abbvie
# SAFETY DATA SHEET

## Section 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product Identifier

**Product Name:** Valproic Acid

**Chemical Name:** 2-Propylpentanoic Acid

**Synonyms:** Valproic Acid, USP: 2-Propylvaleric Acid: Dipropylacetic Acid

**Drug Code Number:** 12680; 12681; 12683; 34698; 35165; 51165; 12316; 22657; 90958; 84199; 82965

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

**Recommended use:** Pharmaceuticals
Process Intermediate
Industrial use

### 1.3 Details of the supplier of the safety data sheet

**Supplier:** AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)
+1-847-937-7433

**E-mail Address:** AbbVie.SDS@abbvie.com

### 1.4 Emergency telephone number

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

## Section 2. Hazards identification

### 2.1 Classification of the substance or mixture

**Regulation (EC) No 1272/2008**

| | |
|---|---|
| **Acute oral toxicity** | Category 4 |
| **Skin corrosion/irritation** | Category 2 |
| **Serious eye damage/eye irritation** | Category 2 |
| **Reproductive toxicity** | Category 1A |

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Xn - Harmful
Xi - Irritant

**Risk Phrases:** R22 - Harmful if swallowed
R36/38 - Irritating to eyes and skin
R61 - May cause harm to the unborn child

### 2.2 Label elements

**Signal Word:** Danger

**Hazard Statements:**
H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child

**Precautionary Statements**
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P281 - Use personal protective equipment as required

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

| Chemical Name | Percent | EINECS/ELINCS Number | EEC Classification | EU - GHS Substance Classification | REACH No. |
|---|---|---|---|---|---|
| Valproic Acid<br>99-66-1 | 100 | Present | Xn, R22; Xi, R36/38; R61 | Acute Tox Oral 4 (H302)<br>Skin Irrit. 2 (H315)<br>Eye Irrit. 2 (H319)<br>Repro Cat1A (H360) | No data available |

**For the full text of the R-phrases mentioned in this Section, see Section 16**
**For the full text of the H-Statements mentioned in this Section, see Section 16**

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Inhalation:** Remove from source of exposure. If signs of irritation or toxicity occur seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Ingestion:** Remove from source of exposure. If irritation persists or signs of toxicity occur, seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Protection of First-aiders:** Use personal protective equipment

### 4.2 Most important symptoms and effects, both acute and delayed

**Signs and Symptoms:** No signs and symptoms from occupational exposure are known. Direct contact with the eyes could result in the following: eye irritation. Direct contact with the skin could result in the following: skin irritation. Clinical data suggests the following: headaches, nausea, lack of energy, dizziness, gastrointestinal upset, muscle weakness, leucopenia, anemia, thrombocytopenia, vomiting, abdominal pain, anorexia, abnormal liver function. Clinical overdose may result in the following: coma.

**Medical Conditions Aggravated by Exposure:** No medical conditions aggravated by occupational exposure are known. Data suggest any pre-existing ailments in the following organs: eyes, skin, pancreas, liver. Hypersensitivity to the material and/or similar materials. liver, nervous system, male reproductive system, female reproductive system, gastrointestinal system, or hematopoietic system.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Notes To Physician:** Treat symptomatically

## Section 5. Firefighting measures

### 5.1 Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

**Unsuitable Extinguishing Media:** Not determined

### 5.2 Special hazards arising from the substance or mixture

**Special Exposure Hazards:** May ignite under fire conditions.

### 5.3 Advice for firefighters

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

## Section 6. Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** For personal protection see section 8.

### 6.2. Environmental precautions

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

### 6.3. Methods and material for containment and cleaning up

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

### 6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

## Section 7. Handling and storage

### 7.1. Precautions for safe handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

### 7.3. Specific end use(s)

**Recommended use:** Pharmaceuticals
Process Intermediate
Industrial use

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

**Exposure limits:**

| Chemical Name | Employee Exposure Limit | Skin Notation |
|---|---|---|
| Valproic Acid<br>99-66-1 | 160 mcg/m$^3$ | None |

### 8.2. Exposure controls

**Engineering Controls:** Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

| | |
|---|---|
| **Gloves:** | Impervious gloves. Butyl or nitrile rubber. Neoprene. |
| **Other PPE Data:** | Wear appropriate body coverings if contact may occur. |
| **Environmental Exposure Controls:** | Not determined |

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance:** | Colorless Liquid |
| **Odor:** | Characteristic odor |
| **Odor Threshold:** | Not determined |
| **pH:** | Not determined. |
| **Boiling Pt. @ 760 mm Hg (°C):** | 222 |
| **Melting/Freezing Point (°C):** | Not determined |
| **Flash Point (°C):** | 111 |
| **Evaporation Rate at 20°C:** | Not determined. |
| **Flammability (Solid):** | Not determined. |
| **Lower Explosive Limit:** | Not determined. |
| **Upper Explosive Limit:** | Not determined. |
| **Vapor Pressure (mm Hg):** | 0.22 mm Hg at 20 C, 32 mm Hg at 121 C |
| **Vapor Density (Air = 1):** | 5 |
| **Density, g / mL:** | 0.9 |
| **Specific Gravity:** | Not determined. |
| **Solubility(ies):** | Not soluble in: water. |
| **Partition coefficient: n-octanol/water** | Not determined. |
| **Autoignition Temp. (°C):** | Not determined. |
| **Decomposition temperature (°C):** | Not determined. |
| **Viscosity (centipoise):** | 6.7 cps at 25 deg. C |
| **Explosion Severity:** | Not determined. |
| **Oxidizer Properties:** | Not determined. |

### 9.2. Other information

Not determined

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

### 10.4. Conditions to avoid

Not determined.

**10.5 Incompatible materials**

Not determined

**10.6 Hazardous decompostion products**

Not determined

## Section 11. Toxicological information

**11.1. Information on toxicological effects**

**Routes of Exposure:**

**Oral:** Clinical Route
**Dermal:** Yes
**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

| Chemical Name | Acute Test | Value | Units | Species |
|---|---|---|---|---|
| Valproic Acid 99-66-1 | LD50 = | 670-2307 | mg/kg | Rats Mice |

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** Produced mild to moderate skin irritation in animals.

**Eye Irritation:** Produced severe eye irritation in animals. Recovery after 24 hours.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** In animal testing, target organs include: male reproductive system, female reproductive system, nervous system, liver, hematopoietic system, gastrointestinal tract, pancreas, eyes.

**Reproductive Effects:** In animals adverse reproductive effects include: male reproductive system, female reproductive sytem, testicular atrophy, reduced sperm count, fetal abnormalities. fetal toxicity. In humans adverse reproductive effects include: fetal abnormalities.

| Chemical Name | Species | Dosage | Units | Route | Duration |
|---|---|---|---|---|---|
| Valproic Acid 99-66-1 | Rats Mice Rabbits | > 65 | mg/kg | Oral | During Gestation |

**Carcinogenicity:** In animals produced tumors in the following tissue (s):

| Chemical Name | Site of Tumors | Species | Dosage | Route | Units | Duration |
|---|---|---|---|---|---|---|
| Valproic Acid 99-66-1 | Liver Lungs | Rats | 80-170 | Oral | mg/kg | 2 years |

**Mutagenicity:** Negative in mutagenicity assays.

**Aspiration hazard:** Not determined

**Notes:**
1. **ALD: Approximate lethal dosage**
2. **LC50: Concentration in air that produces 50% mortality**
3. **LD50: Oral or dermal dosage that produces 50% mortality**

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**
1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## Section 14. Transport information

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

**14.1. UN Number:** Not applicable
**14.2. Proper shipping name:** Not applicable
**14.3. Hazard class:** Not applicable
**14.4. Packing group:** Not applicable
**14.5. Environmental hazard:** Not applicable

**14.6. Special Provisions:** Not applicable
**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

## Section 15. Regulatory Information

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

### International Inventories

| Chemical Name | EINECS/ ELINCS | TSCA | DSL | NDSL | PICCS |
|---|---|---|---|---|---|
| Valproic Acid<br>99-66-1 | Present | - | X | Not listed. | X |

| Chemical Name | ENCS | ISHL | IECSC | AICS | KECL | New Zealand |
|---|---|---|---|---|---|---|
| Valproic Acid<br>99-66-1 | Present | Present | - | X | Present | HSR006827 |

**Legend**
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**ENCS** - Japan Existing and New Chemical Substances
**ISHL** - Japan Industrial Safety and Health Law
**IECSC** - China Inventory of Existing Chemical Substances
**AICS** - Australian Inventory of Chemical Substances
**KECL** - Korean Existing and Evaluated Chemical Substances

### Carcinogenicity Rating:

| Chemical Name | Percent | NTP: | IARC: | ACGIH: |
|---|---|---|---|---|
| Valproic Acid | 100 | Not Listed | Not Listed | Not Listed |

### SARA 313 Information

| Chemical Name | Percent | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|---|---|---|---|---|
| Valproic Acid | 100 | No | Not Applicable | Not applicable |

**Immediate Health:** Yes
**Delayed Health:** No
**Fire:** No
**Sudden Pressure:** No
**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Listed.

| Component | Percent | Proposition 65 Listed Materials |
|---|---|---|
| Valproic Acid<br>99-66-1 ( 100 ) | 100 | developmental toxicity, initial date 7/1/87 |

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**
Health: 2
Fire: 1

Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

### 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

## Section 16. Other information

**Risk Phrases:**
R22 - Harmful if swallowed
R36/38 - Irritating to eyes and skin
R61 - May cause harm to the unborn child

**Document Authored By:** Occupational and Environmental Toxicology

**Issued:** Jul-02-2015

**Supersedes the SDS dated:** Oct-02-2012

**Disclaimer:**
*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*