

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier:

Substance name: Phenibut

EC No.: not available

REACH registration No.: no necessary according REACH regulation p.2, article 5 a)

CAS No.: 3060-41-1

1.2. Relevant identified uses of the substance or mixture and uses advised against:

Relevant identified uses: pharmaceutical industry. API. Tranquilizer

Uses advised against: consumer uses (except finished formulations)

Reason why uses advised against: the risk of overdose

1.3. Details of the supplier of the safety data sheet:

Manufacturer: JSC "OlainFarm"

Address: Rupnicu Street 5, Olaine, Olaines novads, LV-2114,

Telephone number: Latvia

E-mail address for a competent person responsible for the SDS: +371 29478206, +371 67013784 (from 8.30 till 16.30)
olainfarm@olainfarm.lv

1.4. Emergency telephone number:

Centre of Toxicology (Latvia): +371 67042468, +371 67042472

Centre of emergency and disaster medicine (Latvia): +371 29002626

JSC "OlainFarm" (during office hours): +371 67013808, +371 27890055, +371 67962125

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

2.1.1. Classification according to Regulation No.

1272/2008 [CLP]

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

STOT SE 3, H336

2.1.3. Additional information:

For full text R-phrases and Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

Labelling according to Regulation (EC) No

1272/2008 [CLP]

Skin Corrosion/irritation (Category 2)

Serious Eye Damage/Eye Irritation (Category 2A)

Specific target organ toxicity, single exposure,
narcotic effects (Category 3)

Hazard pictogram: GHS07



Signal word: Warning

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

Precautionary statements:

P261 Avoid breathing dust.

P362 Take off contaminated clothing and wash
before reuse.

P264 Wash hands thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

2.1.2. Classification according to Directive

67/548/EEC:

Harmful; Xn; R22

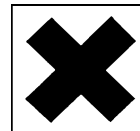
Irritant; Xi; R36/37/38

Labelling according to Directive 67/548/EEC:

Harmful if swallowed.

Irritating to eyes, respiratory system and skin.

Hazards symbols



R-phrases

R22 Harmful if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

S-phrases

S22 Do not breathe dust

S24/25 Avoid contact with skin and eyes

S26 In case of contact with eyes, rinse immediately with
plenty of water and seek medical advice.

S37/39 Wear suitable gloves and eye/face protection.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+ P352 IF ON SKIN: Wash with plenty of soap and water.

P304+P340 IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P332+P313 IF SKIN irritation occurs: Get medical advice/ attention.

P337+P313 IF eye irritation persists: Get medical advice/ attention.

P405 Store locked up.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Supplemental Hazard information (EU): Not applicable.

2.3. Other hazards: For full text of R-phrases and Hazard- and EU Hazard-statements: see SECTION 2.2.

3. COMPOSITION/INFORMATION ON INGREDIENTS

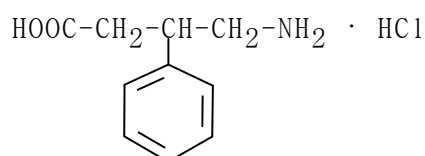
3.1. Substances

IUPAC name: 4-Amino-3-phenyl-butyric acid hydrochloride

Synonyms: β -(Aminomethyl) benzenepropanoic acid hydrochloride; 4-amino-3-phenylbutanoic acid hydrochloride; beta-(Aminomethyl)hydrocinnamic acid hydrochloride; D-Beta-homophenylalanine HCl; D-Beta-homophenylalanine hydrochloride; H-D-beta-homophenylalanine HCl; H-D-beta-homophe-OH HCl; H-D-beta-hophe-OH HCl; H-D-phe-(C*CH₂)OH HCl; 3-Amino-4-phenyl-butyric acid HCl; 3-Amino-4-phenylbutyric acid hydrochloride; RARECHEM AK PT F105; D- β -Homo-Phe-OH HCl; D- β -Homo-Ph-OH HCl; H-D-beta-HPhe-OH HCl; H-D-b-HoPhe-OH HCl

Formula: C₁₀H₁₃NO₂ · HCl

Molecular weight: 215,68 g/mol



Name	Index number in CLP Annex VI	Weight % content (or range)
Phenibut	—	> 98,0

4. FIRST AID MEASURES

4.1. Description of first aid measures

General notes: Seek medical attention if feel unwell.

Following inhalation: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician. For advice, contact a Poisons Information Centre or a doctor. If conscious, give water to drink.

Following skin contact: Immediately flush with plenty of soap and water for at least 15 minutes. Remove contaminated clothes and shoes. Seek medical attention in event of irritation.

Following eye contact: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If pain persists or recurs seek medical attention. Skilled personnel should only undertake removal of contact lenses after an eye injury. Get medical aid immediately.

Following ingestion: Rinse mouth with water. Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Self-protection of the first aider: Attention! Making the "mouth to mouth" artificial respiration may be dangerous. Make a contactless artificial respiration.

4.2. Most important symptoms and effects, both acute and delayed:

Somnolence, depressed activity, hallucinations, distorted perceptions.

Direct contact with eyes may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

Chronic health effects. Hepatotoxicity.

4.3. Indication of any immediate medical attention and special treatment needed:

In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action shall be the responsibility of the medical specialist.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media:

Suitable extinguishing media: Water spray. Carbon dioxide (CO₂). Dry chemical. Chemical foam.

Unsuitable extinguishing media: None.

5.2. Special hazards arising

from the substance or mixture:

Hazardous combustion products:

Thermal decomposition can lead to release of irritating gases and vapors. Emits toxic fumes under fire conditions: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), chlorine, hydrogen chloride (HCl) gas and other pyrolysis products typical of burning organic material. May emit corrosive fumes.

5.3. Advice for firefighters:

Fire fighter's clothing conforming to European standard EN469 provides a basic level of protection for chemical incidents and includes helmets, protective boots and gloves. Clothing not conforming to EN469 may not be suitable in any chemical incident.

Use water delivered as a fine spray to control fire and cool adjacent area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment: wear self - contained breathing apparatus, rubber boots and heavy rubber gloves. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

6.1.1. For non-emergency personnel

Protective equipment: Use personal protective equipment.

Emergency procedures: Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

6.1.2. For emergency responders

Wear self - contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6.2. Environmental precautions - do not let product enter drains.

6.3. Methods and material for containment and cleaning up

6.3.1. For containment

Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. Control personal contact by using protective equipment. In case of major spills alert Emergency Responders and tell them location and nature of hazard. Prevent, by any means available, spillage from entering drains or water courses.

6.3.2. For cleaning up

Use dry clean up procedures and avoid generating dust. Place in a suitable, labeled container for waste disposal. Recover product wherever possible. Wash area down with large amounts of water. If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections: Information on exposure control and personal protection and disposal considerations is given in sections 8 and 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Protective measures:

Measures to prevent fire: Avoid contact with incompatible materials, heat, light and moisture. Keep away from sources of ignition.

Measures to prevent aerosol and dust generation: Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid all personal contact, including inhalation.

Measures to protect the environment:

Wear protective clothing when risk of exposure occurs. Keep containers securely sealed when not in use. Avoid physical damage to containers.

Advice on general occupational hygiene: Use good occupational work practice. Observe manufacturer's storing and handling recommendations. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Do not store above 25 °C. Protect from light and moisture.

Packing materials: Keep container tightly closed when not in use. Store in original containers. Keep containers securely sealed. Check that all containers are clearly labeled. Protect containers against physical damage and check regularly for leaks.

Requirements for storage rooms and vessels: Store in well-ventilated area away from incompatible substances.

7.3. Specific end use(s) – pharmaceutical industry, drug. **Tranquilizer, has nootropic activity.**

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameter:

Phenibut (CAS Nr. 3060-41-1) **1 mg/ m³ - TWA**, (Latvia and Russia)

8.2. Exposure controls:

8.2.1. Appropriate engineering controls – Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powdered by mutual friction. Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.

8.2.2. Personal protection equipment:

8.2.2.1. Eye / face protection – For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs - chemical goggles.

Full-face shield may be required for supplementary but never for primary protection of eyes.

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. DO NOT wear contact lenses.

8.2.2.2. Skin protection – Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 and US F739. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include such as: frequency and duration of contact, chemical resistance of glove material, glove thickness and dexterity.

When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.

When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Contaminated gloves should be replaced.

Other skin protection: Barrier cream, skin-cleansing cream, eye wash unit.

8.2.2.3. Respiratory protection – Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option). Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program. Use approved positive flow mask if significant quantities of dust becomes airborne.

8.2.2.4. Thermal hazards – None.

8.2.2.5. Hygiene measures – Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Wash contaminated clothing before reuse. Discard contaminated shoes.

When handling, DO NOT eat, drink or smoke.

8.2.3. Environmental exposure controls:

Contact a licensed professional waste disposal service to dispose of this material. Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Physical state: crystalline powder	Odour: no
	Colour: white	Odour threshold: no
	pH: 2,3 – 2,7 (2,5 % water solution)	
	Melting point/freezing point: n.l.t. 192,0 °C	
		194,0 °C – 202,0 °C (decomposition)
	Initial boiling point and boiling range: 329,5 °C at 760 mm Hg (est.)	
	Flash point: 153,1 °C	
	Evaporation rate: No information available	
	Flammability (solid, gas): 215 °C	
	Upper/lower flammability or explosive limits: Lower: 26,8 mg/m ³	
	Vapor pressure: 7,09·10 ⁻⁵ mm Hg at 25 °C	
	Vapor density: No information available	
	Relative density: 1,161 g/cm ³	
	Solubility: Freely soluble ~ 10 g/100 ml in 0,1 M HCl, 0,1 M NaOH, ethanol;	
		Practically insoluble in chloroform, ethyl acetate, acetone, isopropyl alcohol, ether
	Water solubility: Freely soluble ~ 10 g/100 ml	
	Partition coefficient n-octanol/water: Log Kow = 1,33 (est.)	
	Auto-ignition temperature: 416 °C	
	Decomposition temperature: No information available	
	Viscosity: No information available	
	Explosive properties: Explosion hazard of powder – air mixture	
	Oxidizing properties: No information available	

9.2. Other information

Optical rotation:	+3,3 ± 0,3 ° (c=6; MeOH)
Polar surface area:	63,32 Å
Enthalpy of vaporization:	63,86 kJ/mol

10. STABILITY AND REACTIVITY

10.1. Reactivity – No dangerous reactions known.

10.2. Chemical stability – Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions – Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc.

10.4. Conditions to avoid – Sources of ignition, moisture, light.

10.5. Incompatible materials – Strong oxidizing agents, acids, acid chlorides, carbon dioxide, acid anhydrides.

10.6. Hazardous decomposition products – Hazardous decomposition products formed under fire conditions - carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), hydrogen chloride (HCl) gas and other pyrolysis products typical of burning organic material.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity (for 4-Amino-3-phenylbutanoic acid, CAS no. 1078-21-3):

TD_{Lo} (oral) – human: 5 mg/kg

TOXIC EFFECTS: Behavioral – sleep, somnolence (general depressed activity), hallucinations, distorted perceptions.

LD₅₀ (intraperitoneal) rat: 700 mg/kg

LD₅₀ (intraperitoneal) mouse: 900 mg/kg

Skin corrosion/irritation – Causes skin irritation.

Serious eye damage/eye irritation – Causes eye irritation.

Respiratory or skin sensitization – May cause sensitization in some persons.

Germ cell mutagenicity – not available.

Carcinogenicity – Not listed as a carcinogen by ACGIH, IARC, NTP, or CA.

Reproductive toxicity – The compound reveals neither teratogenous nor embryotoxic effects.

Summary of evaluation of the CMR properties – Not available.

STOT-single exposure – Not available.

STOT-repeated exposure – Liver.

Additional Information RTECS: ES7175000 (*for 4-Amino-3-phenylbutanoic acid, CAS no. 1078-21-3*)

12. ECOLOGICAL INFORMATION

12.1. Toxicity: not available.

12.2. Persistence and degradability: not available.

12.3. Bioaccumulative potential: Log P = 1,33, substance is stable in the environment, if log P > 1.

12.4. Mobility in soil: not available.

12.5. Results of PBT and vPvB assessment: not available.

12.6. Other adverse effects: not available.

12.7. Additional information: do not let product enter drains.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

13.1.1. Product / Packaging disposal:

Contact a licensed professional waste disposal service to dispose of this material. All waste must be handled in accordance with local, state and federal regulations. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. Decontaminate empty containers.

13.1.2 Waste treatment-relevant information:

Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Recycle wherever possible.

13.1.3 Sewage disposal-relevant information:

Disposal via sewage is strongly prohibited.

13.1.4 Other disposal recommendations:

Consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified. Dispose in Incineration in a licensed apparatus (after admixture with suitable combustible material). Observe all label safeguards until containers are cleaned and destroyed.

14. TRANSPORT INFORMATION – *Not regulated for transport of dangerous goods*

14.1. UN Number ADR/RID – IMDG – IATA –

14.2. UN proper shipping name ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es) ADR/RID – IMDG – IATA –

14.4. Packing group ADR/RID – IMDG – IATA –

14.5. Environmental hazards ADR/RID: no; IMDG Marine pollutant: no; IATA: no

14.6. Special precautions for user none

14.7. Transport in bulk according to Annex

II of MARPOL 73/78 and the IBC Code not provided

15. REGULATORY INFORMATION. This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, No. 453/2010 and No. 1272/2008.

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

Commission Regulation (EU) No. 453/2010 of 20 May 2010 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

Council Directive (1967th on June 27) regulations and administrative provisions relating to the classification, packaging and labelling (67/548/EEC).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on

classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

15.2. Chemical safety assessment

Chemical safety assessment is not necessary.

16. OTHER INFORMATION

Indication of changes: *The second version.*

- 1) The document has been revised according:

“Guidance on the compilation of safety data sheets”

Reference: ECHA-13-G-11-EN

Publ.date: February 2014

Version: 2.1

- 2) Section 7.2. has been specified.
- 3) Some physical and chemical properties in section 9.1. have been specified.
- 4) Section 12.3. has been specified.

Abbreviations and acronyms:

ACGIH – American Conference of Industrial Hygienists.

EC No. – Seven-digit code that is assigned to chemical substances that are commercially available within the European Union, assigned by the Commission of the European Communities.

CAS No. – CAS Registry Number is unique numerical identifiers assigned by the "Chemical Abstracts Service" to every chemical described in the open scientific literature.

CEN (EU) – The European Committee for Standardization.

IARC – The International Agency for Research on Cancer, the part of the World Health Organization.

JSC – Joint-stock company.

LD₅₀ – (Letal Dose 50) is the dose of a chemical which kills 50 % of a sample population.

NIOSH (US) – The National Institute for Occupational Safety and Health.

NTP – National Toxicological Programme.

RTECS – Registry of Toxic Effects of Chemical Substances in NOISH.

TD_{Lo} – Toxic Dose Low is the Lowest published toxic dose per unit of bodyweight of a substance known to have produced signs of toxicity in a particular animal species.

TWA – Time Weighted Averages - are an average value of exposure over the course of an 8-hour work shift.

Key literature references and sources for data:

1. TOXNET (<http://toxnet.nlm.nih.gov/index.html>), CAS No. 3060-41-1 and 1078-21-3, page viewed 25.08.2014.
2. PACKAGE LEAFLET: INFORMATION FOR THE USER, Approved by SAM on 23-08-2012

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

<i>Skin Irrit. 2, H315</i>	Based on test data and [CLP] ANNEX 1, points 3.2.2.1. and 3.2.2.2.
<i>Eye Irrit. 2, H319</i>	Based on test data and [CLP] ANNEX 1, points 3.3.2.2. and 3.3.2.3.
<i>STOT SE 3, H335</i>	Based on [CLP] ANNEX 1, point 3.8.2.2.1.
<i>STOT SE 3, H336</i>	Based on [CLP] ANNEX 1, point 3.8.2.2.1.

Relevant R-phrases and/or H-statements (number and full text):

See Section 2.2.

Training advice:

Carry out regular staff training, instruction and examination in accordance with the company's Safety Code.

Further information:

The data and information presented here correspond to the present state of our knowledge and experience and can be used only as a guide. JSC “Olainfarm” shall not be held liable for any damage resulting from handling or from contact with the product.