

Product Name: Valproic Acid
Issued: Dec-21-2012

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.
North Chicago, IL 60064
U.S.A.
1-800-255-5162
+1-847-937-7433

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

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Section 2. Hazards identification

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

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 99-66-1	100	202-777-3	Xn, R22; Xi, R36/38; R61	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Repro 1A (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

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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

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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 99-66-1	750 mcg/m ³	None

8.2. Exposure controls

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

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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):	6.7cps 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

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Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition 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 system, 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):

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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

Product Name: Valproic Acid
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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 99-66-1	202-777-3	-	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Valproic Acid 99-66-1	(2)-608	2-(4)-768	-	X	KE-29866	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.

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Proposition 65 Status: Listed.

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

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