

1 Identification

- **Product identifier**
- **Trade name:** Clopidogrel bisulfate
- **Article number:** 105000
- **CAS Number:**
120202-66-6
- **EC number:**
686-767-8
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Inc
2400 Pilot Knob Road
St. Paul, MN 55120
www.fagron.us
QA@fagron.us
- **Information department:**
Tel.: 800-423-6967
Fax: 800-339-1596
- **Emergency telephone number:**
Emergency Telephone:
US: 1-800-535-5053
International: 1-352-323-3500

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Corrosion 1B H314 Causes severe skin burns and eye damage.
Toxic to Reproduction - Effects on or via Lactation H362 May cause harm to breast-fed children.
Specific Target Organ Toxicity - Single Exposure H335 May cause respiratory irritation.
3

- **Label elements**
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS05 GHS07

- **Signal word** Danger
- **Hazard statements**
Causes severe skin burns and eye damage.
May cause harm to breast-fed children.
May cause respiratory irritation.
- **Precautionary statements**
Obtain special instructions before use.
Do not breathe dusts or mists.
Avoid contact during pregnancy/while nursing.

(Contd. on page 2)

USA

Trade name: Clopidogrel bisulfate

(Contd. of page 1)

Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.
Wear protective gloves/protective clothing/eye protection/face protection.
If swallowed: Rinse mouth. Do NOT induce vomiting.
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 3
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 3
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
CAS: 120202-66-6 Clopidogrel bisulfate
- **Identification number(s)**
- **EC number:** 686-767-8

4 First-aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Seek medical treatment.

(Contd. on page 3)

USA

Trade name: Clopidogrel bisulfate

(Contd. of page 2)

- **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:**
Carbon dioxide
Fire-extinguishing powder
Water spray
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
In case of fire, the following can be released:
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
Keep away from ignition sources
- **Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Use neutralizing agent.
Ensure adequate ventilation.
Dispose contaminated material as waste according to item 13.
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:** Substance is not listed.
- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Thorough dedusting.
Prevent formation of dust.
- **Information about protection against explosions and fires:** No special measures required.

(Contd. on page 4)

USA

Trade name: Clopidogrel bisulfate

(Contd. of page 3)

- **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 item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **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.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

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.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the 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.

- **Penetration time of glove material**

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

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

USA

(Contd. on page 5)

Trade name: Clopidogrel bisulfate

(Contd. of page 4)

9 Physical and chemical properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Crystalline powder
Color:	White
· Odor:	Characteristic
· Odor threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/Melting range:	178°C (352.4°F)
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Product is not flammable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Not determined.
· 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.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Not determined.
· Partition coefficient (n-octanol/water):	
Not determined.	
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 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** Reacts with strong oxidizing agents.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)
Sulfur oxides (SO_x)

(Contd. on page 6)

USA

Trade name: Clopidogrel bisulfate

Poisonous gases/vapors

(Contd. of page 5)

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

Oral	LD50	>2000 mg/kg (rat)
------	------	-------------------

· Primary irritant effect:

· on the skin: Caustic effect on skin and mucous membranes.

· on the eye: Strong caustic effect.

· Additional toxicological information:

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer) Substance is not listed.

· NTP (National Toxicology Program) Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

· Toxicity

· Aquatic toxicity:

EC50 (48h)	8.3 mg/l (daphnia)
------------	--------------------

· 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.

· Ecotoxicological effects:

· Remark: Toxic for fish

· Additional ecological information:

· General notes:

Do not allow product to reach ground water, water course or sewage system.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Water hazard class 2 (Self-assessment): hazardous for water

Toxic for aquatic organisms

· 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.

(Contd. on page 7)

USA

Safety Data Sheet

acc. to OSHA HCS

Page 7/8

Printing date 05/10/2023



Reviewed on 05/10/2023

Trade name: Clopidogrel bisulfate

(Contd. of page 6)

- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	UN1759
· DOT, IMDG, IATA	
· UN proper shipping name	not regulated
· DOT	CORROSIVE SOLID, N.O.S. (Clopidogrel bisulfate)
· IMDG	
· IATA	Corrosive solid, n.o.s. (Clopidogrel bisulfate)
· Transport hazard class(es)	
· DOT	
	
· Class	8 Corrosive substances
· Label	8
· IMDG, IATA	
	
· Class	8 Corrosive substances
· Label	8
· Packing group	
· DOT, IMDG, IATA	III
· Environmental hazards:	Environmentally hazardous substance, solid
· Special precautions for user	Warning: Corrosive substances
· Hazard identification number (Kemler code):	80
· EMS Number:	F-A,S-B
· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	not regulated

USA

(Contd. on page 8)

Trade name: Clopidogrel bisulfate

(Contd. of page 7)

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:**
Fagron US
Quality Assurance
- **Contact:** QA@fagron.us
- **Date of preparation / last revision** 05/10/2023
- **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial 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
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Corrosion 1B: Skin corrosion/irritation – Category 1B
Toxic to Reproduction - Effects on or via Lactation: Reproductive toxicity – effects on or via lactation
Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3
- *** Data compared to the previous version altered.**

USA