Safety Data Sheet (SDS)

1. IDENTIFICATION OF THE PREPARATION AND OF THE COMPANY/UNDERTAKING

Chemical product name	:	5-aminolevulinic acid hydrochloride
Supplier information		
Company name	:	KIYAN PHARMA Co., Ltd.
Address	:	PMO Kojimachi, 6-2-6, Kojimachi, Chiyoda-ku, 102-0083, Tokyo,Japan
Department in charge	:	Engineering and Manufacturing Department
Phone number	:	+81-3-6272-8641
FAX number	:	+81-3-6272-8995
e-mail address	:	npj_emd_engineering_and_manufacturing@kiyan.jp
Emergency contact number	:	+81-3-6272-8641

Recommended use and restriction on use

Recommended use	:	Chemical products

2. HAZARDS IDENTIFICATION

GHS Classification

Physical hazards		
Corrosive to metals	:	Classification not possible.
Health hazards		
Acute toxicity (Oral)	:	Not classified. (equivalent to UN GHS Category 5)
Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irritation	:	Category 1
Environmental hazard	:	Classification not possible.

Other hazards are either of 'Not applicable' or 'Classification not possible'.

GHS label elements

Pictogram or symbol :

Signal word	:	Danger
Hazard statement	:	H315: Causes skin irritation. H318: Causes serious eye damage

Precautionary statement

Safety measures	:	P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/ eye

protection/face protection.

Response : P302+P352: IF ON SKIN: wash with plenty of water.
P305+P310+P351+P338: 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 or doctor/physician.
P332+P313: IF SKIN irritation occurs: Get medical advice/attention.
P362+P364: Take off contaminated clothing and wash it before reuse.

Other hazards : No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical substance/mixture : Substance

Chemical name or generic name : 5-aminolevulinic acid hydrochloride

Components and concentrations

Component	CAS number	Concentration or concentration range (%)	Reference number in gazetted list
5-aminolevulinic acid hydrochloride	5451-09-2	95.0 or more	2-4032 (CSCL)) 2-(4)-1046 (ISHL)

CSCL: Chemical Substances Control Law

ISHL: Industrial Safety and Health Law

4. FIRST AID MEASURES

IF INHALED : Move victim to fresh air, loosen collar and belt, and have victim rest in a position comfortable for breathing.
If breathing is difficult, administer oxygen.
If the victim has stopped breathing, administer artificial respiration.
If feeling is unwell, contact a doctor for diagnosis and treatment.

IF ON SKIN : Wash with soap and plenty of water (preferably with a shower). Washing with cold water is recommended. Applying ointments to affected areas where skin irritation has occurred.
If skin irritation occurs or the person feels unwell, get medical advice/attention.

IF IN EYES : Wash the eyes carefully with water for at least 15 minutes. Washing with cold water is recommended. Remove contact lenses, if present

		and easy to do. Continue rinsing. If eye irritation persists or the person feels unwell, get medical advice/attention.
IF SWALLOWED	:	Wash out the mouth completely with water (remove dentures if any). Do not induce vomiting. Loosen the collar, belt, etc. If the person is unconscious, nothing should be given by mouth. Get medical advice/attention if you feel unwell.
Expected acute and delayed symptoms and the most important symptoms	:	IF INHALED: it may cause irritation to the respiratory tract.
Protection of the person who gives the first aid	:	When contacting victims, wear protective gloves and clothing if necessary.
Special instructions to the medical doctor	:	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Small fire: Carbon dioxide, Wet chemical spray, Powder, Foam, Dry sand, Water spray Large fire: Sprinkling water, Water spray, Foam
Unsuitable extinguishing media	:	Nothing in particular Care should be taken when using a carbon dioxide extinguisher in a closed space because it may cause asphyxiation.
Specific hazards arising from the fire	:	When 5-aminolevulinic acid hydrochloride combusts, carbon monoxide, carbon dioxide, and nitrogen oxides are generated.
Specific fire fighting method	:	Try to extinguish an early stage fire. Fight fire from the windward. Move containers away from the fire zone if there is no risks. In a large fire, cool containers and buildings around the fire by sprinkling water for prevention of the spread of fire.
Special protective actions for fire-fighters	:	In a large fire, wear an appropriate air respiratory, and chemical fire protection clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Keep unnecessary personnel away, and contact the person responsible for emergency response. Keep away from heat/sparks/open flames/hot surfaces. Ventilate the leakage site. In case of large leakage, sprinkling water is effective to suppress dust generation. Wear appropriate protective equipment and clothing

		during evacuation or clean-up operations (see "Section. 8 EXPOSURE CONTROLS/PERSONAL PROTECTION")
Environmental precautions	:	Not release the product into sewers, drains, rivers, lakes, and sea, or soil.
Methods and materials for containment and cleaning up	:	Collect the leaks as much as possible using a broom, etc., and collect them in an empty container. The contaminated areas are then washed away with water. Dispose of collected leaks appropriately by referring to "Section 13. DISPOSAL CONSIDERATIONS"
Prevention of secondary disaster	:	-

7. HANDLING AND STORAGE

Safe handling

Following with general precautions for combustible powders.

Engineering measures	:	During working with the substance, keep away from heat/sparks/open flames/hot surfaces. It is advisable to take measures to prevent corrosion of chemical facilities and appropriate measures to prevent leakage.
Local exhaust/total ventilation	:	To keep a dust concentration lower than the occupational exposure limits, fully enclose a dust generation source, or install a local exhaust hood with a dust collector at a generation source. Install a general ventilation system.
Precautions for safe handling	:	Keep the container tightly closed after use. Do not leakage, overflow, or scatter the product. Take care of not generating dust in air. Do not handle the container roughly, like overturning, dropping, impacting, or dragging.
Contact avoidance (Incompatible materials)	:	Oxidizing agents
Hygienic measures	:	Do not swallow this product. Because the product causes skin and serious eye damage, wear appropriate protective equipment to avoid contacting this product to the skin and eyes or inhaling. Clean the workplace to keep in good hygiene. Do not eat, drink or smoke at working places. Wash the hands thoroughly after handling. It is preferable to install facilities (safety shower) for washing eyes/body.

Storing conditions

Appropriate storing conditions	:	As the product is hygroscopic, keep the container in dry conditions. Keep the container tightly closed, and store in a dry, cold, and dark place.

		Store away from oxidizing agents which are an incompatible substance.
Incompatible materials	:	As this product is acidic, avoid storing together with alkaline substances in the same place.
Appropriate container material	:	There is no designated container, but use containers without damage, corrosion, crack, etc. Containers should be labeled with a GHS label.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Allowable exposure limit

Administrative Control Level	:	In case of "Specified dusty work" stipulated by Ordinance on Prevention of Hazards Due to Dust: E = 3.0 / (1.19Q+1) E : Administrative Control level (mg/m^3), Q : Content of crystalline silica in dust (%)
ISHA (Kiannhatsu 1021 No.1)	:	Concentration limitation: 2 mg/m^3 (Respirable dust)
The Japan Society for Occupational Health (OELs)	:	Class 3 dust : 2 mg/m^3 (Respirable dust), 10 mg/m^3 (Total dust) [Reference information] Hydrogen chloride: 2 ppm (maximum allowable concentration), 3.0 mg/m^3(maximum allowable concentration)
ACGIH	:	Dusts for insoluble compound unless otherwise specified. 3 mg/m^3 (Respirable particles), 10 mg/m^3 (Inhalable particles)
Facility measures	:	To keep a dust concentration lower than the occupational exposure limits, it is advisable to enclose fully a dust generation source, install a local exhaust hood with a dust collector and/or a general ventilation system in the handling area, and/or adopt a wet-process, etc. Although the above necessary facility measures are taken, if there may be a remaining risk to expose over the exposure limits, wear a dust mask which has been nationally certificated. Because the product causes skin and serious eye damage, wear appropriate protective gloves, working clothes (Boots, long-sleeved clothes, etc.) and/or protective glasses to avoid contacting this product to the skin and eyes, depending on working conditions and hazard risks.

Personal protection equipment

Respiratory protection	:	National certificated dust mask. In temporary maintenance works, or short time works, or even though in the case that the facility measures such as installing a dust collector are taken, if the worker may expose dusts over the exposure limits, wear a dust mask which has been nationally certificated.

Hand protection	:	Protective gloves.
Eye protection	:	Wear safety glasses or chemical resistant goggles to avoid contacting with the eyes.
Skin and body protection	:	Wear long-sleeved working clothing and long working pants to avoid contacting with the skin.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance		
Physical state	:	Crystalline or crystalline powder
Color	:	White
Odor	:	-
Odor threshold	:	No data available.
pH	:	Not applicable. [Reference information] When 1 mL of water is added to 1 g, the pH is below 2.
Melting/freezing point	:	156 - 158℃ (decomp.)
Boiling point, initial boiling point and boiling range	:	No data available.
Flash point	:	No data available.
Evaporation rate	:	No data available.
Combustibility (solid, gas)	:	No data available.
Ignition/Explosion limit, Upper/lower limit	:	No data available.
Vapor pressure	:	No data available.
Vapor density	:	No data available.
Specific gravity	:	No data available.
Solubility	:	Freely soluble in water. Practically insoluble in ethanol and ethers.
n-octanol/water partition coefficient	:	No data available.
Auto-ignition temperature (°C)	:	Not auto-ignition.
Decomposition temperature	:	No data available.
Viscosity	:	No data available.

10. STABILITY AND REACTIVITY

Chemical Stability	:	Stable under normal working conditions at a room temperature.
Reactivity	:	Stable under normal working conditions at a room temperature.
Possibility of hazardous reactions	:	No information available.
Conditions to avoid	:	Direct sunlight, heat
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Nitrogen oxides, Carbon monoxide, Carbon dioxide are produced in combustion.

11. TOXICOLOGICAL INFORMATION

Acute toxicity (Oral)	:	Not classified. LD_{50} (rat, oral) > 2 g/kg (equivalent to

		UN GHS Category 5) *1
Acute toxicity (Dermal)	:	Classification not possible due to lack of data.
Acute toxicity (Inhalation: Dust)	:	Classification not possible due to lack of data.
Skin corrosion/irritation	:	Not classified. P.I.I.0.5, slight irritation (equivalent to UN GHS Category 3) in the skin irritation study (OECD TG404) Category 2 Skin corrosion is expected due to the low pH of the aqueous solution (pH 2 or less when 1 g is added to 1 mL of water)*1
Serious eye damage/eye irritation	:	Category1 Eye irritation is expected due to the low pH of the aqueous solution*1
Respiratory sensitization/ Skin sensitisation	:	Classification not possible due to lack of data.
Germ cell mutagenicity	:	Classification not possible due to lack of data.
Carcinogenicity	:	Classification not possible due to lack of data.
Reproductive toxicity	:	Classification not possible due to lack of data. Reproductive ability is normal in both males and females*2
Specific target organ toxicity (Single exposure)	:	Classification not possible due to lack of data.
Specific target organ toxicity (Repeated exposure)	:	Classification not possible due to lack of data.
Aspiration hazard	:	Classification not possible due to lack of data.

12. ECOLOGICAL INFORMATION

Ecotoxicity		
Aquatic hazard (Acute)	:	Classification not possible due to lack of data.
Aquatic hazard (Long term)	:	Classification not possible due to lack of data.
Persistence/Degradability	:	Degradability test using standard activated sludge showed readily biodegradable *1
Bioaccumulation	:	As this product is an amino acid, bioaccumulation is not considered to be applicable.
Mobility in soil	:	No data available.
Hazard to the ozone layer	:	This product does not contain substances listed in the appendix of the Montreal protocol.
Additional information	:	Nothing in particular.

13. DISPOSAL CONSIDERATIONS

Residual waste	:	Do not contaminate sewers, drains, soil, rivers, lakes, and sea with the waste of the product. Reduce an amount of waste by attempting to use up the product completely. Dispose of contents/containers in accordance with the Waste Management and Public Cleansing Act

and local/prefectural regulations.

Polluted container and packing	:	Dispose of empty containers in accordance with the Waste Management and Public Cleansing Act and local/prefectural regulations.
Additional information	:	It is recommended to consult with your local authority or an approved waste disposal expert how to dispose of the waste to ensure regulatory compliance.

14. TRANSPORT INFORMATION

International regulations

UN number	:	Not applicable.
UN proper shipping name	:	Not applicable.
UN class	:	Not applicable.
Packing group	:	Not applicable.
Marine pollutant	:	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC code	:	Not applicable.

Japanese domestic regulations

Land transport regulations	:	No dangerous goods under the Fire Service Act. No regulated substances under the Poisonous and Deleterious Substances Control Act.
Marine transport regulations	:	Not applicable.
Air transport regulations	:	Not applicable.
Emergency response guidance No.	:	Not applicable.
Special safety measures	:	Ensure that containers have no breakage nor leakage. Load the containers securely to avoid turnover, fall, and/or damage. Ensure to take preventive measures against load collapse. Because the product causes skin andserious eye damage, wear appropriate protective equipment to avoid contacting the product to the skin and eyes or inhaling, if necessary.

15. REGULATORY INFORMATION

Industrial Safety and Health Act

Substance for labeling, etc. and deliver of documents, etc. (Article 57 and 57-2) and for risk assessment (Article 57-3)	:	Not applicable. 【Information】 Hydrogen chloride CAS 7647-01-1 (labelling ≧ 0.2 wt%, SDS ≧ 0.1 wt%)
- Dangerous substances (Enforcement Order, Attached table 1)	:	Not applicable. [Reference information] Corrosive liquid: Hydrochloric acid

- Ordinance on Prevention of Organic Solvent Poisoning	:	Not applicable.
- Ordinance on Prevention of Hazards due to Specified Chemical Substances	:	Not applicable. [Reference information] Specified chemical substance, Class 3 substance: Hydrogen chloride (>1%)
- Ordinance on Prevention of Lead Poisoning	:	Not applicable.
- Ordinance on Prevention of Hazards Due to Dust	:	If a dusty work to be performed falls within a "Dusty work" stipulated in Table 1 and/or a "Specified dusty work" stipulated in table 2 of the ordinance, handle the product in accordance with the ordinance. In case of "Specified dusty work" in table 2 of the ordinance, concentrations of airborne dust should be measured in accordance with Working Environment measurement Act.
Pneumoconiosis Act	:	Not applicable.
Poison and Deleterious Substance Control Act	:	Not applicable. [Reference information] Deleterious substances: Preparations containing hydrogen chloride (excluding those containing 10% or less hydrogen chloride)
PRTR Act	:	Not applicable.
Chemical Substances Control Law	:	This product does not contain Class I and II Specified Chemical Substances, Monitoring Chemical Substances, and Priority Assessment Chemical Substances.
Fire Service Act	:	Not applicable.
Explosives Control Act	:	Not applicable.
High Pressure Gas Safety Act	:	Not applicable.
Ship Safety Act	:	Not applicable.
Civil Aeronautics Act	:	Not applicable.
Act on Prevention of Marine Pollution and Maritime Disaster	:	Not applicable.
Basic Environment Act		【Water Quality Environmental Standards (Living Environment)】: pH, BOD, COD, Total nitrogen This product does not contain "Investigated substances" and "Monitoring substances".
Water Pollution Control Act	:	【Effluent standard (Living Environment)】: BOD, COD, Nitrogen content [Reference Information] Emergency Measures Designated Substance: Hydrogen Chloride
Sewerage Act	:	【Standards of water quality of Sewage discharged from Specified Factories into Public Sewerage Systems by Prefectural or Municipal Ordinance】: pH, BOD, Nitrogen content
Air Pollution Control Act	:	Not applicable. [Reference Information] Emergency Measures Designated Substance: Hydrogen Chloride
Soil Contamination Countermeasures Act	:	Not applicable.

16. OTHER INFORMATION

Reference: *1 non-published data.

*2 Fd. Consmet. Toxicol. 45-48(1976)

Disclaimer: This SDS was issued based on the SDS's provided by raw materials manufacturers, GHS classification performed by The Ministry of Health and Welfare and Ministry of the Environment, and various literatures, but not based on all information. Therefore precautions for handling this product should be taken.
The SDS shall be revised according to amendments of related Acts or regulations, or new information, in future. All precautions described herein are for normal handling. If this product is used under special conditions, suitable safety measures against its intended use/process should be taken. The contents herein such as chemical compositions, physical and chemical properties, or hazard information are for a purpose of provision of information only, and does not provide any guarantees.