Safety Data Sheet

Section 1: Identification

Product Name Glute Out®
Chemical Name Mixture

Product Identification: Sodium Bicarbonate
Chemical Name: Sodium Bicarbonate
Molecular formula: NaHCO3 **Molecular weight:** 84.01G/MOL

Product Identification: Glycine –USP, Pharma, Glycine-USP-NF, Glycine Technical Grade.
Chemical Name: Aminoacetic Acid
Molecular formula: C2H5NO2 **Molecular weight:** 75.G/MOL

Use of the Substance/Mixture: Pharmaceuticals.
Food additive.
Cosmetic additive.
Photochemicals.

Details of the supplier of the safety data sheet
Manufacturer PCI Medical Inc.
6 Winter Avenue
Deep River, CT 06417
United States
www.pcimedical.com
info@pcimedical.com
Telephone (General) 1-860-526-2862

Emergency telephone number
1-800-424-9300 **CHEMTREC**
1-703-527-3887 **International CHEMTREC**

Section 2: Hazard Identification

2.1. Emergency Overview: Sodium Bicarbonate
NFPA: ***H= 1 F= 0 I = 0 S= None***
HMIS: ***H= 1 F= 0 R= 0 PPE = Supplied by User; dependent on local*** **conditions**
2.2 **Emergency Overview:** Aminoacetic Acid
NFPA: ***H= 1 F= 1 I = 0 S= None***
HMIS: ***H= 1 F= 1 R= 0 PPE = Supplied by User; dependent on local conditions***
General Information
Appearance: **Powder** Color: **White** Odor: **Odorless**
Main effects May cause skin, eye, and respiratory tract irritation.
Hazard Information: ***CAUTION*** May cause eye, skin and respiratory tract irritation.
Eye contact
Not expected to cause eye irritation.
Skin contact
Health injuries are not known or expected under normal use.
Inhalation
No adverse effects expected under ordinary conditions of use.
Ingestion
Single dose oral toxicity is considered to be extremely low. No hazards anticipated from swallowing small amounts incidental to normal handling operations.
Aggravated Medical Conditions
None known

Section 3 - Composition/Information on Ingredients

Chemical Name	Weight - %	CAS Number
Sodium Bicarbonate	100 %	144-55-8
Aminoacetic Acid	> 98.5 %	56-40-6

Section 4: First-Aid Measures

Eye contact
Remove contact lenses, if worn. Immediately flush with plenty of water for at least 15 minutes, holding eyelids apart to ensure flushing of the entire surface. Washing within one minute is essential to achieve maximum effectiveness. Seek medical advice immediately.
Skin contact
Immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/ attention.
Inhalation
Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion
Do NOT induce vomiting. If vomiting should occur spontaneously, keep airway clear. Never give anything by mouth to an unconscious person. Get medical attention.
Aggravated Medical Conditions
None known.
Notes to Physician
Treat symptomatically.

Section 5 - Firefighting Measures

Flash point: Not applicable

Auto ignition temperature: No information available
Flammable Limits in Air - Lower (%) No information available
Flammable Limits in Air - Upper (%) No information available
Suitable extinguishing media
Water fog, carbon dioxide, foam, dry chemical.
Firefighting measures
Keep people away. Isolate fire area and deny unnecessary entry. Soak thoroughly with water to cool and prevent re-ignition. Cool surroundings with water to localize fire zone. Fight fire from protected location or safe distance. Consider use of unmanned hose holder or monitor nozzles. Immediately withdraw all personnel from area in case of rising sound from venting safety device or discoloration of the container. Move container from fire area if this is possible without hazard. Hand held carbon dioxide or dry chemical extinguishers may be used for small fires. Dust explosion hazard may result from forceful application of fire extinguishing agents.
Special Hazard
Container may rupture from gas generation in a fire situation. Do not permit dust to accumulate. Dust layers can be ignited by spontaneous combustion or other ignition sources. When suspended in air dust can pose an explosion hazard.
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire -fighting personnel.

Section 6 - Accidental Release Measures

Methods for cleaning up
Clear non-emergency personnel from area. Remove with shovel. Transfer to suitable **and properly labeled** containers for disposal.
Personal precautions
Wear suitable protective clothing and gloves.
Environmental precautions
Avoid runoff to waterways and sewers.

Section 7- Handling and Storage

Advice on safe handling
- Avoid generation of dust Do not breathe (dust, vapor, mist, gas)
- Use only with adequate ventilation
- Use respiratory protection where dust may be generated
- Avoid contact with eyes, skin and clothing
- Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing
- Wash thoroughly after handling
- Keep container closed when not in use
- ***FOR INDUSTRIAL USE ONLY***

Technical measures and storage conditions
- Store in a dry place
- Store in a cool, well ventilated area
- Keep away from heat, sparks and flame

Section 8 - Exposure Controls/Personal Protection

Engineering controls
Local exhaust ventilation as necessary to maintain exposures to within applicable limits. Please refer to the ACGIH document, "Industrial Ventilation, A Manual of Recommended Practices", most recent edition, for details. If there are no applicable or established exposure limit requirements or guidelines, general ventilation should be sufficient. *See section 3 for more information.*
Respiratory protection
If exposures exceed the PEL or TLV, use NIOSH/MSHA approved respirator in accordance with OSHA Respiratory Protection Requirements under 29 CFR 1910.134. See section 3 for more information.
Hand protection
Appropriate chemical resistant gloves should be worn.
Skin and Body Protection
Standard work clothing and work shoes.
Eye/face protection
Chemical goggles or a face shield if splashing hazard exists.
Other Personal Protection Data
Eyewash fountains and safety showers must be easily accessible.

Section 9: Physical and Chemical Properties

General Information
Appearance: powder
Color: white
Odor: odorless

pH	No information available
Specific Gravity	No information available
Density	1.161 g/cm3.
Bulk Density	No information available
Flash Point	Not applicable
Autoignition Temperature	No information available
Boiling point / Boiling Range	No information available

Melting / Freezing Point	Product decomposes at elevated temperatures
Vapor Pressure	0.0000171 Pa @ 25 °C
Vapor Density	No information available
Percent Volatile	wt.% 0.2 % max
Evaporation Rate	No information available
Solubility (Water)	250 g/L
Solubility in Other Solvents	No information available
Volatile Organic Compounds (VOCs) Content	No information available
Dynamic Viscosity	Not applicable
Kinematic Viscosity	Not applicable
Molecular Weight	75.07 g/mol

Section 10 – Stability and Reactivity

Stability
Stable under recommended storage conditions.
Conditions to avoid
Avoid temperatures above (180°C) 356°F. Product decomposes above the melting temperature.
Materials to avoid
Avoid contact with oxidizing materials. Avoid unintended contact with acids, bases, halogenated hydrocarbons
Hazardous decomposition products
Hazardous decomposition products depend upon temperature, air supply and the presence of other materials. Gases are released during decomposition. Carbon dioxide, carbon monoxide, and nitrogen oxides can be expected.
Hazardous polymerization
Not anticipated under normal or recommended handling and storage conditions.
Additional Guidelines:
None

Section 11 – Toxicological Information

PRINCIPAL ROUTES OF EXPOSURE: Skin, eyes and respiratory tract.
Eye contact
Not expected to cause eye irritation.
Skin contact
Health injuries are not known or expected under normal use.
Inhalation
No adverse effects expected under ordinary conditions of use.
Ingestion
Single dose oral toxicity is considered to be extremely low. No hazards anticipated from swallowing small amounts incidental to normal handling operations.
Carcinogenicity Status
Mutagenicity/Genotoxicity: No mutagenicity or genotoxicity studies have been carried out with this product.
This product does not contain any components in concentrations greater than or equal to 0.1% that are listed as known or suspected carcinogens by NTP, IARC, ACGIH, or OSHA.
Acute toxicity

Oral LD50	> 5000 mg/kg body weight
Dermal LD50	No information available
Ingestion	Single dose oral toxicity is considered to be extremely low. No hazards anticipated from swallowing small amounts incidental to normal handling operations.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Bicarbonate	3360 mg/kg (Mouse)	-	-
Aminoacetic Acid	7930 mg/kg (Rat)	-	-

Eye Contact Not expected to cause eye irritation.
Inhalation LC50 No information available.
Sensitization
Dermal sensitization: non-sensitizing
OECD 429
Repeated dose toxicity
No adverse effects observed. (Oral route)
OECD Test No. 407: Repeated Dose 28-day Oral Toxicity Study in Rodents
Other information
Conclusions are drawn from sources other than direct testing.

Section 12 - Ecological Information

Ecotoxicity effects
Acute toxicity
- Fishes, Lepomis macrochirus, LC50, 96 h, 1000 mg/l
  Method: OECD Test No. 203: Fish, Acute Toxicity Test.
- Crustaceans, Ceriodaphnia dubia, EC50, 48 h, > 220 mg/l
  Method: Acute daphnia toxicity according to test method OECD 202.
- Algae/aquatic plants, EC50, 72h, > 1000 mg/l.
  Method: OECD Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test

Mobility
Not expected to adsorb on soil
Persistence and degradability
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)
Bioaccumulative potential
Ultimate biodegradation
Readily biodegradable. All organic substances contained in the product achieve > 60% BOD/COD or CO2 liberation, or > 70% DOC reduction in tests for ease of degradability. Threshold values for 'readily degradable' (e.g. to OECD method 301) are reached. Method: OECD Test No. 302C: Inherent Biodegradability: Modified MITI Test (II).
Chemical Fate Information
No information available Remarks
Other information
None

Section 13 - Disposal Considerations

Disposal of wastes
Since the emptied container retains product residue, all labeled hazard precautions must be observed. Do not put solutions containing this product into sewer systems. Dispose of product in an approved chemical waste landfill or incinerate in accordance with applicable Federal, state and local regulations.
RCRA
Fish LC50 (96 h): > 1000 mg/L (Oryzias latipes)
Method: OECD Test No. 203: Fish, Acute Toxicity Test.
Persistence and degradability
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)
Is the unused product a RCRA hazardous waste if discarded? (Yes/No) **No**
If **yes,** the EPA Hazardous Waste Code is: **N/A**

Section 14 – Transport Information

DOT
Status Not regulated
IMDG
Status Not regulated
ICAO/IATA
Flash point Not applicable

Section 15 – Regulatory Information

Inventory Information

TSCA (United States)
All ingredients are on the inventory or exempt from listing
Australia (AICS)
All ingredients are on the inventory or exempt from listing
Canada (DSL)
All ingredients are on the inventory or exempt from listing
Canada (NDSL)
None of the ingredients are on the inventory.
China (IECSC)
All ingredients are on the inventory or exempt from listing
EINECS (European Inventory of Existing Chemical Substances)
All ingredients are on the inventory or exempt from listing
ELINCS (European List of Notified Chemical Substances)
All of the components of this product are not listed on ELINCS.
ENCS (Japan)
All ingredients are on the inventory or exempt from listing.
South Korea (KECL)
All ingredients are on the inventory or exempt from listing
Philippines (PICCS)
All ingredients are on the inventory or exempt from listing
Glycine (56-40-6) CAA - Hazardous Air Pollutants
New Jersey Trade Secret Registry Number(s):
N/A
SARA Section 311/ 312 Hazard Class
This product is classified as a SARA ACUTE HEALTH HAZARD.
Other information
This product does not contain any ingredients subject to the reporting requirements of SARA Title III, Section 313 (40CFR Part 372).

Section 16 - Other Information

NFPA Overall Rating
Health: 1 Flammability: 1 Reactivity: 0
Special = Supplied by User, dependent on local conditions

HMIS Overall Rating
Health: 1 Flammability: 1 Reactivity: 0
PPE = Supplied by User; dependent on local conditions.

Last Revision Date: 06.12.15

Disclaimer/Statement of Liability
The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of need that information is current, applicable and suited to the circumstance of use. Vendor assumes no responsibility for injury to vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, vendor assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed. Any questions regarding this product should be directed to the manufacturer of the product as described in Section 1.