Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.12.2023
Revision: 19.12.2023
Version number 3.4 (replaces version 3.3)

*

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

· **1.1 Product identifier**

· **Trade name:** **Hydralazine hydrochloride**
Hydralazini hydrochloridum

· **Article number:** 104062
· **CAS Number:**
304-20-1
· **EC number:**
206-151-0
· **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 pharmaceutic preparations

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
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**

Acute Tox. 3	H301 Toxic if swallowed.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
STOT SE 3	H335 May cause respiratory irritation.

· **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**

GHS06

· **Signal word** Danger
· **Hazard statements**
H301 Toxic if swallowed.

(Contd. on page 2)

Trade name: Hydralazine hydrochloride
Hydralazini hydrochloridum

(Contd. of page 1)

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

· **Precautionary statements**

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P362+P364	Take off contaminated clothing and wash it before reuse.
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: 304-20-1 Hydralazine hydrochloride
Hydralazini hydrochloridum
· **Identification number(s)**
· **EC number:** 206-151-0

*

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **General information:**
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:**
If skin irritation continues, consult a doctor.
Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** Do not induce vomiting; call for medical help immediately.
· **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.

(Contd. on page 3)

Trade name: Hydralazine hydrochloride
Hydralazini hydrochloridum

(Contd. of page 2)

*

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents:**
Water spray
Foam
Fire-extinguishing powder
Carbon dioxide
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)
Hydrogen chloride (HCl)
Phosgene gas
· **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** Not required.
· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
· **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**
Keep receptacles tightly sealed.
Thorough dedusting.
· **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:** Store only in the original receptacle.
· **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.

(Contd. on page 4)

(Contd. of page 3)

*

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 section 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.
· **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**
Rubber gloves
Nitrile rubber, NBR
PVC 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

(Contd. on page 5)

(Contd. of page 4)

*

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Physical state**	Solid
· **Colour:**	Whitish
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	273°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:**	Soluble.
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Vapour pressure:**	Not applicable.
· **Density and/or relative density**	
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not applicable.
· **9.2 Other information**	
· **Appearance:**	
· **Form:**	Crystalline powder
· **Important information on protection of health and environment, and on safety.**	
· **Ignition temperature:**	Not determined.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Molecular weight**	196.64 g/mol
· **Change in condition**	
· **Evaporation rate**	Not applicable.
· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Void

(Contd. on page 6)

(Contd. of page 5)

· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void
· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

*

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** No dangerous reactions known.
· **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
Hydrogen chloride (HCl)
Phosgen
Nitrogen oxides (NOx)

*

SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Toxic if swallowed.

· **LD/LC50 values relevant for classification:**		
Oral	LD50	280 mg/kg (rat)

· **Skin corrosion/irritation** Causes skin irritation.
· **Serious eye damage/irritation** Causes serious eye irritation.
· **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:** No further relevant information available.
· **12.2 Persistence and degradability** No further relevant information available.
· **12.3 Bioaccumulative potential** No further relevant information available.

(Contd. on page 7)

Trade name: Hydralazine hydrochloride
Hydralazini hydrochloridum

(Contd. of page 6)

· **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**
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

*
SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must be specially treated adhering to official regulations.
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.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

*
SECTION 14: Transport information

· **14.1 UN number or ID number**	
· **ADR, IMDG, IATA**	UN3249
· **14.2 UN proper shipping name**	
· **ADR, IMDG**	MEDICINE, SOLID, TOXIC, N.O.S.
· **IATA**	Medicine, solid, toxic, n.o.s.
· **14.3 Transport hazard class(es)**	
· **ADR, IMDG, IATA**	
· **Class**	6.1 Toxic substances.
· **Label**	6.1
· **14.4 Packing group**	
· **ADR, IMDG, IATA**	III
· **14.5 Environmental hazards:**	Not applicable.
· **14.6 Special precautions for user**	Warning: Toxic substances.
· **Hazard identification number (Kemler code):**	60

(Contd. on page 8)

Trade name: Hydralazine hydrochloride
Hydralazini hydrochloridum

(Contd. of page 7)

· **EmS Number:**	F-A,S-A
· **Stowage Category**	E
· **Stowage Code**	SW2 Clear of living quarters.
· **14.7 Maritime transport in bulk according to IMO instruments**	Not applicable.
· **Transport/Additional information:**	
· **ADR**	
· **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
· **Transport category**	2
· **Tunnel restriction code**	E
· **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":**	UN 3249 MEDICINE, SOLID, TOXIC, N.O.S. 6.1, III

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.
· **Seveso category** H2 ACUTE TOXIC
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 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

(Contd. on page 9)

Trade name: Hydralazine hydrochloride
Hydralazini hydrochloridum

(Contd. of page 8)

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
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
· *** Data compared to the previous version altered.**