# U.S. Pharmacopeial Convention

# SAFETY DATA SHEET

#### 1. Identification

Product identifier Aripiprazole Related Compound H

Other means of identification

 Catalog number
 1042714

 CAS number
 1796928-63-6

Chemical name 7-{4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]butoxy}-

3,4-dihydroquinolin-2(1H)-one)

**Recommended use** Specified quality tests and assay use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

**Telephone** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

# 2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

Hazard symbol None.
Signal word None.

Hazard statement Not available.

**Precautionary statement** 

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information None.

# 3. Composition/information on ingredients

**Substance** 

Chemical nameCommon name and synonymsCAS number%Aripiprazole Related Compound H1796928-63-6100

## 4. First-aid measures

**Inhalation** If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

**Skin contact** Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

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Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Most important

symptoms/effects, acute and delayed

None known.

Indication of immediate medical attention and special

treatment needed

Treat symptomatically.

**General information** 

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

# 5. Fire-fighting measures

Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials

Unsuitable extinguishing

media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

Specific methods General fire hazards

No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

Personal precautions. protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

**Environmental precautions** 

Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

**Biological limit values** 

Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is

recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

## Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

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Other For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant

quantities are handled, work clothing may be necessary to prevent take-home contamination.

Where respirators are deemed necessary to reduce or control occupational exposures, use Respiratory protection NIOSH-approved respiratory protection and have an effective respirator program in place

(applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

**Appearance** 

Solid. Physical state

Crystalline powder. **Form** Color White. Pale yellow. Odor Not available. Not available.

Odor threshold Not available. pН Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available. Vapor pressure Not available. Not available. Vapor density Relative density Not available.

Solubility(ies)

Insoluble. Solubility (water)

Dimethyl sulfoxide: Slightly soluble. Solubility (other)

> Methanol: Slightly soluble. Dimethyl sulfoxide: Soluble.

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. Viscosity

Other information

C27H35Cl2N3O3 Molecular formula

Molecular weight 520.49

#### 10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

**Chemical stability** Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Cl-. NOx.

# 11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete. Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and

toxicological characteristics

Not available.

#### Information on toxicological effects

Acute toxicity Not known.

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization
Skin sensitization
Knowledge about health hazard is incomplete.
Knowledge about health hazard is incomplete.
Knowledge about mutagenicity is incomplete.
Carcinogenicity
Knowledge about carcinogenicity is incomplete.

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not listed

**Reproductive toxicity** Knowledge about health hazard is incomplete.

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

**Aspiration hazard** Based on available data, the classification criteria are not met.

# 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability** No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

#### 13. Disposal considerations

**Disposal instructions** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied. Empty containers should be taken to an approved waste handling site for recycling or

disposal.

# 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and

Not applicable.

the IBC Code

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or applicable.

shipment.

## 15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No Delayed Hazard - No

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous No

chemical

SARA 313 (TRI reporting)

Not regulated.

## Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

Inventory name

**US state regulations**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

## **International Inventories**

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing

country(s)

# 16. Other information, including date of preparation or last revision

 Issue date
 02-08-2012

 Revision date
 06-29-2017

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On inventory (yes/no)\*

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