



Famotidine

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form : Substance
 Substance name : Famotidine
 EC-No. : 616-396-9
 CAS-No. : 76824-35-6
 REACH registration No : &
 C&L notification reference no : 02-2119560615-37-0000
 Formula : C8 H15 N7 O3S3

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category : Industrial use.
 Industrial/Professional use spec : Industrial
 Use of the substance/mixture : Restricted use as an active ingredient in pharmaceutical industry.
 Function or use category : Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Unión Químico Farmacéutica, S.A
 Mallorca, 262, 3 planta
 ES- 08008 Barcelona
 SPAIN
 T +34.934 674 810 - F +34 934 880 491
uquifareach@uquifa.com - <http://www.uquifa.com>

1.4. Emergency telephone number

Emergency number : Tel. +34 938 439 003 +34 938 670 421
 Office hours (monday to friday, 9 am- 17 pm GTM+1)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Respiratory sensitisation, Category 1 H334
 Skin sensitisation, Category 1 H317

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

Adverse physicochemical, human health and environmental effects

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)





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	GHS08
Signal word (CLP)	: Danger
Hazard statements (CLP)	: H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements (CLP)	: P261 - Avoid breathing dust, mist, vapours. P280 - Wear eye protection, protective gloves, face protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P342+P311 - If experiencing respiratory symptoms, call a doctor.

2.3. Other hazards

PBT: not yet assessed.

vPvB: not yet assessed.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%
Famotidine	CAS-No.: 76824-35-6 EC-No.: 616-396-9 REACH-no: &	100

3.2. Mixtures

Not applicable.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
First-aid measures after skin contact	: Remove/Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Get medical advice/attention if you feel unwell.
First-aid measures after ingestion	: Rinse mouth. Do NOT Induce vomiting. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after skin contact	: There are reports of contact allergy. May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.





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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Sand. Foam. Dry powder.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : May intensify fire; oxidiser.
- Explosion hazard : Explosion may result if is dispersed and finds an ignition source.
- Hazardous decomposition products in case of fire : Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

- Precautionary measures fire : Evacuate area. Fight fire remotely due to the risk of explosion. Stop leak if safe to do so.
- Firefighting instructions : Eliminate all ignition sources if safe to do so. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Fight fire with normal precautions from a reasonable distance.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Use self-contained breathing apparatus and chemically protective clothing. NBC suit. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Collect spillage.

6.1.1. For non-emergency personnel

- Protective equipment : Concerning personal protective equipment to use, see section 8.
- Emergency procedures : Avoid breathing dust, mist, vapours. Avoid contact with skin and eyes. Only qualified personnel equipped with suitable protective equipment may intervene.
- Measures in case of dust release : Avoid dust formation. Avoid dust to spread. Dust production: have neighbourhood close doors and windows.

6.1.2. For emergency responders

- Protective equipment : Special protective equipment for fire-fighters. Do not attempt to take action without suitable protective equipment. Concerning personal protective equipment to use, see section 8. For further information refer to section 8: "Exposure controls/personal protection".
- Emergency procedures : Evacuate unnecessary personnel.

6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
- Methods for cleaning up : Mechanically recover the product. Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage. On land, sweep or shovel into suitable containers.
- Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls/personal protection. For further information refer to section 13.





SECTION 7: Handling and storage

7.1. Precautions for safe handling

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|-----------------------------------|---|--|
| Additional hazards when processed | : | Provide adequate ventilation of the area to prevent the formation of explosive atmospheres. |
| Precautions for safe handling | : | Ensure good ventilation of the work station. Avoid breathing dust, mist, vapours. Avoid contact with skin and eyes. Wear personal protective equipment. Take any precaution to avoid mixing with incompatible materials. |
| Hygiene measures | : | Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Wash hands, forearms and face thoroughly after handling. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. |

7.2. Conditions for safe storage, including any incompatibilities

- | | | |
|-------------------------------|---|--|
| Technical measures | : | Provide local exhaust or general room ventilation. Provide adequate ventilation of the area to prevent the formation of explosive atmospheres. |
| Storage conditions | : | Store in a well-ventilated place. Keep container tightly closed. Store in a well-ventilated place. Keep cool. |
| Incompatible products | : | Strong acids. Strong bases. |
| Incompatible materials | : | Heat sources. Combustible materials. Sources of ignition. |
| Heat and ignition sources | : | Keep away from sparks, heat, open flames, hot surfaces. - No smoking. |
| Prohibitions on mixed storage | : | Incompatible materials. Incompatible products. |
| Storage area | : | Store in a dry place. Store in a well-ventilated place. |
| Special rules on packaging | : | Store in a closed container. Keep only in original container. |
| Packaging materials | : | Store always product in container of same material as original container. |

7.3. Specific end use(s)

Restricted use as an active ingredient in pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods

Monitoring methods	Respirable Fraction.
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8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding	:	Band 4 - (Very toxic on single exposure; reproductive hazard; sensitizer) : Seek expert advice.
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Melting point	: 163,5 (163 – 164) °C
Freezing point	: Not determined. Reason: No additional information available
Softening point	: Not determined. Reason: No additional information available
Boiling point	: 662,4 °C at 760mmHg #
Flammability	: Not determined. Reason: No available data Non flammable.
Explosive properties	: Explosion may result if is dispersed and finds an ignition source. Not classified as explosive according to EC criteria, but may present risks in the event of a fire.
Oxidising properties	: May intensify fire; oxidiser.
Explosive limits	: Not determined. Reason: No additional information available
Lower explosion limit	: Not applicable.
Upper explosion limit	: Not applicable.
Class	: St1
Kst	: 46 bar m/s
Maximum pressure	: 6,4 bar
Volume resistivity (Electric conductivity)	: 6800000 Ωm
Minimum Ignition Temperature (cloud)	: 440 °C
Minimum ignition energy	: > 1000 mJ
Flash point	: 400 °C
Auto-ignition temperature	: Not determined. Reason: No additional information available
Decomposition temperature	: Not determined. Reason: No additional information available
SADT	: Not determined. Reason: No additional information available
pH	: 6,25 Source: Akron Univ.
pH solution	: Not determined. Reason: No additional information available
Viscosity, kinematic	: Not determined. Reason: No additional information available
Viscosity, dynamic	: Not determined. Reason: No additional information available
Solubility	: Water.: 1000 mg/l Source: NLM; chemIDplus
Log Kow	: Not available
Log Pow	: 0,64 Source: NLM; chemIDplus
Vapour pressure	: 0 mm Hg #
Vapour pressure at 50 °C	: Not determined. Reason: No additional information available
Critical pressure	: Not determined. Reason: No additional information available
Saturation concentration	: Not determined. Reason: No additional information available
Density	: Not determined. Reason: No additional information available
Relative density	: Not determined. Reason: No additional information available
Relative vapour density at 20 °C	: Not determined. Reason: No additional information available
Relative density of saturated gas/air mixture	: Not determined. Reason: No additional information available
Relative gas density	: Not determined. Reason: No additional information available
Particle size	: To check Certificate of analysis
Particle size distribution	: Not determined. Reason: No additional information available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not determined. Reason: No additional information available
Particle agglomeration state	: Not determined. Reason: No additional information available





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Particle specific surface area	:	Not determined. Reason: No additional information available
Particle dustiness	:	Not determined. Reason: No additional information available

9.2. Other information**9.2.1. Information with regard to physical hazard classes**

Critical temperature	:	Not determined. Reason: No additional information available
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9.2.2. Other safety characteristics

Minimum ignition energy	:	> 1000 mJ
Relative evaporation rate (butylacetate=1)	:	Not determined. Reason: No additional information available
Relative evaporation rate (ether=1)	:	Not determined. Reason: No additional information available
Miscibility	:	Not determined. Reason: No additional information available
Specific conductivity	:	Not determined. Reason: No additional information available
Sublimation point	:	Not determined. Reason: No additional information available
VOC content	:	Not determined. Reason: No additional information available
Fat solubility	:	Not determined. Reason: No additional information available
Bulk density	:	Not determined. Reason: No additional information available
Refractive index	:	Not determined. Reason: No additional information available

SECTION 10: Stability and reactivity**10.1. Reactivity**

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Safety: Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

See SECTION 7: Incompatible materials.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity (oral)	:	Not classified (Based on available data, the classification criteria are not met.)
Acute toxicity (dermal)	:	Not classified (No reference available)
Acute toxicity (inhalation)	:	Not classified (No reference available)

Famotidine (76824-35-6)

LD50 oral rat	:	4049 mg/kg Source: NLM; ChemIDPlus;
Skin corrosion/irritation	:	Not classified (No reference available) pH: 6,25 Source: Akron Univ.





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Serious eye damage/irritation	: Not classified (No reference available) pH: 6,25 Source: Akron Univ.
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Additional information	: There are reports of contact allergy.
Germ cell mutagenicity	: Not classified (No reference available)
Carcinogenicity	: Not classified (No reference available)
Reproductive toxicity	: Not classified (No reference available)
STOT-single exposure	: Not classified (No reference available)
STOT-repeated exposure	: Not classified (No reference available)
Aspiration hazard	: Not classified (No reference available)

Famotidine (76824-35-6)

Viscosity, kinematic	Not determined. Reason: No additional information available
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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Not established.
Ecology - water	: Not established.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No reference available)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (No reference available)

Famotidine (76824-35-6)

EC50 Daphnia 1	136,577 mg/l Source: EPISUITE
EC50 96h - Algae [1]	4,07 mg/l Source: EPISUITE

12.2. Persistence and degradability

Famotidine (76824-35-6)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

Famotidine (76824-35-6)

Log Pow 0,64 Source: NLM; chemIDplus

Bioaccumulative potential Not established.

12.4. Mobility in soil

Famotidine (76824-35-6)

Mobility in soil 4,647

Ecology - soil Not established.

12.5. Results of PBT and vPvB assessment

Famotidine (76824-35-6)

PBT: not yet assessed.

vPvB: not yet assessed.

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	:	Disposal must be done according to official regulations.
Waste treatment methods	:	Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	:	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment. Do not pierce or burn, even after use.
Additional information	:	Follow the instructions on handling and technical measures of paragraph 7. Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	:	Avoid release to the environment.
European List of Waste (LoW) code	:	16 03 05* - organic wastes containing dangerous substances
HP Code	:	HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR)	:	Not regulated
UN-No. (IMDG)	:	Not regulated
UN-No. (IATA)	:	Not regulated





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14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated
 Proper Shipping Name (IMDG) : Not regulated
 Proper Shipping Name (IATA) : Not regulated

14.3. Transport hazard class(es)**ADR**

Transport hazard class(es) (ADR) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

14.4. Packing group

Packing group (ADR) : Not regulated
 Packing group (IMDG) : Not regulated
 Packing group (IATA) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : No
 Marine pollutant : No
 Other information : No supplementary information available

14.6. Special precautions for user**Overland transport**

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

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****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Famotidine is not on the REACH Candidate List

Famotidine is not on the REACH Annex XIV List

Famotidine is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.



according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Famotidine

Famotidine is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

VOC content : Not determined. Reason: No additional information available

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the Canadian DSL (Domestic Substances List)

Bulgaria

Bulgarian National Regulations : Environmental Protection Act.
Health and Safety at Work Act.
Law of protection from the harmful impact of the chemical substances and mixtures.
Ordinance No 13 on protection of workers from the risks related to exposure to chemical agents at work.
Ordinance No. 6 on the terms and conditions for granting permission for work of persons under 18 years of age.
Ordinance No. RD-07-4 on improvement of the working conditions of pregnant workers and workers have recently given birth or nursing mothers.
Ordinance No.3 on the minimum requirements for the workers' safety and health protection in using personal protection means at the workplace.
Ordinance on the conditions and manner for storage of hazardous chemical substances and mixtures.
Waste management law.

Croatia

Croatian National Regulations : Chemicals Act, Regulation on classification, labelling and packaging of chemicals, Regulations on dangerous substances.
Waste Act, Waste types regulations, Packaging Waste Regulation, Dangerous.
Waste Regulation.

Czech Republic

Czech National Regulations : Government Regulation no. 9/2013 Coll, amending Regulation no. 361/2007 Coll, governing the conditions of Health Protection at Work, as amended.
Act no. 185/2001 Coll, on waste and amendment of some other acts, as amended.
Act no. 20/1966 Coll, on Public Health Care.
Act no. 350/2011 Coll. on chemical substances and mixtures and amendment of some other acts (Chemical Act).
Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.
Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).





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Germany

- Employment restrictions : Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.
Employment prohibitions or restrictions on the protection of young people at work according to § 22 JArbSchG in the case of formation of hazardous substances have to be observed.
Employment prohibitions and restrictions according to § 11 and § 12 MuSchG have to be observed.
- Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)
- 12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)
- National Rules and Recommendations : TRBA/TRGS 406: Sensitizing substances for respiratory system
Observe prohibitions in accordance with chemicals Prohibition Ordinance
Note information and record-keeping obligations for the supply to third parties in accordance with the Chemicals Prohibition Ordinance
Note permission and notification requirements in accordance with the Chemicals Prohibition Ordinance
TRGS 400: Risk Assessment for Activities Involving Hazardous Substances
TRGS 500: Protective measures
TRGS 555: Working instruction and information for workers
TRGS 910: Risk-related concept of measures for activities involving carcinogenic hazardous substances
- Technical Instructions on Air Quality Control (TA Luft) : 5.2.5 Organic Substances
- Storage class (LGK, TRGS 510) : LGK 13 - Non-combustible solids

Hungary

- Hungarian National Regulations : 25/2000. (IX.30.) Joint Provision of the Ministry of Health and Social and Family Affairs on the Occupational Safety in Chemistry.
Act CLXXXV of 2012 on waste.
Act XXV. of 2000 on the Safety in Chemistry, 44/2000. (XII. 27.) Provision of the Ministry of Health on detailed rules of procedures and activities related to hazardous substances and preparations.

Netherlands

- ABM category : B(4) - low hazard for aquatic organisms
- SZW-lijst van kankerverwekkende stoffen : The substance is not listed
- SZW-lijst van mutagene stoffen : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

- Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Norway

- Norwegian National Regulations : The user needs to be instructed on how to execute such work, on the dangers surrounding such a product and on the necessary safety instructions.
This training must be provided by a qualified staff.

Slovenian National Regulations

- ## Switzerland

- ### Swiss National Regulations

- Storage class (LK)

- : LK 6.1 - Toxic materials

- Ordinance on Air Pollution Control (SR 814.318.142.1) : Annex 1, number 4

15.2. Chemical safety assessment

Exempted from REACH registration.

SECTION 16: Other information

Indication of changes

Revision date: 18/11/2021



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Indication of changes

Section	Changed item	Change	Comments
9.1	Particle dustiness	Added	
9.1	Particle agglomeration state	Added	
9.1	Particle size	Added	
9.1	Particle specific surface area	Added	
9.1	Particle aggregation state	Added	
11	Adverse health effects caused by endocrine disrupting properties	Added	
12.	Adverse effects on the environment caused by endocrine disrupting properties	Added	
12.	Mobility in soil	Added	
12.	EC50 96h algae (1)	Added	

Abbreviations and acronyms:

&	Exempt under REACH for Active Ingredients, <1000 kg, natural substances...
#	Estimated or calculated values.
*	Transmission of information in the supply chain.
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
Lit	Bibliography
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources : Bibliography. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Training advice : Training staff on good practice.

Safety Data Sheet



according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Famotidine

Notes : THIS DOCUMENT HAS BEEN AUTOMATICALLY APPROVED, SO IT IS NOT SIGNED.

Full text of H- and EUH-statements:

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Sens. 1	Skin sensitisation, Category 1

SDS EU (Anexo II REACH)

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This document is the English version.



