

# Material Safety Data Sheet

## Metformine Hydrochloride Extended-release Tablets USP

Strength: 500/750 mg

Pack Size: 100/500 tablets per bottle

Revision No.: 00

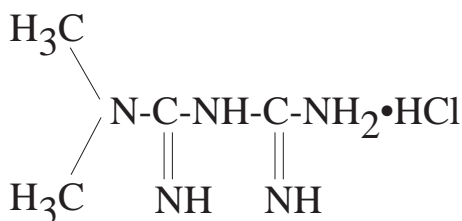
### EMERGENCY OVERVIEW

Metformine Hydrochloride Extended-release Tablets that contains Metformine Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

#### Section 1. Identification of the substance

##### Identification of the product

|                             |                                                               |
|-----------------------------|---------------------------------------------------------------|
| <b>Product name:</b>        | Metformine Hydrochloride Extended-release Tablets USP         |
| <b>Formula:</b>             | $C_4H_{11}N_5 \cdot HCl$                                      |
| <b>Chemical Name:</b>       | <i>N,N</i> -dimethylimidodicarbonimidic diamide hydrochloride |
| <b>Therapeutic Category</b> | Oral antihyperglycemic agents                                 |



**Metformin hydrochloride**

##### Manufacturer / supplier identification

|                                 |                                                |
|---------------------------------|------------------------------------------------|
| <b>Company:</b>                 | <b>Cadila Healthcare Ltd. Ahmedabad, India</b> |
| <b>Contact for information:</b> | Tel.: +91 79 6868100 Fax: +91 79 3750319       |
| <b>Emergency telephone No.</b>  | Tel.: +91 79 6868100                           |

#### Section 2. Composition / information on ingredients

| Component                     | Exposure Limit | CAS No.    |
|-------------------------------|----------------|------------|
| <b>Principle Component :</b>  |                |            |
| Metformine hydrochloride      | Not Found      | 1115-70-4  |
| <b>Inactive Ingredients :</b> |                |            |
| Glyceryl behenate             | Not Found      | 18641-57-1 |
| Hypromellose                  | Not Found      | 9004-65-3  |
| Microcrystalline cellulose    | Not Found      | 9004-34-6  |
| Povidone                      | Not Found      | 9003-39-8  |

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### Section 3. Health Hazards Information

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Dose and Administration</b> | Metformin hydrochloride extended-release tablets should generally be given once daily with the evening meal. Metformin hydrochloride extended-release tablets should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycemic control of the patient.                                                                                                                                                                                                                                  |
| <b>Adverse Effects</b>         | Diarrhea, Nausea, Vomiting, Flatulence, Asthenia, indigestion, Abdominal discomfort, Headache,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Over Dose Effect</b>        | Hypoglycemia and Lactic acidosis has been reported                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Medical Conditions</b>      | In following conditions patient should inform to doctor: kidney problems, liver problems, heart failure that is treated with medicines, such as Lanoxin <sup>®</sup> (digoxin) or Lasix <sup>®</sup> (furosemide), drink a lot of alcohol, lost a lot of water from body, are going to have an x-ray procedure with injection of dyes (contrast agents), are going to have surgery, develop a serious condition, such as heart attack, severe infection, or a stroke, are 80 years or older and you have not had your kidney function tested                                                                       |
| <b>Contraindications</b>       | Metformin hydrochloride extended-release tablets are contraindicated in patients with Renal disease or renal dysfunction which may also result from conditions such as cardiovascular collapse, acute myocardial infarction, and septicemia, known hypersensitivity to Metformin hydrochloride, Acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function |
| <b>Pregnancy Comments</b>      | Metformin should not be used during pregnancy unless clearly needed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Pregnancy Category</b>      | B                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

### Section 4. First aid measures

|                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General</b> | <p><b>Eye Contact:</b> Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.</p> <p><b>Skin Contact:</b> Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.</p> <p><b>Serious Skin Contact:</b> Not available.</p> <p><b>Inhalation:</b> If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.</p> <p><b>Serious Inhalation:</b> Not available.</p> <p><b>Ingestion:</b> Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as</p> |
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a collar, tie, belt or waistband.

**Serious Ingestion:** Not available.

**Overdose Treatment** Hemodialysis may be useful for removal of accumulated drug from patients in whom Metformin over dosage is suspected.

### Section 5. Fire – fighting measures

|                                   |                                                                                                                                           |                                  |                                                                                                                                                                             |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Flash point</b>                | Not Found                                                                                                                                 | <b>Upper Flammable Limit:</b>    | May be combustible at high temperature.                                                                                                                                     |
| <b>Auto-Ignition Temperature:</b> | Not Found                                                                                                                                 | <b>Lower Flammable Limit:</b>    | Not Found                                                                                                                                                                   |
| <b>Extinguishing Media</b>        | Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.                                       | <b>Fire and Explosion Hazard</b> | Slightly flammable in presence of heat and non-flammable in presence of shocks. Slightly explosive in presence of open flame and spark non explosive in presence of shocks. |
| <b>Fire Fighting Procedure</b>    | As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing. |                                  |                                                                                                                                                                             |

### Section 6. Accidental Release Measures

**Spill Response** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

### Section 7. Handling and Storage

**Storage** Store at 20° - 25°C (68° - 77°F )  
Dispense in light-resistant containers.

### Section 8. Exposure controls and personal protection

**Respiratory Protection** Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

**Skin Protection** Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

**Eye protection** Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

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|                            |                                                                                          |
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| <b>Protective Clothing</b> | Protective clothing is not normally necessary, however it is good practice to use apron. |
|----------------------------|------------------------------------------------------------------------------------------|

### Section 9. Physical and chemical properties

|                   |                                                                                                                                                                                   |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Appearance</b> | Metformin Hydrochloride Extended-release Tablets USP, 500 mg are white to off-white, capsule shaped, uncoated tablets, debossed with "63" on one side and "Z" on the other side . |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|  |                                                                                                                                                                                        |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Metformin Hydrochloride Extended-release Tablets USP, 750 mg are white to off-white, capsule shaped, uncoated tablets, debossed with "Z", "C" on one side and "20" on the other side . |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                            |                                                                                                                                                 |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Solubility in water</b> | Metformin hydrochloride is freely soluble in water, slightly soluble in alcohol and is practically insoluble in acetone and methylene chloride. |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|

|                      |                   |                      |                         |
|----------------------|-------------------|----------------------|-------------------------|
| <b>Boiling point</b> | No Data Available | <b>Melting Point</b> | 223°C (433.4°F) - 226 C |
|----------------------|-------------------|----------------------|-------------------------|

|                         |                   |                       |                   |
|-------------------------|-------------------|-----------------------|-------------------|
| <b>Evaporation rate</b> | No Data Available | <b>Vapour density</b> | No Data Available |
|-------------------------|-------------------|-----------------------|-------------------|

|                            |                   |                         |                   |
|----------------------------|-------------------|-------------------------|-------------------|
| <b>Reactivity in water</b> | No Data Available | <b>Evaporation rate</b> | No Data Available |
|----------------------------|-------------------|-------------------------|-------------------|

|                                      |                   |                         |                   |
|--------------------------------------|-------------------|-------------------------|-------------------|
| <b>Percentage Volatile by volume</b> | No Data Available | <b>Specific gravity</b> | No Data Available |
|--------------------------------------|-------------------|-------------------------|-------------------|

|                        |                   |             |          |
|------------------------|-------------------|-------------|----------|
| <b>Vapour pressure</b> | No Data Available | <b>Odor</b> | Odorless |
|------------------------|-------------------|-------------|----------|

|                          |                |
|--------------------------|----------------|
| <b>Other information</b> | Not Applicable |
|--------------------------|----------------|

### Section 10. Stability and Reactivity

|                           |                                                     |               |                                                                              |
|---------------------------|-----------------------------------------------------|---------------|------------------------------------------------------------------------------|
| <b>Condition to avoid</b> | Avoid exposure to extreme heat, light and moisture. | <b>Stable</b> | Stable under normal ambient and anticipated storage and handling conditions. |
|---------------------------|-----------------------------------------------------|---------------|------------------------------------------------------------------------------|

|                               |                   |                           |                    |
|-------------------------------|-------------------|---------------------------|--------------------|
| <b>Decomposition Products</b> | No Data Available | <b>Hazardous Reaction</b> | No data available. |
|-------------------------------|-------------------|---------------------------|--------------------|

|                          |                                |
|--------------------------|--------------------------------|
| <b>Incompatibilities</b> | Reactive with oxidising agent. |
|--------------------------|--------------------------------|

### Section 11. Toxicological information

|                |                                                                                                                                                                              |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General</b> | Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation. |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                     |                                                                                       |
|---------------------|---------------------------------------------------------------------------------------|
| <b>Target organ</b> | Eye contact, Skin contact and inhalation is not great risk as this product is tablet. |
|---------------------|---------------------------------------------------------------------------------------|

|              |                                                                             |
|--------------|-----------------------------------------------------------------------------|
| <b>Other</b> | <b>Toxicity to Animals:</b> Acute oral toxicity (LD50): 350 mg/kg [Rabbit]. |
|--------------|-----------------------------------------------------------------------------|

|  |                                                                                                                                               |
|--|-----------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>Chronic Effects on Humans:</b> May cause damage to the following organs: central nervous system (CNS).cardiovascular system, blood, liver. |
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**Other Toxic Effects on Humans:** Slightly hazardous in case of skin contact (irritant) of ingestion, of inhalation.

**Special Remarks on Chronic Effects on Humans:** May cause adverse reproductive effects based on animal test data. May affect genetic test material.

**Special Remarks on other Toxic Effects on Humans:**

Acute Potential Health Effects: Skin: Causes skin irritation. Eyes: Causes eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: May be harmful if swallowed. May cause diarrhea, and hyper motility. May affect behavior/central nervous system(hallucinations, convulsions), liver (jaundice), blood (changes in serum composition (e.g. TP, bilirubin, cholesterol)), respiration.

### Section 12. Ecological information

**Products of Biodegradation:**

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

**Toxicity of the Products of Biodegradation:** The products of degradation are less toxic than the product itself.

### Section 13. Disposal Consideration

**Disposal**

Dispose the waste in accordance with all applicable Federal, State and local laws.

### Section 14. Transport Information

May be shipped normally as a non hazardous material.

### Section 15. Regulatory Information

- 1) Metformin Hydrochloride Extended-release Tablets - 500 mg ANDA no. is 077060
- 2) Metformin Hydrochloride Extended-release Tablets - 750 mg ANDA no. is 077078

### Section 16. Other information

None

**Date of issue:** 04/11/2011

**Supersedes edition of:** New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.