SAFETY DATA SHEET

1. Identification

Product identifier Cetirizine Related Compound G

Other means of identification

Catalog number 1102963

2-{4-[(4-Chlorophenyl)phenylmethyl)piperazin-1-yl}ethanol dihydrochloride **Chemical name**

Synonym(s) Desacetic cetirizine

Recommended use Specified quality tests and assay use only.

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

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

Website www.usp.org

E-mail RSTECH@usp.org

CHEMTREC within US & **Emergency phone number**

Canada

CHEMTREC outside US &

1-800-424-9300 +1 703-527-3887

301-816-8129

Canada

2. Hazard(s) identification

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

Label elements

Hazard symbol None. None. Signal word

Hazard statement Not available.

Precautionary statement

Prevention Not available. Not available. Response Not available. Storage Disposal Not available. Not classified.

Hazard(s) not otherwise

classified (HNOC)

Other hazards which do not

result in classification

None known.

3. Composition/information on ingredients

Substance

Non-hazardous components

Chemical name Common name and synonyms **CAS** number % Cetirizine Related Compound G Desacetic cetirizine 164726-80-1 100

4. First-aid measures

Material name: Cetirizine Related Compound G

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.

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

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

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

Most important

symptoms/effects, acute and

delayed

Provide general supportive measures and treat symptomatically.

Indication of immediate medical attention and special

treatment needed

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.

Not available.

Specific hazards arising from

the chemical

Specific methods

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.

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.

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

Biological limit values

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

Exposure guidelines Appropriate engineering

controls

No exposure standards allocated.

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

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.

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

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.

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.

Respiratory protection Where respirators are deemed necessary to reduce or control occupational exposures, use

NIOSH-approved respiratory protection and have an effective respirator program in place

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

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance Off-white solid.

Physical state Solid.
Form Solid.

OdorNot available.Odor thresholdNot available.pHNot available.Melting point/freezing pointNot available.Initial boiling point and boilingNot available.

range

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available. Vapor pressure Not available. Vapor density Not available. Not available. Relative density Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. **Viscosity**

Other information

Molecular formula C19H25Cl3N2O

Molecular weight 403.77

10. Stability and reactivity

Reactivity None known.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid None known.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

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

11. Toxicological information

Information on likely routes of exposure

IngestionClassification not possible.InhalationClassification not possible.Skin contactClassification not possible.Eye contactClassification not possible.

Symptoms related to the physical, chemical, and toxicological characteristics

Not available.

Acute toxicity Not available.

Skin corrosion/irritation

Serious eye damage/eye

irritation

Classification not possible. Classification not possible.

Respiratory or skin sensitization

Respiratory sensitization Classification not possible. Skin sensitization Classification not possible.

Germ cell mutagenicity

Classification not possible. Data from germ cell mutagenicity tests were not found.

Carcinogenicity

Classification not possible. This product is not considered to be a carcinogen by IARC, ACGIH,

NTP, or OSHA.

Reproductive toxicity Specific target organ toxicity -

single exposure

Classification not possible. Classification not possible.

Specific target organ toxicity -

repeated exposure

Classification not possible.

Not classified. **Aspiration hazard**

12. Ecological information

No ecotoxicity data noted for the ingredient(s). **Ecotoxicity**

Persistence and degradability Not available. Not available. **Bioaccumulative potential** Not available. Mobility in soil Not available. Other adverse effects

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 available.

the IBC Code

General information

It is the shipper's responsibility to determine the correct transport classification at the time of

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. One or more components are not listed on TSCA.

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

Material name: Cetirizine Related Compound G

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Safe Drinking Water Act

(SDWA)

Not regulated.

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Food and Drug Not regulated.
Administration (FDA)

US state regulations

US. California Proposition 65

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

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Country(s) or region	Inventory name	On inventory (yes/no)*
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

^{*}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
 11-25-2015

 Revision date
 03-04-2016

Version # 02

Further information Not available.

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herein.

Revision Information Product and Company Identification: Product and Company Identification

Physical & Chemical Properties: Multiple Properties

Material name: Cetirizine Related Compound G

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