck-chemicals.com).
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1.3 Details of the supplier of the safety data sheet

Company	Merck KGaA * 64271 Darmstadt * Germany * Phone:+49 6151 72-0
Responsible Department	EQ-RS * 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)

Eye irritation, Category 2, H319

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

Classification (67/548/EEC or 1999/45/EC)

Xi Irritant R36

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word

Warning

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Hazard statements

H319 Causes serious eye irritation.

Precautionary statements

Response

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

Reduced labelling (≤125 ml)


Hazard pictograms



Signal word
Warning

Index-No. 607-146-00-X

Labelling (67/548/EEC or 1999/45/EC)

Symbol(s)  Xi Irritant

R-phrase(s) 36 Irritating to eyes.

S-phrase(s) 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

EC-No. 203-743-0 EC Label

Reduced labelling (≤125 ml)

Symbol(s)  Xi Irritant

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

3.1 Substance

Formula	HOOCCH ₂ CHCOOH	C ₄ H ₄ O ₄ (Hill)
CAS-No.	110-17-8	
Index-No.	607-146-00-X	
EC-No.	203-743-0	
Molar mass	116,07 g/mol	

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

Chemical Name (Concentration)

CAS-No.	Registration number	Classification
<i>fumaric acid (<= 100 %)</i>		
110-17-8	*)	Eye irritation, Category 2, H319

*) A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

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Hazardous components (1999/45/EC)

Chemical Name (Concentration)

CAS-No.	Classification
fumaric acid (<= 100 %)	
110-17-8	Xi, Irritant; R36

For the full text of the R-phrases mentioned in this Section, see Section 16.

3.2 Mixture

not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

After skin contact: wash off with plenty of water. Remove contaminated clothing.

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, Nausea

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

Water, Carbon dioxide (CO₂), Foam, Dry powder

Unsuitable extinguishing media

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

5.2 Special hazards arising from the substance or mixture

Combustible.

Forms explosive mixtures with air on intense heating.

Development of hazardous combustion gases or vapours possible in the event of fire.

Risk of dust explosion.

5.3 Advice for firefighters

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

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. Avoid inhalation of dusts. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

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Advice for emergency responders: Protective equipment see section 8.

6.2 Environmental precautions

Do not empty into 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 dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

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.

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

Storage conditions

Tightly closed. Dry.

Store at +15°C to +25°C.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Engineering measures

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

Safety glasses

Hand protection

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm

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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).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

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 dusts are generated.

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 empty into drains.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	white
Odour	odourless
Odour Threshold	No information available.
pH	2,1 at 4,9 g/l 20 °C
Melting point	287 °C
Boiling point/boiling range	290 °C at 1.013 hPa (sublimed)
Flash point	273 °C Method: DIN 51758

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Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	< 0,001 hPa at 20 °C
Relative vapour density	No information available.
Relative density	1,64 g/cm ³ at 20 °C
Water solubility	4,9 g/l at 20 °C
Partition coefficient: n-octanol/water	log Pow: 0,33 (experimental) Bioaccumulation is not expected. (Lit.)
Auto-ignition temperature	No information available.
Decomposition temperature	> 350 °C
Viscosity, dynamic	No information available.
Explosive properties	No information available.
Oxidizing properties	No information available.

9.2 Other data

Ignition temperature 375 °C

SECTION 10. Stability and reactivity

10.1 Reactivity

Forms explosive mixtures with air on intense heating.
Risk of dust explosion.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Oxidizing agents, Bases, Reducing agents, Amines

10.4 Conditions to avoid

Strong heating.

A range from approx. 15 Kelvin below the flash point is to be rated as critical.

10.5 Incompatible materials

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no information available

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 rat: 9.300 mg/kg (RTECS)

Symptoms: After uptake of large quantities:, Irritation of mucous membranes, Nausea

Acute inhalation toxicity

Symptoms: Possible damages:, Irritation symptoms in the respiratory tract.

LC0 rat: > 1.306 mg/l; 4 h (ECHA)

OECD Test Guideline 403

Acute dermal toxicity

LD50 rabbit: 20.000 mg/kg

OECD Test Guideline 402 (IUCLID)

Skin irritation

rabbit

Result: No irritation

OECD Test Guideline 404

Eye irritation

rabbit

Result: Eye irritation

OECD Test Guideline 405

Causes serious eye irritation.

Sensitisation

Sensitisation test: guinea pig

Result: negative

Method: OECD Test Guideline 406

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

(National Toxicology Program)

Mutagenicity (mammal cell test):

Mouse lymphoma test

Result: negative

Method: OECD Test Guideline 476

Carcinogenicity

No carcinogenic properties suspected. (IUCLID)

Reproductive toxicity

No impairment of reproductive performance suspected. (IUCLID)

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

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Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

Toxicity to fish

LC50 Danio rerio (zebra fish): 245 mg/l; 48 h (Lit.)

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 212 mg/l; 48 h (ECOTOX Database)

Toxicity to algae

IC50 Desmodesmus subspicatus (green algae): 41 mg/l; 72 h (IUCLID)

NOEC Pseudokirchneriella subcapitata (green algae): > 100 mg/l; 72 h

OECD Test Guideline 201

Toxicity to bacteria

EC10 Pseudomonas putida: 23,2 mg/l; 6 h (IUCLID)

12.2 Persistence and degradability

Biodegradability

98 %; 21 d

OECD Test Guideline 301E

Readily biodegradable.

Theoretical oxygen demand (ThOD)

827 mg/g

(Lit.)

Ratio BOD/ThBOD

BOD5 34 %

(Lit.)

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

log Pow: 0,33

(experimental)

Bioaccumulation is not expected. (Lit.)

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects

Henry constant

Transition from water solution into the atmosphere is not to be expected.

Additional ecological information

Discharge into the environment must be avoided.

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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 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

Sea transport (IMDG)

14.1 - 14.6 Not classified as dangerous in the meaning of transport regulations.

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 96/82/EC

Legislation Directive 96/82/EC does not apply

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

National legislation

Storage class 10 - 13

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.

H319 Causes serious eye irritation.

Full text of R-phrases referred to under sections 2 and 3

R36 Irritating to eyes.

Training advice

Provide adequate information, instruction and training for operators.

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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.