

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Aripiprazole Oral Solution

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Amneal Pharmaceuticals
85 Adams Ave
Hauppauge, NY 11788
T 631-952-0214 - F 631-656-1009

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Not classified

2.2. Label elements

GHS-US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

| Name | Product identifier | % | Classification (GHS-US) |
|-----------------------------------|----------------------|--------------|---|
| Sucrose | (CAS No) 57-50-1 | Trade Secret | Not classified |
| D-Fructose | (CAS No) 57-48-7 | Trade Secret | Not classified |
| Water | (CAS No) 7732-18-5 | Trade Secret | Not classified |
| Glycerin | (CAS No) 56-81-5 | Trade Secret | Not classified |
| 1,2-Propylene glycol | (CAS No) 57-55-6 | Trade Secret | Not classified |
| Butanedioic acid, hydroxy-, (+-)- | (CAS No) 617-48-1 | Trade Secret | Not classified |
| Propyl 4-hydroxybenzoate | (CAS No) 94-13-3 | Trade Secret | Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 |
| Flavoring | None | Trade Secret | Not classified |
| Sodium hydroxide | (CAS No) 1310-73-2 | Trade Secret | Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 |
| Aripiprazole | (CAS No) 129722-12-9 | Trade Secret | Not classified |
| Disodium EDTA | (CAS No) 139-33-3 | Trade Secret | Not classified |

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Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures after inhalation | : Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. |
| First-aid measures after skin contact | : Flush with water for at least 15 minutes. Seek medical attention if irritation develops or persists. |
| First-aid measures after eye contact | : Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists. |
| First-aid measures after ingestion | : Do NOT induce vomiting. Seek medical attention. |

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

| | |
|--------------------------------------|----------------------------------|
| Symptoms/injuries after inhalation | : None under normal use. |
| Symptoms/injuries after skin contact | : May cause moderate irritation. |
| Symptoms/injuries after eye contact | : May cause slight irritation. |
| Symptoms/injuries after ingestion | : None under normal use. |

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--------------------------------|---------------------------------------|
| Suitable extinguishing media | : Dry chemical, foam, carbon dioxide. |
| Unsuitable extinguishing media | : None. |

5.2. Special hazards arising from the substance or mixture

| | |
|------------------|---------------|
| Fire hazard | : None known. |
| Explosion hazard | : None known. |

5.3. Advice for firefighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Firefighters should wear full protective gear. |
|--------------------------------|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| For containment | : Stop the flow of material, if this is without risk. |
| Methods for cleaning up | : Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations. |

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|-------------------------------|----------------------------|
| Precautions for safe handling | : Avoid contact with eyes. |
|-------------------------------|----------------------------|

7.2. Conditions for safe storage, including any incompatibilities

| | |
|--------------------|--|
| Storage conditions | : Keep container tightly closed. Store in dry, cool, well-ventilated area. |
|--------------------|--|

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Sucrose (57-50-1) | | |
|---|-------------------------------------|---|
| ACGIH | ACGIH TWA (mg/m ³) | 10 mg/m ³ |
| OSHA | OSHA PEL (TWA) (mg/m ³) | 15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction) |
| Sodium hydroxide (1310-73-2) | | |
| ACGIH | ACGIH Ceiling (mg/m ³) | 2 mg/m ³ |
| OSHA | OSHA PEL (TWA) (mg/m ³) | 2 mg/m ³ |
| Aripiprazole (129722-12-9) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| Disodium EDTA (139-33-3) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| Propyl 4-hydroxybenzoate (94-13-3) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| Glycerin (56-81-5) | | |
| ACGIH | Not applicable | |
| OSHA | OSHA PEL (TWA) (mg/m ³) | 15 mg/m ³ (mist, total particulate) 5 mg/m ³ (mist, respirable fraction) |
| 1,2-Propylene glycol (57-55-6) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| D-Fructose (57-48-7) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| Butanedioic acid, hydroxy-, (+-)- (617-48-1) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |
| Water (7732-18-5) | | |
| ACGIH | Not applicable | |
| OSHA | Not applicable | |

8.2. Exposure controls

| | |
|----------------------------------|---|
| Appropriate engineering controls | : Local exhaust and general ventilation must be adequate to meet exposure standards. |
| Hand protection | : Use impervious gloves such as neoprene, nitrile, or rubber for hand protection. |
| Eye protection | : Safety glasses. |
| Skin and body protection | : Wear suitable working clothes. |
| Respiratory protection | : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|----------------|----------|
| Physical state | : Liquid |
|----------------|----------|

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| | |
|---|---------------------|
| Appearance | : Clear. |
| Color | : Colorless |
| Odor | : odorless |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |
| Vapor pressure | : No data available |
| Relative density | : No data available |
| Relative vapor density at 20 °C | : No data available |
| Solubility | : Soluble |
| Log Pow | : No data available |
| Log Kow | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

| Sodium hydroxide (1310-73-2) | |
|------------------------------|----------------|
| LD50 dermal rabbit | 1350 mg/kg |
| ATE US (dermal) | 1350.000 mg/kg |

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| Glycerin (56-81-5) | |
|----------------------------|--|
| LD50 dermal rabbit | > 10 g/kg |
| LC50 inhalation rat (mg/l) | > 570 mg/m ³ (Exposure time: 1 h) |
| ATE US (oral) | 12600.000 mg/kg |

| 1,2-Propylene glycol (57-55-6) | |
|---------------------------------------|-----------------------------|
| LD50 oral rat | 20000 mg/kg |
| LD50 dermal rabbit | 20800 mg/kg |
| ATE US (oral) | 20000.000 mg/kg body weight |
| ATE US (dermal) | 20800.000 mg/kg body weight |

| Water (7732-18-5) | |
|--------------------------|------------|
| LD50 oral rat | > 90 ml/kg |

| | |
|--|------------------|
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitization | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| Specific target organ toxicity (single exposure) | : Not classified |
| Specific target organ toxicity (repeated exposure) | : Not classified |
| Aspiration hazard | : Not classified |

SECTION 12: Ecological information

12.1. Toxicity

| Sodium hydroxide (1310-73-2) | |
|-------------------------------------|---|
| LC50 fish 1 | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |

| Disodium EDTA (139-33-3) | |
|---------------------------------|---|
| LC50 fish 1 | 320 mg/l (Exposure time: 96 h - Species: Poecilia reticulata [semi-static]) |

| Glycerin (56-81-5) | |
|---------------------------|--|
| LC50 fish 1 | 51 - 57 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |

| 1,2-Propylene glycol (57-55-6) | |
|---------------------------------------|--|
| LC50 fish 1 | 51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 Daphnia 1 | > 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static]) |
| LC50 fish 2 | 41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

| Glycerin (56-81-5) | |
|---------------------------|----------------------|
| BCF fish 1 | (no bioaccumulation) |
| Log Pow | -1.76 |

| 1,2-Propylene glycol (57-55-6) | |
|---------------------------------------|-----|
| BCF fish 1 | < 1 |

| D-Fructose (57-48-7) | |
|-----------------------------|----------------------|
| BCF fish 1 | (no bioaccumulation) |

12.4. Mobility in soil

No additional information available

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12.5. Other adverse effects

| | |
|------------------------------|--|
| Effect on ozone layer | : No additional information available |
| Effect on the global warming | : No known ecological damage caused by this product. |

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--------------------------------|---|
| Waste disposal recommendations | : Dispose of contents/container in accordance with local/regional/national/international regulations. |
|--------------------------------|---|

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT
Not a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

Sucrose (57-50-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Disodium EDTA (139-33-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propyl 4-hydroxybenzoate (94-13-3)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Glycerin (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

EPA TSCA Regulatory Flag

Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

1,2-Propylene glycol (57-55-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

EPA TSCA Regulatory Flag

Y2 - Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

D-Fructose (57-48-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sucrose (57-50-1)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

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Glycerin (56-81-5)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

1,2-Propylene glycol (57-55-6)

U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases::

| | |
|---------------|---|
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H290 | May be corrosive to metals |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product