Valproic Acid, Sodium Salt

sc-202378

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Valproic Acid, Sodium Salt

STATEMENT OF HAZARDOUS NATURE
CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA


SUPPLIER
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EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
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SYNONYMS
C8-H15-O2.Na, (CH3CH2CH2)2CHCO2Na, "acetic acid, dipropyl-, sodium salt", "acetic acid, 2-propyl-, sodium salt", "dipropylacetic acid, sodium salt", "di-n-propylacetic acid, sodium salt", "n-dipropylacetic acid, sodium salt", "n-DPA, sodium salt", "2-propylpentanoic acid, sodium salt", "2-propylvaleric acid, sodium salt", "sodium bispropylacetate", "sodium dipropylacetate", "sodium alpha, alpha-dipropylacetate", "sodium n-dipropylacetate", "sodium 2-propylacetate", "sodium 2-propylpentanoate", 2-propylvalerate, "sodium valproate", Convulex, Depakene, Depakine, Depekane, Epilim, Ergenyl, Eurekene, KW-066, Labazene, "anticonvulsant/ antiepileptic", Valpro

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	3		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

CANADIAN WHMIS SYMBOLS
None

EMERGENCY OVERVIEW

RISK
Harmful if swallowed.
May cause harm to the unborn child.
Irritating to eyes and skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED
■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
■ Antiepileptic drugs (AEDs) act as anticonvulsants and increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Persons exposed to AEDs for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior (such as anxiety, agitation, hostility, pressured/rapid speech).
The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.
The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analysed.
The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.
■ At sufficiently high doses the material may be hepatotoxic(i.e. poisonous to the liver).
■ Side-effects of valproate treatment include nausea, vomiting, gastrointestinal irritation, increased appetite, excessive weight gain, ataxia, transient alopecia with regrowth of curly hair. High doses may produce tremor, prolongation of bleeding time (reversible), thrombocytopenia.
Liver dysfunction, which may be fatal, has been reported. The mechanism of liver damage is considered to be ideosyncratic or may be a result of hypersensitivity reactions resulting from an abnormal metabolic pathway producing increased proportions of toxic metabolites.
Hyperammonaemia (raised levels of blood ammonia) has been evident in several patients. This does not appear to result from liver dysfunction.

EYE
■ This material can cause eye irritation and damage in some persons.

SKIN
■ This material can cause inflammation of the skin oncontact in some persons.
■ The material may accentuate any pre-existing dermatitis condition.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Solution of material in moisture on the skin, or perspiration, mayincrease irritant effects.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED
■ The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
■ Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS
■ Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.
Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.
Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.
<\p>.
Several off-spring of eight pregnant women taking valproate as an antiepileptic drug were deformed - two babies had facial abnormalities and one baby had a heart lesion.
Intraperitoneal administration to mice (340 mg/kg on days 6-18 of gestation) produced a 30% incidence of neural tube defect in the cranial region of embryos and a reduced head size.
When the free acid was given by gavage to rats, 600 mg/kg was maternally toxic and produced 100% embryonic resorption. At 400 mg/kg 52% of all embryos were resorbed and 49% of survivors were malformed. Defects included ectrodactyly, hydronephrosis, cardiovascular defects, hypoplastic bladder, rib and vertebral defects. At 200 mg/kg, defects included hydronephrosis, cardiovascular abnormalities and rib defects (primarily wave ribs).
Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
valproic acid, sodium salt	1069-66-5	>98

Section 4 - FIRST AID MEASURES

SWALLOWED
· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

EYE
■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · 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.

SKIN
■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED
· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN
■ for poisons (where specific treatment regime is absent):
----------BASIC TREATMENT

· Establish a patent airway with suction where necessary.
· Watch for signs of respiratory insufficiency and assist ventilation as necessary.
For anticonvulsants:
It is recommended that the physician withdraw the drug slowly on the appearance of unusual depression, aggressiveness, or other behavioral alterations.
As with other anticonvulsants, it is important to proceed slowly when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.
Treat symptomatically.
For valproic acid overdose :
· The stomach should be emptied by aspiration and lavage, although lavage may be of limited value in view of the rapid absorption of valproic acid.
· Supportive therapy alone may then suffice for patients who are not severely poisoned.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA
· Foam.
· Dry chemical powder.

FIRE FIGHTING
· Alert Emergency Responders and tell them location and nature of hazard.
· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS
· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), metal oxides, other pyrolysis products typical of burning organic material.
May emit poisonous fumes.
May emit corrosive fumes.

FIRE INCOMPATIBILITY
■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION
Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate dust filter.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS
· Remove all ignition sources.
· Clean up all spills immediately.
· Avoid contact with skin and eyes.
· Control personal contact by using protective equipment.
· Use dry clean up procedures and avoid generating dust.

· Place in a suitable, labelled container for waste disposal.
MAJOR SPILLS
■ Moderate hazard.
· CAUTION: Advise personnel in area.
· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING
· Avoid all personal contact, including inhalation.
· Wear protective clothing when risk of exposure occurs.
Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
· Do NOT cut, drill, grind or weld such containers.
· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS
· Polyethylene or polypropylene container.
· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS
· Store in original containers.
· Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
• valproic acid, sodium salt: CAS:1069-66-5

PERSONAL PROTECTION



RESPIRATOR
BR2
Consult your EHS staff for recommendations

EYE
· Safety glasses with side shields.
· Chemical goggles.

HANDS/FEET
■ 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
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
· 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.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
· polychloroprene
· nitrile rubber
· butyl rubber
· fluorocaoutchouc
· polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER

· Overalls.
· P.V.C. apron.
· Barrier cream.
· Skin cleansing cream.
· Eye wash unit.

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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Does not mix with water.

State	DIVIDED SOLID	Molecular Weight	166.2
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

White, odourless, crystalline, deliquescent powder with saline taste; mixes with water (1:5) and alcohol.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents, bases and strong reducing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

VALPROIC ACID, SODIUM SALT

TOXICITY AND IRRITATION

VALPROIC ACID, SODIUM SALT:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (child) LDLo: 750 mg/kg	
Oral (rat) LD50: 670 mg/kg	
Intraperitoneal (rat) LD50: 970 mg/kg	
Subcutaneous (rat) LD50: 1029 mg/kg	
Intravenous (rat) LD50: 509 mg/kg	
Oral (mouse) LD50: 977 mg/kg	
Intraperitoneal (mouse) LD50: 470 mg/kg	
Subcutaneous (mouse) LD50: 860 mg/kg	
Intravenous (mouse) LD50: 750 mg/kg	
Intramuscular (mouse) LD50: 832 mg/kg	
Oral (dog) LD50: 1420 mg/kg	
Intraperitoneal (dog) LD50: 1420 mg/kg	

Intraperitoneal (cat) LD50: 565 mg/kg

Oral (rabbit) LD50: 1468 mg/kg

Intraperitoneal (rabbit) LD50: 1200 mg/kg

Oral (g.pig) LD50: 824 mg/kg

Oral (hamster) LD50: 1740 mg/kg

■ Reports suggest an association between the use of anticonvulsant drugs by women with epilepsy and an elevated incidence of birth defects in children born to these women. Data are more extensive with respect to phenytoin and phenobarbital, but these are also the most commonly prescribed anticonvulsants; less systematic or anecdotal reports suggest a possible similar association with the use of all known anticonvulsant drugs.

The frequency of major malformations, growth retardation, and hypoplasia of the midface and fingers, known as "anticonvulsant embryopathy", is increased in infants exposed to anticonvulsant drugs in utero. However, whether the abnormalities are caused by the maternal epilepsy itself or by exposure to anticonvulsant drugs is not known

The reports suggesting an elevated incidence of birth defects in children of drug-treated epileptic women cannot be regarded as adequate to prove a definite cause and effect relationship. There are intrinsic methodologic problems in obtaining adequate data on drug teratogenicity in humans; the possibility also exists that other factors, eg, genetic factors or the epileptic condition itself, may be more important than drug therapy in leading to birth defects. The great majority of mothers on anticonvulsant medication deliver normal infants.

At least one study has shown a distinctive pattern of physical abnormalities in infants of mothers with epilepsy is associated with the use of anticonvulsant drugs during pregnancy, rather than with epilepsy itself (L.B. Holmes etal New England Jnl of Med, 344: 1132-1138; 2001).

It is important to note that anticonvulsant drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and threat to life. In individual cases where the severity and frequency of the seizure disorder are such that the removal of medication does not pose a serious threat to the patient, discontinuation of the drug may be considered prior to and during pregnancy, although it cannot be said with any confidence that even minor seizures do not pose some hazard to the developing embryo or foetus.

Reproductive dysfunction in epilepsy is attributed to the seizures themselves and also to antiepileptic drugs (AEDs), which affect steroid production, binding, and metabolism. In turn, neuroactive steroids may influence neuronal excitability. A previous study in this cohort of consecutive women with epilepsy showed that patients with more frequent seizures had higher cortisol and lower dehydroepiandrosterone sulfate levels than those with rare or absent seizures. Actual hormone titers were not significantly correlated with seizure frequency scores (SFS) rather these hormonal changes were explained by AED treatments, mainly when enzyme-inducing AEDs (EIAED) polytherapies were given.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Oral (infant) LDLo: 250 mg/kg/10d - I Nil reported

Sleep, somnolence, muscle weakness, tremor, ataxia, coma, cardiac changes, dyspnea, changes in exocrine pancreas, diarrhoea, nausea, vomiting, haemorrhage, effects of fertility, effects on embryo, specific developmental abnormalities (central nervous system, eye, ear, craniofacial, musculoskeletal, cardiovascular, hepatobiliary, urogenital) recorded.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

¦ Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

· Reduction
· Reuse
· Recycling
· Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

· Recycle wherever possible.
· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

No data for valproic acid, sodium salt (CAS: , 1069-66-5)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ Inhalation may produce health damage*.
* (limited evidence).

ND

Substance CAS Suggested codes valproic acid, sodium salt 1069- 66- 5

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■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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