SAFETY DATA SHEET

KLONOPIN(R) Tablets (1.0 mg)

SECTION 1. IDENTIFICATION

Product name : KLONOPIN(R) Tablets (1.0 mg)
Product code : RO005-4023/F06

Manufacturer or supplier’s details
Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Substance name : RIVOTRIL Tablets 1.0 mg

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonazepam</td>
<td>1622-61-3</td>
<td>0.6</td>
</tr>
<tr>
<td>Lactose-monohydrate</td>
<td>10039-26-6</td>
<td>71.56</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>14.71</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>11.76</td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td>0.78</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>0.59</td>
</tr>
</tbody>
</table>
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SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : None known.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire fighting : No information available.

Hazardous combustion products : Carbon oxides

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid exposure
Avoid dust formation.
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Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Pick up and arrange disposal without creating dust.
- Sweep up and shovel.
- Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
- Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling:
- For personal protection see section 8.
- Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage:
- Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions:
- See label, package insert or internal guidelines

Materials to avoid:
- No materials to be especially mentioned.

Storage temperature:
- Protected from heat and light
- Protect from moisture.

Further information on storage stability:
- No decomposition if stored and applied as directed.

Packaging material:
- Suitable material: Polyethylene bag in metal drum, Plastic container of HDPE, glass bottles, Blister packages

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m3</td>
<td>OSHA P0</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Material</th>
<th>CAS Number</th>
<th>TWA</th>
<th>Limit</th>
<th>Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m3</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m3</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>1622-61-3</td>
<td>IOEL</td>
<td>0.01 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: No data available

Personal protective equipment
Respiratory protection: No personal respiratory protective equipment normally required.
Hand protection
Material: Protective gloves
Remarks: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection: Safety glasses
Skin and body protection: Protective suit
Protective measures: Instruction of employees recommended
Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
Appearance: tablet
Color: blue
Odor: Not applicable
Odor Threshold : Not applicable
pH : No data available
Melting point/range : No data available
Boiling point/boiling range : No data available
Evaporation rate : No data available
Self-ignition : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor density : Not applicable
Relative density : No data available
Solubility(ies)
   Water solubility : No data available
   Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, dynamic : Not applicable
   Viscosity, kinematic : Not applicable

SECTION 10. STABILITY AND REACTIVITY
Reactivity : No dangerous reaction known under conditions of normal use.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Stable under recommended storage conditions. No hazards to be specially mentioned.
Incompatible materials : No data available
SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

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

Components:
Clonazepam:
Acute oral toxicity: LD50 Oral (Rat): > 15,000 mg/kg
LD50 Oral (Mouse): 2,000 mg/kg

Lactose-monohydrate:
Acute oral toxicity: LD50 Oral (Rat): > 10,000 mg/kg

Cellulose:
Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg

Starch:
Acute oral toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment
Acute inhalation toxicity: Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
Acute dermal toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

non hazardous compounds:
Acute oral toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment
Acute inhalation toxicity: Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment
Acute dermal toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Octadecanoic acid, magnesium salt (2:1):
Acute oral toxicity: LD50 Oral (Rat): > 2,000 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:
Clonazepam:
Remarks : This information is not available.

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Clonazepam:
Remarks : This information is not available.

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
Clonazepam:
Germ cell mutagenicity - Assessment : The substance has been tested for mutagenicity and other types of genotoxic effects in in vitro and in vivo experiments and is evaluated as being non-mutagenic.

Carcinogenicity
Not classified based on available information.

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

Lactose-monohydrate:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Cellulose:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
IARC
No ingredient of this product 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 on OSHA’s list of regulated carcinogens.

NTP
No ingredient 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.

Components:

Clonazepam:
Effects on fetal development  : Species: Rat
                              Application Route: Oral
                              Dose: < or = 40 mg/kg/d
                              Result: No teratogenic effects., No embryotoxic effects.

STOT-single exposure
Not classified based on available information.

Components:

Clonazepam:
Assessment  : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Starch:
Assessment  : The substance or mixture is not classified as specific target organ toxicant, single exposure.

non hazardous compounds:
Assessment  : The substance or mixture is not classified as specific target organ toxicant, single exposure.

Octadecanoic acid, magnesium salt (2:1):
Assessment  : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.

Components:

Clonazepam:
Assessment  : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Starch:
Assessment  : The substance or mixture is not classified as specific target
organ toxicant, repeated exposure.

**non hazardous compounds:**
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

**Octadecanoic acid, magnesium salt (2:1):**
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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

**Components:**

**Clonazepam:**
No data available

**Starch:**
No data available

**non hazardous compounds:**
No data available

**Octadecanoic acid, magnesium salt (2:1):**
No data available

---

**SECTION 12. ECOLOGICAL INFORMATION**

**Components:**

**Clonazepam:**

**Toxicity to fish**
: LC0 (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
  Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
: EC50 (Daphnia magna (Water flea)): 30.3 mg/l
  Exposure time: 48 h

**Toxicity to algae**
: ErC50 (Desmodesmus subspicatus (green algae)): > 240 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  GLP: no

  NOEC (Desmodesmus subspicatus (green algae)): < 2.46 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  GLP: no

  ErC10 (Desmodesmus subspicatus (green algae)): 3.9 mg/l
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Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: no

Cellulose:

Ecotoxicology Assessment
Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.

Starch:
Toxicity to fish: LC50: > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment
Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.
Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available

non hazardous compounds:
Toxicity to fish: LC50 (Fish): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Ecotoxicology Assessment
Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available

Octadecanoic acid, magnesium salt (2:1):

Ecotoxicology Assessment
Acute aquatic toxicity: This product has no known ecotoxicological effects.
Chronic aquatic toxicity: This product has no known ecotoxicological effects.
Toxicity Data on Soil: Not expected to adsorb on soil.
Other organisms relevant to the environment: No data available
### Persistence and degradability

**Components:**

**Clonazepam:**
- Biodegradation: 0%
- Exposure time: 21 d
- GLP: no

### Bioaccumulative potential

**Components:**

**Clonazepam:**
- Partition coefficient: n-octanol/water
  - log Pow: 2.41 (25 °C / 25 °C)
  - pH: 7.4

**Lactose-monohydrate:**
- Bioaccumulation: Remarks: No bioaccumulation is to be expected (log Pow <= 4).
- Partition coefficient: n-octanol/water
  - log Pow: -5.03

**Cellulose:**
- Partition coefficient: n-octanol/water
  - Remarks: No data available

**Starch:**
- Partition coefficient: n-octanol/water
  - Remarks: No data available

**non hazardous compounds:**
- Partition coefficient: n-octanol/water
  - Remarks: No data available

**Octadecanoic acid, magnesium salt (2:1):**
- Partition coefficient: n-octanol/water
  - log Pow: 0.8
  - Method: OECD Test Guideline 107

### 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).
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation
49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know
CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.
SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>No SARA Hazards</td>
<td></td>
</tr>
</tbody>
</table>

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 112 (40 CFR 61).
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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 SOCMI 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. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know
Cellulose 9004-34-6
Starch 9005-25-8

Pennsylvania Right To Know
Lactose-monohydrate 10039-26-6
Cellulose 9004-34-6
Starch 9005-25-8

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

California Prop. 65
WARNING: This product can expose you to chemicals including Clonazepam, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6
Starch 9005-25-8

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
         non hazardous compounds
AICS : Not in compliance with the inventory
NZIoC : On the inventory, or in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
SECTION 16. OTHER INFORMATION

NFPA:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
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</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The """" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH Rel : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC
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US / Z8 / 1810