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SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Hydrochlorothiazide

Synonyms: Hydrochlorothiazide

Drug Code Number: 53710: 41654; 71605

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.

1 North Waukegan Road North Chicago, IL 60064

USA

1-800-255-5162 +1-847-937-7433

Customer Service Telephone: 1-800-255-5162 (US and Canada only)

+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)

or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Not classified

2.2 Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3 Other hazards

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Not determined

Section 3. Composition/information on ingredients

| Chemical Name | Percent | EINECS/ELINCS Number | EEC Classification | EU - GHS Substance Classification | REACH No. |
|--------------------------------|---------|-------------------------|---------------------------|---|-------------------|
| Hydrochlorothiazide 58-93-5 | 100 | 200-403-3 | | Not Hazardous* | No data available |

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation

persists or signs of toxicity occur, seek medical attention. Provide

symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation

persists or signs of toxicity occur, seek medical attention. Provide

symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Provide symptomatic/supportive care as necessary. Provide replacement of fluids and

electrolytes as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Provide symptomatic/supportive care as necessary. Provide replacement of fluids and

electrolytes as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Clinical overdose may result in the following: electrolyte imbalances, low blood

potassium, confusion, dizziness, muscle weakness, gastrointestinal upset. Other adverse effects: abnormal liver function, skin irritation, hypotension, increased urine

output, photosensitivity responses.

Medical Conditions

Aggravated by Exposure:

None known from occupational exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

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Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters:

As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

| Chemical Name Employee Exposure Limit Skin Notation | ļ | Chemical Name | Employee Exposure Limit | Skin Notation |
|---|---|---------------|-------------------------|---------------|
|---|---|---------------|-------------------------|---------------|

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| Hydrochlorothiazide | 0.25 mg/m ³ for 8-hour TWA | None |
|---------------------|---------------------------------------|------|
| 58-93-5 | | |

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are

expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to exposures when handling the product

formulation.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure

Controls:

Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Crystalline Solid Odor: Not determined. **Odor Threshold:** Not determined Not determined. pH: **Boiling Pt.** @ **760** mm **Hg** (°C): Not determined. **Melting/Freezing Point (°C):** Not determined **Flash Point (°C):** Not determined. **Evaporation Rate at 20°C:** Not determined. Flammability (Solid): Not determined. **Lower Explosive Limit:** Not determined. **Upper Explosive Limit:** Not determined. Vapor Pressure (mm Hg): Not determined. Vapor Density (Air = 1): Not determined. **Specific Gravity:** Not determined. **Solubility(ies):** Not determined. Partition coefficient: n-Not determined.

octanol/water

Autoignition Temp. (°C):

Decomposition temperature (°C):

Viscosity (centipoise):

Explosion Severity:

Oxidizer Properties:

Not determined.

Not determined.

Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

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Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decompostion products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route

Dermal: Yes **Inhalation:** Yes

Acute Toxicity - Oral: Data for component (s) given below.

| Chemical Name | Acute Test | Value | Units | Species |
|---------------------|------------|-------|-------|---------|
| Hydrochlorothiazide | | 2750 | mg/kg | Rats |
| 58-93-5 | | | | |

Acute Toxicity - Dermal: Not determined.

Acute Toxicity - Inhalation: Not determined.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: Animal testing did not show any effects on fetal development. Animal testing did not

show any effects on fertility.

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Carcinogenicity: Not determined.

Mutagenicity: Not determined.

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage

2. LC50: Concentration in air that produces 50% mortality 3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

- 1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
- 2. LC50: Concentration in water that produces 50% mortality in fish.
- 3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local

regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN Number: Not applicable

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14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according Not applicable

to Annex II of MARPOL 73/78

and the IBC Code:

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

| Chemical Name | EINECS/ ELINCS | TSCA | DSL | NDSL | PICCS |
|---------------------|----------------|------|-----|-------------|-------|
| Hydrochlorothiazide | 200-403-3 | X | X | Not listed. | X |
| 58-93-5 | | | | | |

| Chemical Name | ENCS | ISHL | IECSC | AICS | KECL | New Zealand |
|---------------------|------|-----------|-------|------|------|-------------|
| Hydrochlorothiazide | - | 8-(7)-769 | - | X | - | HSR007104 |
| 58-93-5 | | | | | | |

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

| Chemical Name | Percent | NTP: | IARC: | ACGIH: |
|---------------------|---------|------------|------------|------------|
| Hydrochlorothiazide | 100 | Not Listed | Not Listed | Not Listed |

SARA 313 Information

| Chemical Name | Percent | SARA 313 Chemical: | CERCLA RQ/SARA | SARA EHS TPQ (lbs): |
|---------------------|---------|--------------------|----------------|---------------------|
| | | | EHS RQ (lbs): | |
| Hydrochlorothiazide | 100 | No | Not Applicable | Not applicable |

Immediate Health:YesDelayed Health:NoFire:NoSudden Pressure:NoReactivity:No

RCRA Status: Not determined.

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Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or

reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:

Health: 1 Fire: 1 Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.

2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.

3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.

4. TSCA = Toxic Substances Control Act.

5. EC = European Community.

6. WHMIS = Canadian Workplace Hazardous Materials Information System.

7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

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Supersedes the SDS dated: Sep-26-2011

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