

SAFETY DATA SHEETS

This SDS packet was issued with item:

078939105

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078939107 078939111



Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g), Rev. 2012 and GHS Rev 03.

Printing date 08/14/2014

Reviewed on 08/14/2014

1 Identification

· **Product identifier**

· **Trade name: Famotidine Tablets USP 20 mg & 40mg**

· **Product description**

Famotidine Tablet USP is a white round tablet.

Famotidine Tablet USP is indicated for short-term treatment and maintenance therapy of duodenal ulcer, short-term treatment of active benign gastric ulcer, short-term treatment of gastroesophageal reflux disease (GERD), and treatment of pathological hypersecretory conditions.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Carlsbad Technology Inc.
5922 Farnsworth Court, Carlsbad, CA 92008
Ph: 760-431-8284
Fax: 760-431-7507

2 Hazard(s) identification

· **Classification of the substance or mixture**



Health hazard

Suspected of causing cancer.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Warning

· **Hazard-determining components of labeling:**

titanium dioxide
Talc (Mg₃H₂(SiO₃)₄)

· **Hazard statements**

Suspected of causing cancer.

· **Precautionary statements**

Use personal protective equipment as required.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 2
Fire = 0
Reactivity = 0

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Trade name: Famotidine Tablets USP 20 mg & 40mg

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· HMIS-ratings (scale 0 - 4)

HEALTH	2	Health = 2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

* 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous Components:

9004-34-6	Cellulose
76824-35-6	Famotidine ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
9005-25-8	Starch ⚠ STOT SE 3, H335
9063-38-1	Sodium Starch Glycolate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
102-76-1	triacetin ⚠ Acute Tox. 3, H311
13463-67-7	titanium dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335
25322-68-3	Polyethylene glycol
68424-04-4	Polydextrose ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄) ⚠ Carc. 2, H351; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320

* 4 First-aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.
In case of unconsciousness, place patient securely on side position for transportation.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

* 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**

• **Components with occupational exposure limits:**

9004-34-6 Cellulose

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

9005-25-8 Starch

PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³

13463-67-7 titanium dioxide

PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A

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TLV	Long-term value: (10) NIC-1* mg/m ³ *respirable fraction, NIC-A3
25322-68-3 Polyethylene glycol	
WEEL	Long-term value: 10 mg/m ³ (H); MW>200
14807-96-6 Talc (Mg₃H₂(SiO₃)₄)	
PEL	Long-term value: 20 mppcf ppm (containing <1% Quartz)
REL	Long-term value: 2* mg/m ³ *respirable dust
TLV	Long-term value: 2* mg/m ³ *as respirable fraction; E

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- **Breathing equipment:** Not required.

- **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Select glove material based on penetration times, rates of diffusion and degradation.

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Tablets

Color: Off white to white

- **Odor:** Odorless

- **Odor threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

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**Safety Data Sheet (SDS)**

OSHA HazCom Standard 29 CFR 1910.1200(g), Rev. 2012 and GHS Rev 03.

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Trade name: Famotidine Tablets USP 20 mg & 40mg

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- **Ignition temperature:** 340 °C (644 °F)
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with Water:** Insoluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **Solvent content:**
 - Organic solvents:** 0.0 %
 - Solids content:** 100.0 %
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

***11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:

76824-35-6 Famotidine

Oral	LD50	4049 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:

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Harmful

- **Carcinogenic categories**

• IARC (International Agency for Research on Cancer)		
13463-67-7	titanium dioxide	2B
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	2B
• NTP (National Toxicology Program)		
None of the ingredients are listed.		
• OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients are listed.		

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Water hazard class 1 (Self-assessment): slightly hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

* 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

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Trade name: Famotidine Tablets USP 20 mg & 40mg

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* 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients are listed.

- **TLV (Threshold Limit Value established by ACGIH)**

9005-25-8	Starch	A4
13463-67-7	titanium dioxide	A4
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

13463-67-7 titanium dioxide

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS08

- **Signal word** Warning

- **Hazard-determining components of labeling:**

titanium dioxide
Talc (Mg₃H₂(SiO₃)₄)

- **Hazard statements**

Suspected of causing cancer.

- **Precautionary statements**

Use personal protective equipment as required.

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Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g), Rev. 2012 and GHS Rev 03.

Printing date 08/14/2014

Reviewed on 08/14/2014

Trade name: Famotidine Tablets USP 20 mg & 40mg

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Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 IF exposed or concerned: Get medical advice/attention.
 Store locked up.
 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **National regulations:**

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

• **State Right to Know**

9004-34-6	Cellulose
76824-35-6	Famotidine ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
9005-25-8	Starch ⚠ STOT SE 3, H335
9063-38-1	Sodium Starch Glycolate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
102-76-1	triacetin ⚠ Acute Tox. 3, H311
13463-67-7	titanium dioxide ⚠ Carc. 2, H351; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335

All ingredients are listed.

• **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

• **Date of preparation / last revision** 08/14/2014 / 6

• **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
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 NFPA: National Fire Protection Association (USA)
 HMIS: Hazardous Materials Identification System (USA)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 Acute Tox. 4: Acute toxicity, Hazard Category 4
 Acute Tox. 3: Acute toxicity, Hazard Category 3
 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
 Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
 Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B
 Carc. 2: Carcinogenicity, Hazard Category 2
 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 04/26/2019

Reviewed on 04/25/2019

1 Identification

· **Product Identifier**

· **Trade Name: Famotidine Tablets USP 20 mg & 40mg**

· **Relevant identified uses of the substance or mixture and uses advised against:**

· **Product Description:**

Famotidine Tablet USP is a white round tablet.

Famotidine Tablet USP is indicated for short-term treatment and maintenance therapy of duodenal ulcer, short-term treatment of active benign gastric ulcer, short-term treatment of gastroesophageal reflux disease (GERD), and treatment of pathological hypersecretory conditions.

· **Details of the Supplier of the Safety Data Sheet:**

· **Manufacturer/Supplier:**

Carlsbad Technology Inc.
5922 Farnsworth Court, Carlsbad, CA 92008
Ph: 760-431-8284
Fax: 760-431-7507

· **Emergency telephone number:** 760-431-8284

2 Hazard(s) Identification

· **Classification of the substance or mixture:**



Health hazard

Carc. 2 H351 Suspected of causing cancer.



STOT SE 3 H335 May cause respiratory irritation.

· **Label elements:**

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labeling:**

Famotidine
Titanium Dioxide
Starch
Sodium Starch Glycolate

· **Hazard statements:**

H351 Suspected of causing cancer.
H335 May cause respiratory irritation.

· **Precautionary statements:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 04/26/2019

Reviewed on 04/25/2019

Trade Name: Famotidine Tablets USP 20 mg & 40mg

- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P312 Call a poison center/doctor if you feel unwell.
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Unknown acute toxicity:**

This value refers to knowledge of known, established toxicological or ecotoxicological values.
20.4 % of the mixture consists of component(s) of unknown toxicity.

· **Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Hazard(s) not otherwise classified (HNOC):** None known

3 Composition/Information on Ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with non-hazardous additions.

· **Dangerous Components:**

CAS: 9004-34-6	Cellulose
CAS: 76824-35-6 RTECS: UA2300000	Famotidine ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
CAS: 9005-25-8	Starch ⚠ STOT SE 3, H335; Combustible Dust
CAS: 9063-38-1	Sodium Starch Glycolate ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
CAS: 102-76-1 RTECS: AK 3675000	(tri-)Acetin ⚠ Acute Tox. 3, H311
CAS: 13463-67-7	Titanium Dioxide ⚠ Carc. 2, H351
CAS: 25322-68-3	Polyethylene Glycol
CAS: 68424-04-4	Polydextrose ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320
CAS: 14807-96-6	Talc (Mg3H2(SiO3)4) ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320

· **Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

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Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 04/26/2019

Reviewed on 04/25/2019

Trade Name: Famotidine Tablets USP 20 mg & 40mg

4 First-Aid Measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may occur after exposure to dust, fumes or particulates; seek medical attention if feeling unwell.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.
In case of unconsciousness place patient stably in the side position for transportation.
- **After skin contact:** If skin irritation occurs, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
If eye irritation occurs, consult a doctor.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

* 5 Fire-Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** No further relevant information.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
- **Special protective equipment for firefighters:**
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** Do not allow to enter sewers/surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
Dispose of the collected material according to regulations.
- **Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

· PAC-1:

102-76-1	(tri-)Acetin	19 mg/m ³
13463-67-7	Titanium Dioxide	30 mg/m ³
25322-68-3	Polyethylene Glycol	30 mg/m ³

· PAC-2:

102-76-1	(tri-)Acetin	210 mg/m ³
13463-67-7	Titanium Dioxide	330 mg/m ³
25322-68-3	Polyethylene Glycol	1,300 mg/m ³

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Trade Name: Famotidine Tablets USP 20 mg & 40mg

· PAC-3:		
102-76-1	(tri-)Acetin	1,200 mg/m ³
13463-67-7	Titanium Dioxide	2,000 mg/m ³
25322-68-3	Polyethylene Glycol	7,700 mg/m ³

7 Handling and Storage

- **Handling**
- **Precautions for safe handling:**
Avoid creating and breathing dust/fume/gas/mist/vapors/spray.
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in the original container.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s):** No further relevant information available.

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

9004-34-6 Cellulose	
PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³
9005-25-8 Starch	
PEL	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	Long-term value: 10 mg/m ³
13463-67-7 Titanium Dioxide	
PEL	Long-term value: 15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	Long-term value: 10 mg/m ³
25322-68-3 Polyethylene Glycol	
WEEL	Long-term value: 10 mg/m ³ (H); MW>200

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Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 04/26/2019

Reviewed on 04/25/2019

Trade Name: Famotidine Tablets USP 20 mg & 40mg

14807-96-6 Talc (Mg ₃ H ₂ (SiO ₃) ₄)	
PEL	Long-term value: 20 mppcf ppm (containing <1% Quartz)
REL	Long-term value: 2* mg/m ³ *respirable dust; and <1% Quartz
TLV	Long-term value: 2* mg/m ³ *as respirable fraction; E

· **Additional information:** The lists that were valid during the creation of this SDS were used as basis.

· **Exposure controls:**

· **Personal protective equipment**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing and wash before reuse.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Breathing equipment:** Not required.

· **Protection of hands:**



Protective gloves

· **Material of gloves:** Not applicable.

· **Penetration time of glove material:** Not applicable.

· **Eye protection:** Not required.

· **Limitation and supervision of exposure into the environment:** None

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Tablets

Color: Off white to white

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

· **Flash point:** None

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:** ≥340 °C (≥644 °F)

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

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Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 04/26/2019

Reviewed on 04/25/2019

Trade Name: Famotidine Tablets USP 20 mg & 40mg

- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density:** Not determined.
- **Vapor density:** Not applicable.
- **Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with:**
 - Water:** Insoluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **Solvent content:**
 - VOC content:** 0.00 %
 - Solids content:** 100.0 %
- **Other information:** No further relevant information available.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

*** 11 Toxicological Information**

- **Information on toxicological effects:**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
9004-34-6 Wood Fibers		
Oral	LD50	>5,000 mg/kg (Rat)
Dermal	LD50	>2,000 mg/kg (Rabbit)
76824-35-6 Famotidine		
Oral	LD50	4,049 mg/kg (Rat)
102-76-1 (tri-)Acetin		
Oral	LD50	3,000 mg/kg (Rat)
13463-67-7 Titanium Dioxide		
Oral	LD50	>10,000 mg/kg (Rat)
Dermal	LD50	>10,000 mg/kg (Rabbit)
Inhalative	LC50/4 h	>6.82 mg/l (Rat)

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25322-68-3 Polyethylene Glycol		
Oral	LD50	>5,000 mg/kg (Rat)
Dermal	LD50	>5,000 mg/kg (Rabbit)
Inhalative	LC50/96 hours	10,000 mg/l (Fish - Poecilia reticulata, 96h)
68424-04-4 Polydextrose		
Oral	LD50	15,000 mg/kg (Rat)

- **Primary irritant effect:**

- **On the skin:** No irritating effect.

- **On the eye:** No irritating effect.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories:**

- **IARC (International Agency for Research on Cancer):**

(a) Although IARC has classified titanium dioxide as possible carcinogenic to human (2B), their summary concludes: "No significant exposure to titanium dioxide is thought to occur during the use of products which titanium dioxide is bound to other materials, such as in cosmetics or in paints."

(b) OSHA does not regulate Titanium Dioxide as a carcinogen. However, under 29 CFR 1910.1200 the SDS must convey the fact that Titanium Dioxide is a potential carcinogen to rats.

Group 1 - Carcinogenic to humans

Group 2A - Probably carcinogenic to humans

Group 2B - Possibly carcinogenic to humans

Group 3 - Not classifiable as to its carcinogenicity to humans

Group 4 - Probably not carcinogenic to humans

13463-67-7	Titanium Dioxide	2B
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	3

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

12 Ecological Information

- **Toxicity:**

- **Aquatic toxicity:**

13463-67-7 Titanium Dioxide

EC50 >1,000 mg/l (Water flea)

- **Persistence and degradability:** No further relevant information available.

- **Behavior in environmental systems:**

- **Bioaccumulative potential:** No further relevant information available.

- **Mobility in soil:** No further relevant information available.

- **Additional ecological information:**

- **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

- **Results of PBT and vPvB assessment:**

- **PBT:** Not applicable.

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- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

13 Disposal Considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

· Section 355 (extremely hazardous substances):
--

None of the ingredients are listed.

· Section 313 (Specific toxic chemical listings):
--

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

9004-34-6	Cellulose	ACTIVE
9005-25-8	Starch	ACTIVE
9063-38-1	Sodium Starch Glycolate	ACTIVE
102-76-1	(tri-)Acetin	ACTIVE
13463-67-7	Titanium Dioxide	ACTIVE
25322-68-3	Polyethylene Glycol	ACTIVE
14807-96-6	Talc (Mg3H2(SiO3)4)	ACTIVE
557-04-0	Magnesium Stearate	ACTIVE

· Hazardous Air Pollutants

None of the ingredients are listed.

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· **California Proposition 65:**

· **Chemicals known to cause cancer:**

13463-67-7	Titanium Dioxide
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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

· **New Jersey Right-to-Know List:**

9004-34-6	Cellulose
13463-67-7	Titanium Dioxide
25322-68-3	Polyethylene Glycol
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)

· **New Jersey Special Hazardous Substance List:**

14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	CA
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· **Pennsylvania Right-to-Know List:**

9004-34-6	Cellulose
9005-25-8	Starch
13463-67-7	Titanium Dioxide
25322-68-3	Polyethylene Glycol
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)

· **Pennsylvania Special Hazardous Substance List:**

None of the ingredients are listed.

· **Carcinogenic categories:**

· **EPA (Environmental Protection Agency):**

None of the ingredients are listed.

· **TLV (Threshold Limit Value established by ACGIH):**

9005-25-8	Starch	A4
13463-67-7	Titanium Dioxide	A4
14807-96-6	Talc (Mg ₃ H ₂ (SiO ₃) ₄)	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health):**

13463-67-7	Titanium Dioxide
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· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labeling:**

Famotidine

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Titanium Dioxide

Starch

Sodium Starch Glycolate

· Hazard statements:

H351 Suspected of causing cancer.

H335 May cause respiratory irritation.

· Precautionary statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P271 Use only outdoors or in a well-ventilated area.

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P312 Call a poison center/doctor if you feel unwell.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· National regulations:

None of the ingredients are listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.**16 Other Information**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· Date of last revision/ revision number: 04/26/2019 / 8**· Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B

Carc. 2: Carcinogenicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· * Data compared to the previous version altered.

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