

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

· 1.1 Product identifier

· Trade name: 5-Aminolaevulinic acid hydrochloride (Gleolan®)

· Article number: 89730068

· CAS Number:
5451-09-2

· 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 clinic diagnostics

· Manufacturer/Supplier:

· Further information obtainable from:

Salvatore Desena MD,MBA
870 Corporate Drive
Suite 403
Lexington, KY 40503 USA
+1 (917) 365 3946
E-mail: sdesena@nxdevcorp.com

· Emergency telephone number: Emergency Contact
(24-Hour-Phone Number)
+1 (917) 365 3946 Salvatore Desena MD, MBA

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· OSHA Regulatory Status

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

· 2.2 Label elements

· Labeling according to OSHA Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Chemical characterization: Substances

· CAS No. Description

5451-09-2 5-Aminolaevulinic acid hydrochloride

SECTION 4: First aid measures

4.1 Description of first aid measures

- **General information:** Consult a physician if necessary
- **Inhalation:** Supply fresh air; consult doctor in case of complaints.
- **Skin contact:** Immediately rinse with water.
- **Eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **Ingestion:** Rinse mouth with water.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

- **Suitable extinguishing agents:** CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet

5.2 Special hazards arising from the substance or mixture

Possible formation of toxic gases during heating or in case of fire.

Hydrogen chloride (HCl)
Carbon monoxide
(CO) Nitrogen oxides
(NO_x)

5.3 Advice for firefighters

- **Protective equipment:** Wear self-contained respiratory protective device, MSHA/NIOSH (approved or equivalent). Wear fully protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.
Avoid formation of dust. Ensure adequate ventilation

6.2 Environmental precautions

Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.

6.3 Methods and material for containment and cleaning up

Pick up mechanically.
Send for recovery or disposal in suitable receptacles.

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

Wear protective equipment. Keep unprotected persons away.

The usual precautionary measures are to be adhered to when handling chemicals. Ensure adequate ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Recommended storage temperature: - 20 °C +/- 5 °C

Keep container tightly sealed

SECTION 8: Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see item 7.

8.1 Exposure controls

Engineering controls: Showers, eyewash stations, ventilation systems

8.2 Personal protective equipment (PPE)

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Do not eat or drink while working. Be sure to clean skin thoroughly after work and before breaks. Do not inhale dust /smoke / mist.

Respiratory protection: Use respiratory protective device against the effects of fumes/dust/aerosol. Filter P3

Protection of hands: Protective gloves

Eye protection: Tightly sealed goggles

Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Physical state:** Solid
- Appearance:** White
- Odor:** Odorless

Property	Values
Melting point/Melting range:	154 °C
Boiling point/Boiling range:	No information available
Flash point:	No information available
Flammability (solid, gaseous):	No information available
Danger of explosion	Product does not present an explosion hazard
Density:	No information available
Solubility in/Miscibility with water at 20°C	100 g/L

SECTION 10: Stability and reactivity

Reactivity:	Not applicable
Chemical stability:	Stable under recommended storage conditions
Conditions to avoid:	No decomposition if used according to specifications.
Hazardous decomposition products:	No decomposition if used according to specifications. No dangerous decomposition products known.
Incompatible materials:	No further relevant information available.
Possibility of hazardous reactions:	No dangerous reactions known.

SECTION 11: Toxicological information

· <u>11.1 Acute toxicity:</u>	
Product information	Product does not present an acute toxic hazard based on known or supplied information
· <u>11.2 Chronic toxicity:</u>	
Target organ effects	None known

SECTION 12: Ecological information

Bioaccumulation	No information available
Degradability and Persistence	No information available
Ecotoxicity	The environmental impact of this product has not been explored

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods**
- Recommendation**
If residues of products are classified as waste, use the legal requirements to assign the appropriate waste code.
- Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

DOT	Not regulated
IATA	Not regulated
IMDG	Not regulated

SECTION 15: Regulatory information

- **15.1 International Inventories**
No further relevant information available.
- **15.2 US Federal Regulations**
- **15.3 US State Regulations**

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.

IMDG: International Maritime Code for Dangerous Goods