

SAFETY DATA SHEETS

This SDS packet was issued with item:

078937544

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078937545

LEADING

P H A R M A

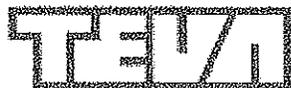
Material Safety Data Sheet
Furosemide Tablets USP, 20 mg, 40 mg and 80mg

Material Safety Data Sheet for Furosemide Tablets USP

Material Safety Data Sheet

Furosemide Tablets USP, 20 mg, 40 mg and 80mg

<p>Drug Product:</p> <p>Furosemide Tablets USP, 20 mg, 40 mg and 80mg</p>	<p>The drug product meets the specification per USP monograph. Further the drug product is approved by US-FDA</p>																
<p>Excipients:</p>	<table border="1"> <tr> <td>1</td> <td>Pregelatinized Starch NF (1551)</td> </tr> <tr> <td>2</td> <td>Sodium Starch Glycolate NF</td> </tr> <tr> <td>3</td> <td>Purified Water USP</td> </tr> <tr> <td>4</td> <td>Corn Starch NF (Purity 826)</td> </tr> <tr> <td>5</td> <td>Microcrystalline Cellulose NF (PH102)</td> </tr> <tr> <td>6</td> <td>Lactose Anhydrous, NF (DT)</td> </tr> <tr> <td>7</td> <td>Colloidal Silicon Dioxide, NF</td> </tr> <tr> <td>8</td> <td>Magnesium Stearate NF</td> </tr> </table> <p>All the excipients of the formulation meet USP/NF specifications and are approved by FDA</p>	1	Pregelatinized Starch NF (1551)	2	Sodium Starch Glycolate NF	3	Purified Water USP	4	Corn Starch NF (Purity 826)	5	Microcrystalline Cellulose NF (PH102)	6	Lactose Anhydrous, NF (DT)	7	Colloidal Silicon Dioxide, NF	8	Magnesium Stearate NF
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<p>Drug Substance- Furosemide Tablets USP</p>	<p>Furosemide Tablets USP meets USP monograph specifications</p>																
<p>MSDS for Furosemide Tablets USP</p>	<p>Refer to the attached MSDS for Furosemide Tablets USP</p>																



SAFETY DATA SHEET

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 29-Oct-2009

Revision Date 06-Jan-2016

Revision Number 12

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

1.1. Product identifier

Product Name	FUROSEMIDE
Chemical Name	4-chloro-2-(furan-2-ylmethylamino)-5-sulfamoylbenzoic acid
Synonyms	Aisemide; Aluzine; 5-(Aminosulfonyl)-4-chloro-2-((2-furanylmethyl)amino)benzoic acid; Aquamide; Aquasin; Arasemide; Benzoic acid, 5-(aminosulfonyl)-4-chloro-2-((2-furanylmethyl)amino)-(9CI); Beronald; Chlor-N-(2-furymethyl)-5-sulfamoylanthranilsaeure (German); 4-Chloro-N-furfuryl-5-sulfamoylanthranilic acid; 4-Chloro-N-(2-furymethyl)-5-sulfamoylanthranilic acid; Desdemin; Discoid; Diural; Diuresal; Diurolasa; Dryptal; Durafurid; Errolon; Eutensin; Franyl; Frusemide; Frusemin; Frusetic; Frusid; Fulsix; Fuluvamide; Furanthril; Furanthryl; Furantril; Furesis; Furose; Furosedon; Furosemid; Furosemide; Furosemide "Mita"; Furosemidu (Polish); Furoside; Fursemid; Fursemide; Fusid; Hydrex; Hydrorapid; Impugan; Kattex; Lasex; Lasifetten; Lasilix; Lasix; Laxur; LB 502; Lowpstron; Macasirool; Moilarorin; NCI-C55936; Neo-renal; Nicorol; Nevosemide; Odemase; Prefemin; Profemin; Promedes; Puresis; Radonna; Rosemide; Salix; Seguril; Sigasalur; Transit; Urex; Urex-M; Uritol; Urosemide
Formula	C ₁₂ H ₁₁ Cl N ₂ O ₅ S
CAS	54-31-9
EINECS	200-203-6
Index No	No information available
Reach Registration Number	No information available

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

Identified Use	Active Pharmaceutical Ingredient
Uses advised against	No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier	Assia Chemical Industries Ltd. - Teva-Tech site Neot-Hovav Eco-Industrial Park P.O Box 2049, Emek Sara Be'er Sheva 8412316 Israel Tel: 972-8-6509555 Fax: 972-8-6509500
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For further information, please contact

E-mail Address	SDS.TevaL@teva.co.il
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1.4. Emergency Telephone Number

Emergency Telephone Number	972 (8) 6509442
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SECTION 2: Hazards identification

2.1. - Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008

Muta. 2 H341
Carc. 2 H351
Repr. 1A H360D
Full text of phrases reported in section 16.
Main effects: see sections from 9 to 12.

2.2. Label Elements

Signal Word **Danger**



Hazard Statements

H341 - Suspected of causing genetic defects
H351 - Suspected of causing cancer
H360D - May damage the unborn child

Precautionary Statements

P201 - Obtain special instructions before use
P260 - Do not breathe dust
P280 - Wear protective gloves/protective clothing/eye protection/face protection

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %
4-chloro-2-(furan-2-ylmethyl amino)-5-sulfamoylbenzoic acid	EEC No. 200-203-6	Not available	54-31-9	100

3.2. Mixtures

N.A.

SECTION 4. First aid measures

4.1. Description of first aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Ingestion	Clean mouth with water, only if the person is conscious. Get medical attention.
Inhalation	If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Remove from exposure, lie down.

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

Irritation	May cause irritation.
Corrosivity	No information available.
Eyes	May cause, blurred vision, Changes in sense acuity.
Skin	May cause: pruritus, skin rash, urticaria, Dermatitis, Photosensitization.
Inhalation	No information available.
Ingestion	May cause: Pancreatitis, Jaundice, Anorexia, Oral and gastric irritation, Abdominal cramps, diarrhea, constipation, nausea, vomiting, Stomach pain.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician	Treat symptomatically.
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SECTION 5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Protect from light. Keep in a tight container. Store at Up to 25°C.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits No occupational exposure limit values have been defined by authorities in production Country.

Biological occupational exposure limits No information available.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Measures Provide engineering control according to Teva Guidelines.

Special Requirements Avoid exposure of pregnant women.

Personal protective equipment

- Eye/face protection** Use eye protection appropriate for the task.
- Skin protection:**
 - Body protection Use protective clothing appropriate for the task.
 - Hand protection Use appropriate protective gloves.
- Respiratory Protection** Use appropriate respiratory protection.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Color	White to slightly yellow
Physical State	crystalline powder
Odor	Odourless
Odour Threshold	No information available
pH	No information available
Melting Point/Range	206-210 °C
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper	No information available
Lower	No information available
Vapor Pressure	No information available
Vapor Density	No information available
Relative Density	No information available
Solubility	Soluble in Alcohol. Freely Soluble in Dilute alkali solutions. Slightly soluble in water.
Water Solubility	Slightly soluble
Octanol/water Partition Coefficient (Log Kow)	1.4
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight 330.8

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4. Conditions to avoid

Heat, Exposure to light.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Toxic fumes of: Nitrogen oxides (NOx), carbon oxides, sulphur oxides, hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity

LD50 Oral rat 2600 mg/kg

LD50 Oral mouse 2000 mg/kg

skin corrosion/irritation No information available.

serious eye damage/irritation No information available.

respiratory or skin sensitization No information available.

germ cell mutagenicity

No evidence of mutagenicity in non-clinical studies.

carcinogenicity

Listed IARC Group 3. Some evidence of carcinogenicity in animal studies.

reproductive toxicity

Evidence of teratogenicity in animal studies.

STOT - single exposure

No information available.

STOT - repeated exposures

No information available.

aspiration hazard

No information available.

Other Information

Target Organ Effects

Cardiac, Kidney, Bladder, Organ senses, Liver.

Central nervous system

May cause tinnitus and hearing loss, May cause xanthopsia, May cause: Paresthesia, vertigo, dizziness, headache.

Hematological effects

May cause: Thrombocytopenia, Hemolytic anemia, Leukopenia, Anemia.

Cardiovascular system

May cause: Orthostatic Hypotension.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity effects

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Not expected to bioaccumulate : Log Po/w <3 (EC) or <4 (GHS). Half-Life Elimination in Human: 2h.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused

Dispose of in accordance with local regulations.

Products

Contaminated Packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1.

UN-No

Not hazardous for transport

14.2.

Proper Shipping Name

Not hazardous for transport

14.3. Transport hazard class(es)

ADR / RID / ADN (land transport)

Not hazardous for transport

IMDG (sea transport)

Not hazardous for transport

IATA / ICAO (air transport)

Not hazardous for transport

14.4.

Packing Group

Not hazardous for transport

14.5. Environmental hazards

Marine Pollutant

No information available

14.6. Special precautions for user

Emergency No.

No information available

ADR/RID-Labels

No information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Technical name

No information available

Ship type

No information available

Annex II

No information available

SECTION 15: Regulatory information

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

- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other Information

CLP/GHS - Regulation

Hazard Statements

H341 - Suspected of causing genetic defects

H351 - Suspected of causing cancer

H360D - May damage the unborn child

Training appropriate for workers is required to ensure protection of human health and environment.

Application/Drug Class Antihypertensive / Diuretic.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

ECHA (European chemicals agency) databases

FDA (Food & Drug administration) database

EMA (European Medicines agency) documents

ChemAdvisor

Chemspider database

Issuing Date 29-Oct-2009

Revision Date 06-Jan-2016

Revision Note

Not applicable

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, and disposal of the designated material 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