

Safety Data Sheet

Issuing date: 3/30/2015

Revision date: 11/26/2024

Revision number: 04

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Valproic Acid Oral Solution, USP

Other means of identification

Product code(s): 0121-0675-16, 0121-0675-85, 0121-4675-05, 0121-4675-10, 0121-4675-55, 0121-4675-40, 0121-4675-00, 0121-1350-10, 0121-1350-00

UN-Number: NA

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used as an anti-epileptic drug.
Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family: Mixture

Statement of Hazard: May be harmful if swallowed. May cause skin irritation, serious eye irritation
May damage the unborn child.
May cause nervous system and reproductive effects

Additional Hazard Information:

Short term:

May damage fertility or the unborn child.
Hepatotoxicity, including fatalities, usually during the first 6 months of treatment have been reported. Children with a mitochondrial disorder are at particular risk. Fetal risk, particularly neural tube defects, other malformations and decreased IQ have reported for infants born to mothers who took Valproic Acid during pregnancy. Cases of pancreatitis, including fatal hemorrhagic cases have also been reported.

Long term:

No additional information available

EU Indication of danger: Not classified.

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Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

| Chemical name | CAS-No | mg/5mL | Trade Secret |
|-------------------|------------|--------------|--------------|
| Valproic Acid | 99-66-1 | 250 mg/ 5 mL | |
| Sucrose | 57-50-1 | | X |
| Methylparaben | 99-76-3 | | X |
| Sorbitol Solution | Mixture | | X |
| Glycerin | 56-81-5 | | X |
| Sodium Hydroxide | 1310-73-2 | | X |
| Cherry Flavor | Mixture | | X |
| FD&C Red No. 40 | 25956-17-6 | | X |
| Citric Acid | 77-92-9 | | X |

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4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Overdosage or accidental ingestion, contact medical personnel or poison control immediately if overdosage is suspected.

Most important symptoms/effects, acute and delayed

Overdosage somnolence, heart block, and deep coma

Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

Specific hazards arising from the chemical

May burn emitting oxides of chlorine and nitrogen.

Explosion data:

Not applicable

Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures. Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

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7. Handling and storage

Precautions for safe handling

Handling: No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: As a precautionary measure, keep away from strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

| Chemical name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|-------------------|--------------------------|--------------------------|--------------------------|
| Valproic Acid | Not Available | Not Available | Not Available |
| Sucrose | 10 mg/m ³ | 15 mg/m ³ | 10 mg/m ³ TWA |
| Methylparaben | Not Available | Not Available | Not Available |
| Sorbitol Solution | Not Available | Not Available | Not Available |
| Glycerin | 10 mg.m ³ TWA | 10 mg.m ³ TWA | Not Available |
| Sodium Hydroxide | 2 mg/m ³ | 2 mg/m ³ TWA | Not Available |
| Cherry Flavor | Not Available | Not Available | Not Available |
| FD&C Red No. 40 | Not Available | Not Available | Not Available |

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

9. Physical and chemical properties

Information on basic physical and chemical properties

| | |
|-----------------|------------------|
| Physical state: | Solution |
| Odor: | Cherry |
| Appearance: | Clear red liquid |
| Odor threshold: | Not available |

| Property | Values | Remarks/Method |
|--|----------------|----------------|
| pH | 7.0 – 8.0 | Current USP |
| Melting point/range | Not applicable | |
| Boiling point/boiling range | Not available | |
| Flash point | Not applicable | |
| Evaporation rate | Not applicable | |
| Flammability (solid, gas) | Not applicable | |
| Flammability limits in air | Not applicable | |
| -upper flammability limit | Not applicable | |
| -lower flammability limit | Not applicable | |
| Vapor pressure | Not applicable | |
| Vapor density | Not applicable | |
| Specific gravity | 1.2 | Current USP |
| Water solubility | Not applicable | |
| Solubility in other solvents | Not applicable | |
| Partition coefficient: n-octanol/water | Not applicable | |
| Autoignition temperature | Not applicable | |
| Decomposition temperature | Not applicable | |
| Viscosity | Not available | |
| Flammable properties | Not applicable | |
| Explosive properties | Not applicable | |
| Oxidizing properties | Not applicable | |

Other information VOC content (%) Not applicable

10. Stability and reactivity

Reactivity Stable at normal conditions

Chemical stability Stable at normal conditions

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| | |
|---|--|
| Possibility of hazardous reactions | Stable at normal conditions |
| Conditions to avoid | None known |
| Incompatible materials | As a precautionary measure, keep away from strong oxidizers. |
| Hazardous decomposition products | None known |

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

| Chemical name | LD50 oral | LD50 dermal | LC50 inhalation |
|-------------------|-----------------|---------------------------------|-----------------|
| Valproic Acid | 670 mg/kg Rat | Not Available | Not Available |
| Sucrose | 29700 mg/kg Rat | Not Available | Not Available |
| Methylparaben | 2100 mg/kg rat | No skin irritation 24 hr Rabbit | Not Available |
| Sorbitol Solution | Not Available | Not Available | Not Available |
| Glycerin | 12600 mg/kg Rat | 10000 mg/kg Rabbit | Not Available |
| Sodium Hydroxide | Not Available | Severe burns 24 hr Rabbit | Not Available |
| Cherry Flavor | Not available | Not Available | Not Available |
| FD&C Red No.40 | >10000mg/kg Rat | >10000 mg/kg Rabbit | Not Available |

Symptoms related to the physical, chemical and toxicological characteristics

Hepatotoxicity, including fatalities, usually during the first 6 months of treatment have been reported. Children with a mitochondrial disorder are at particular risk. Fetal risk, particularly neural tube defects, other malformations and decreased IQ have reported for infants born to mothers who took Valproic Acid during pregnancy. Cases of pancreatitis, including fatal hemorrhagic cases have also been reported.

Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

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Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability

No data available

Bioaccumulation

No data available

Other adverse effects:

No data available.

The following table lists the data for the individual components, if available.

| Chemical name | Toxicity to algae | Toxicity to fish | Toxicity to micro-organisms | Daphnia Magna (water flea) |
|-------------------|--|------------------------------------|-----------------------------|----------------------------|
| Valproic Acid | Not Available | Not Available | Not Available | Not Available |
| Sucrose | Not Available | Not Available | Not Available | Not Available |
| Methylparaben | 91 mg/L 72 hr. Pseudokirchneriella subcapitata | 59.5 mg/L 89 hr Oryzias latipes | Not Available | 41.1 mg/L 48 hr |
| Sorbitol Solution | Not Available | Not Available | Not Available | Not Available |
| Glycerin | Not Available | 58.5 ppm 96 hr Trout | Not Available | Not Available |
| Sodium Hydroxide | Not Available | 125 mg/L 96 hr Gambusia affinis | Not Available | 40.38 mg/L 48 hr |
| Cherry Flavor | Not Available | Not Available | Not Available | Not Available |
| FD&C Red No. 40 | Not Available | Not Available | Not Available | Not Available |

13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

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14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories

Legend

TSCA:

United States Toxic Substances Control Act 8(b) inventory Not applicable for product. The following components are included on the inventory: Sucrose, Glycerin, Sodium Hydroxide, Methylparaben and FD&C Red No. 40.

EINECS:

Valproic Acid, FD&C Red no. 40, Methylparaben, Sodium Hydroxide, Glycerin, and Sucrose are listed on the inventory.

U.S. Federal regulations:

Not Applicable

SARA 311/312 Hazard categories:

Not Applicable

Clean Water Act

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA:

Sodium Hydroxide is listed under CERCLA.

California Proposition 65:

This product contains Valproic acid which is listed as Proposition 65 chemical.

U.S. state Right-to-Know regulations

“X” designates that the ingredients are listed on the state Right-to-Know list

| Chemical name | New Jersey | Massachusetts | Pennsylvania | Illinois | Rhode Island |
|-------------------|------------|---------------|--------------|----------|--------------|
| Valproic Acid | X | X | X | | |
| Sucrose | X | X | X | | |
| Methylparaben | X | | X | | |
| Sorbitol Solution | X | | X | | |
| Glycerin | X | X | X | X | X |
| Sodium Hydroxide | X | X | X | X | X |
| FD&C Red No. 40 | | | | | |

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U.S. EPA label information Not applicable

16. Other information

Rev 01 Added NDC number for case pack out.

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Issuing date: 04/27/2020

Revision date: 04/27/2020
Revision note: Rev 03:

- Added NDC Number 0121-0675-85

Revision date: 05/23/2015
Revision note: Rev 02:

- Added NDC Numbers 0121-4675-40, 0121-4675-00, 0121-1350-10, 0121-1350-00
- Corrected NDC Number 0121-467555 to 0121-4675-55
- Removed Synonym Information
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Revision date: 03/30/2015
Revision note: Rev 01:

- Added NDC Number 0121-467555

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet