

SAFETY DATA SHEET

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product identifier: GASTRO RESISTANT ESOMEPRAZOLE TABLETS – 20 mg and 40mg

Synonyms: GASFLUM

Manufacturer Name: Crassula Pharmaceuticals Pvt. Ltd.

Address: PF-23 GIDC Industrial Estate Ahmadabad
3821110 Gujarat State, India

Telephone number: 1-954-676-7060

Emergency phone number: 1-800-424-9300

Alternative Names

Esomeprazole gastro-resistant tablets
CAS No. : Not applicable.

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

Use of the Substance/Mixture : Symptomatic treatment of gastro-oesophageal reflux disease (GERD)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitisation : Category 1

Chronic aquatic toxicity : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

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Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Esomeprazole Magnesium Trihydrate

Other hazards which do not result in classification

May cause irritation to skin, eyes and respiratory system.

See Section 11.

The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	70 -71
Esomeprazole Magnesium Trihydrate	217087-09-7	5 -8

SECTION 4. FIRST AID MEASURES

- If inhaled : Remove patient from exposure.
Obtain medical attention if ill effects occur.
- In case of skin contact : Wash skin with soap and water.
- In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.
Obtain medical attention if ill effects remain.
- If swallowed : Wash out mouth with water and give 200-300ml of water to drink.
Obtain medical attention if ill effects occur.
Do NOT induce vomiting as a First-Aid measure.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
May cause an allergic skin reaction.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.
For further information consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO2.
- Unsuitable extinguishing media : Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

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- Specific hazards during firefighting : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.
Avoid dispersal of dust in the air.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
Collect spillage.
- Methods and materials for containment and cleaning up : Avoid dust generation.
Transfer spilled tablets to a suitable container for disposal.
Wash the spillage area with water.
Avoid release to the environment.

SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
Wear protective gloves.
See Section 8.
Minimize dust generation and accumulation.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
- Conditions for safe storage : Keep container tightly closed.
Protect from light.
- Recommended storage temperature : < 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m ³	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m ³	ACGIH
Esomeprazole Magnesium Trihydrate	217087-09-7	TWA	0.1 mg/m ³	COM; HYG

- Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate

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controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.
See Section 6 for environmental precautions.

Personal protective equipment

- Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.
- Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
- Skin and body protection : Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.
- Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : coated tablets
- Color : 20 mg-light red, 40 mg-red oxide
- Odour : No data available
- Odour Threshold : No data available

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pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	Not applicable
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.

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Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	Acids , decomposes
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Esomeprazole Magnesium Trihydrate :

Acute oral toxicity : Evident toxicity with mortality in rats at a dose of: 480 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.
Remarks: By analogy with
Esomeprazole

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Result: Mild skin irritation

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Remarks: May cause eye irritation.
May cause conjunctivitis.

11.4 Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

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Respiratory sensitisation

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Result: May cause sensitisation by skin contact.

Remarks: Omeprazole:

It is an extreme skin sensitiser in animal tests.

Many cases of occupational skin sensitisation have been reported.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Germ cell mutagenicity - Assessment : The substance is not considered to be genotoxic.

11.6 Carcinogenicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Carcinogenicity - Assessment : The substance is not considered to be carcinogenic.

11.7 Reproductive toxicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Reproductive toxicity - Assessment : There is no evidence of a teratogenic potential or any other adverse effects on reproductive function.

11.8 STOT - single exposure

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Exposure routes: Oral, Inhalation

Remarks: May cause nausea and vomiting.

Rare cases of hypersensitivity (including allergic reactions) and CNS-effects (including dizziness and muscle jerks) have been reported in patients.

Exposure routes: Inhalation

Remarks: Dust may be irritant to the respiratory tract.

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11.9 STOT - repeated exposure

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

Exposure routes: Oral

Target Organs: Stomach

Remarks: Repeated exposure may produce adverse effects.

These effects are derived from studies in animals.

Remarks: Common side effects reported from patients include headache, gastrointestinal disorders, sinusitis and respiratory infection.

May cause effects as described under single exposure.(STOT)

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Esomeprazole Magnesium Trihydrate :

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.
Remarks: Information refers to
Omeprazole sodium

Components:

Esomeprazole Magnesium Trihydrate :

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 42 mg/l
Exposure time: 96 H
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates : Exposure time: 48 H
Method: OECD Test Guideline 202

Toxicity to algae : ErC50 (green algae): > 76 mg/l
Exposure time: 72 H
Method: OECD Test Guideline 201

NOEC (green algae): 1.8 mg/l
Exposure time: 72 H
Method: OECD Test Guideline 201

Toxicity to fish (Chronic : NOEC (Pimephales promelas (fathead minnow)): 1 mg/l

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toxicity)	Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: NOEC (Sewage sludge organisms): 100 mg/l Exposure time: 3 H Test Type: Respiration inhibition

Persistence and degradability

Components:

Esomeprazole Magnesium Trihydrate:

Biodegradability	: Result: Not rapidly biodegradable Biodegradation: < 60 % Method: OECD Test Guideline 301C
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Bioaccumulative potential

Components:

Esomeprazole Magnesium Trihydrate:

Bioaccumulation	: Remarks: The substance has low potential for bioaccumulation.
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Mobility in soil

Components:

Esomeprazole Magnesium Trihydrate:

Mobility	: Remarks: Water solubility ≥ 1 mg/l.
Distribution among environmental compartments	: Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Dispose of contents/ container to an approved incineration plant.
Contaminated packaging	: Empty container will retain product residue. Observe all hazard precautions.

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SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Standard for the Uniform : No poison schedule number allocated
Scheduling of Medicines and
Poisons

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Esomeprazole Magnesium Trihydrate 217087-09-7

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

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SECTION 16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1* Flammability = 1 Physical Hazard = 0

SDS Revision History: Corrections to Sections 11 and 15.

Date of preparation: February 4, 2023

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Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).