

**Loperamide Anti-Diarrheal Caplets**

Version 1.1      Revision Date: 06/03/2015      MSDS Number: 000000037606      Date of last issue: 05/28/2015  
Date of first issue: 05/28/2015

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**SECTION 1. IDENTIFICATION**

Product name : Loperamide Anti-Diarrheal Caplets  
Synonyms : Active ingredient: Loperamide hydrochloride <= 60 %  
Product code : 000000037606

**Manufacturer or supplier's details**

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated  
Address : 900 Ridgebury Road  
Ridgefield, Connecticut  
06877-0368  
Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number  
CHEMTREC – 24 Hours  
Routine Contact Number : (203) 778-7759

**Recommended use of the chemical and restrictions on use**

Recommended use : Mixture for production of finished medicinal products.  
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services  
[EHS-service@boehringer-ingelheim.com](mailto:EHS-service@boehringer-ingelheim.com)

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Loperamide Hydrochloride	34552-83-5	2

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**SECTION 4. FIRST AID MEASURES**

General advice : Remove from exposure, lie down.  
Take off immediately all contaminated clothing.  
Victim to lie down in the recovery position, cover and keep him warm.  
First Aid responders should pay attention to self-protection and use the recommended protective clothing

If inhaled : Move to fresh air.  
Call a physician immediately.

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In case of skin contact	:	Wash off immediately with plenty of water. Cover wound with sterile dressing. Call a physician immediately.
In case of eye contact	:	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
If swallowed	:	Rinse mouth. Drink plenty of water. Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	Observe the summary of product characteristics of proprietary medicinal products

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### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water Foam Dry chemical Carbon dioxide (CO <sub>2</sub> )
Specific hazards during fire-fighting	:	In case of fire and/or explosion do not breathe fumes. Can be released in case of fire: Carbon oxides Nitrogen oxides (NO <sub>x</sub> ) Hydrogen chloride gas
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment for firefighters	:	Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Ensure adequate ventilation. Knock down dust with water spray jet.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Wear personal protective equipment. Clean-up methods - large spillage Dampen, pick up mechanically and dispose of. Clean-up methods - small spillage Use approved industrial vacuum cleaner for removal. Keep in suitable, closed containers for disposal.

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### SECTION 7. HANDLING AND STORAGE

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- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Minimize dust generation and accumulation. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.
- Conditions for safe storage : Store in original container. Protect from heat and direct sunlight. Jointless smooth floor. Keep container tightly closed.
- Materials to avoid : Keep away from food, drink and animal feed. Advice on Segregation
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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

- Engineering measures** : Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

#### Personal protective equipment

- Respiratory protection : Protecting mask (EN 136) particle filter P3 (EN 143)  
Use NIOSH approved respiratory protection.
- Hand protection Material : Nitrile rubber  
Break through time : 480 min  
Glove thickness : 0.43 mm  
Directive : Protective gloves against chemicals and micro-organisms  
Protective index : Class 6
- Eye protection : Safety glasses with side-shields  
(Not necessary when using full face mask)
- Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.
- Protective measures : Handle in accordance with good industrial hygiene and safety practice.  
Do not breathe dust.  
Avoid contact with skin, eyes and clothing.  
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
- Hygiene measures : General industrial hygiene practice.

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Wash hands and face before breaks and immediately after handling the product.  
Keep working clothes separately.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: solid
Color	: light green
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Boiling point/boiling range	: Not applicable
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: Not applicable
Relative vapor density	: Not applicable
Relative density	: No data available
Bulk density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: Not applicable
Explosive properties	: No data available
Oxidizing properties	: No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : Dust may form explosive mixture in air.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION**

**Acute toxicity**  
Not classified based on available information.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:****Loperamide Hydrochloride:**

Acute oral toxicity : LD50 (Rat): 185 mg/kg  
LD50 (Mouse): 105 mg/kg  
LD50 (Guinea pig): 41.5 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Loperamide Hydrochloride:**

Remarks: No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Loperamide Hydrochloride:**

Remarks: No data available

**Respiratory or skin sensitization**

Skin sensitization: Not classified based on available information.  
Respiratory sensitization: Not classified based on available information.

**Components:****Loperamide Hydrochloride:**

Remarks: No data available

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### Germ cell mutagenicity

Not classified based on available information.

### Carcinogenicity

Not classified based on available information.

#### IARC

No component of this product is present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

#### NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Not classified based on available information.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Aspiration toxicity

Not classified based on available information.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No data available

### Persistence and degradability

No data available

### Bioaccumulative potential

No data available

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
 Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

#### Components:

#### **Loperamide Hydrochloride:**

Additional ecological information : At present there are no ecotoxicological assessments. Do not flush into surface water or sanitary sewer system.

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.  
Uncontaminated packaging can be recycled.

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**SECTION 14. TRANSPORT INFORMATION****International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations**

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**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act**

**SARA 311/312 Hazards** : Acute Health Hazard

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM/I Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

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Non-hazardous galenic excipients      Not Assigned      90 - 100 %

### New Jersey Right To Know

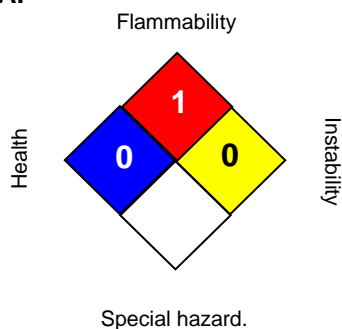
Non-hazardous galenic excipients      Not Assigned      90 - 100 %  
Loperamide Hydrochloride      34552-83-5      1 - 5 %

**California Prop 65**      : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA:



#### HMIS III:

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

0 = not significant, 1 = Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.