


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

- **1.1 Product identifier**
- **Trade name:** Clopidogrel bisulfate
- **Article number:** 105000
- **CAS Number:**
120202-66-6
- **EC number:**
686-767-8
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Additive for cosmetic or pharmaceutical preparations
- **1.3 Details of the supplier of the safety data sheet**
Fagron UK Ltd
4B Coquet St
Newcastle upon Tyne
England NE1 2QB
Tel. 0845 6522525
- **Further information obtainable from:**
Emergency response telephone number:
+44 (0) 845 652 2525
- **1.4 Emergency telephone number:**
Emergency response telephone number:
+44 (0) 845 652 2525

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Corr. 1B H314 Causes severe skin burns and eye damage.
Lact. H362 May cause harm to breast-fed children.
STOT SE 3 H335 May cause respiratory irritation.
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the GB CLP regulation.
- **Hazard pictograms**

GHS05 GHS07 GHS09
- **Signal word** Danger
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
H362 May cause harm to breast-fed children.
H335 May cause respiratory irritation.
H411 Toxic to aquatic life with long lasting effects.

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· **Precautionary statements**

- P263 Avoid contact during pregnancy and while nursing.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

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

SECTION 3: Composition/information on ingredients

· **3.1 Substances**

· **CAS No. Description**

CAS: 120202-66-6 Clopidogrel bisulfate

· **Identification number(s)**

· **EC number:** 686-767-8

SECTION 4: First aid measures

· **4.1 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.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

Carbon dioxide
Fire-extinguishing powder
Water spray
Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture**

In case of fire, the following can be released:

Carbon monoxide (CO)
Nitrogen oxides (NOx)

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- Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 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.
- **6.2 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.
- **6.3 Methods and material for containment and cleaning up:**
Use neutralising agent.
Ensure adequate ventilation.
Dispose contaminated material as waste according to item 13.
Dispose of the material collected according to regulations.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Thorough dedusting.
Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as 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.

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· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Hand protection**



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/face protection**



Tightly sealed goggles

· **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Physical state**

Solid

· **Colour:**

White

· **Odour:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

178°C

· **Boiling point or initial boiling point and boiling range**

Undetermined.

· **Flammability**

Product is not flammable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable.

· **Decomposition temperature:**

Not determined.

· **pH**

Not applicable.

· **Viscosity:**

· **Kinematic viscosity**

Not applicable.

· **Dynamic:**

Not applicable.

· **Solubility**

· **water:**

Not determined.

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Vapour pressure:**

Not applicable.

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<ul style="list-style-type: none"> · Density and/or relative density · Density: · Relative density · Vapour density 		<p>Not determined.</p> <p>Not determined.</p> <p>Not applicable.</p>
<ul style="list-style-type: none"> · 9.2 Other information · Appearance: · Form: · Important information on protection of health and environment, and on safety. · Auto-ignition temperature: · Explosive properties: · Change in condition · Evaporation rate 		<p>Crystalline powder</p> <p>Not determined.</p> <p>Product does not present an explosion hazard.</p> <p>Not applicable.</p>
<ul style="list-style-type: none"> · Information with regard to physical hazard classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures · Pyrophoric liquids · Pyrophoric solids · Self-heating substances and mixtures · Substances and mixtures, which emit flammable gases in contact with water · Oxidising liquids · Oxidising solids · Organic peroxides · Corrosive to metals · Desensitised explosives 		<p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p> <p>Void</p>

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** Reacts with strong oxidising agents.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
Carbon monoxide and carbon dioxide
Nitrogen oxides (NO_x)
Sulphur oxides (SO_x)
Poisonous gases/vapours

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

LD/LC50 values relevant for classification:

Oral	LD50	>2000 mg/kg (rat)
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• **Skin corrosion/irritation** Causes severe skin burns and eye damage.

• **Reproductive toxicity** May cause harm to breast-fed children.

• **STOT-single exposure** May cause respiratory irritation.

11.2 Information on other hazards

• **Endocrine disrupting properties** Substance is not listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

EC50 (48h)	8.3 mg/l (daphnia)
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• **12.2 Persistence and degradability** No further relevant information available.

• **12.3 Bioaccumulative potential** No further relevant information available.

• **12.4 Mobility in soil** No further relevant information available.

12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse 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 sewage water or drainage ditch undiluted or unneutralised.

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 (German Regulation) (Self-assessment): hazardous for water

Toxic for aquatic organisms

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA

UN1759

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Safety data sheet

according to 1907/2006/EC, Article 31

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<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR · IMDG · IATA 	<p>not regulated</p> <p>CORROSIVE SOLID, N.O.S. (Clopidogrel bisulfate)</p> <p>Corrosive solid, n.o.s. (Clopidogrel bisulfate)</p>
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR <div>   </div> <ul style="list-style-type: none"> · Class · Label 	<p>8 Corrosive substances.</p> <p>8</p>
<ul style="list-style-type: none"> · IMDG, IATA <div>  </div> <ul style="list-style-type: none"> · Class · Label 	<p>8 Corrosive substances.</p> <p>8</p>
<ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA 	<p>III</p>
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Special marking (ADR): 	<p>Environmentally hazardous substance, solid</p> <p>Symbol (fish and tree)</p>
<ul style="list-style-type: none"> · 14.6 Special precautions for user · Hazard identification number (Kemler code): · EmS Number: · Stowage Category 	<p>Warning: Corrosive substances.</p> <p>80</p> <p>F-A,S-B</p> <p>A</p>
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	<p>Not applicable.</p>
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADR · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5 kg</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 g</p> <p>Maximum net quantity per outer packaging: 1000 g</p>
<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	<p>3</p> <p>E</p>
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	<p>5 kg</p> <p>Code: E1</p> <p>Maximum net quantity per inner packaging: 30 g</p> <p>Maximum net quantity per outer packaging: 1000 g</p>

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· UN "Model Regulation": not regulated

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - Directive 2012/18/EU
 - **Named dangerous substances - ANNEX I** Substance is not listed.
 - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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 UK
Quality Assurance
- **Contact:** quality@fagron.co.uk
- **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Lact.: Reproductive toxicity – effects on or via lactation
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
- *** Data compared to the previous version altered.**

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