SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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

1.1 Product identifier
   Trade name : Aprepitant Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   National Poison Control Center (UZEM): 114
   Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification T.R. SEA No 28848
   Specific target organ toxicity - repeated exposure, Category 2
   Long-term (chronic) aquatic hazard, Category 1
   H373: May cause damage to organs through prolonged or repeated exposure.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling T.R. SEA No 28848
   Hazard pictograms :
   Signal word : Warning
   Hazard statements : H373 May cause damage to organs through prolonged or repeated exposure.
   H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P260 Do not breathe dust.
- P273 Avoid release to the environment.

**Response:**
- P314 Get medical advice/attention if you feel unwell.
- P391 Collect spillage.

Hazardous components which must be listed on the label:

**Aprepitant**

**2.3 Other hazards**

- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aprepitant</td>
<td>170729-80-3</td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

**Substances with a workplace exposure limit:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td></td>
<td></td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td></td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

**General advice:**

In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
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Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed
Risks: May cause damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: 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. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides Fluorine compounds
Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling:
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aprepitant</td>
<td>170729-80-3</td>
<td>TWA</td>
<td>0.2 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>ZOAD/TWA (Total dust)</td>
<td>15 mg/m3</td>
<td>TR OEL DU</td>
</tr>
</tbody>
</table>

Further information: Allowable occupational exposure limit values of chemicals in dust form

<table>
<thead>
<tr>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZOAD/TWA (Respirable dust)</td>
<td>5 mg/m3</td>
<td>TR OEL DU</td>
</tr>
</tbody>
</table>

Further information: Allowable occupational exposure limit values of chemicals in dust form.
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<table>
<thead>
<tr>
<th>Cellulose</th>
<th>ZOAD/TWA (Total dust)</th>
<th>15 mg/m3</th>
<th>TR OEL DU</th>
</tr>
</thead>
<tbody>
<tr>
<td>9004-34-6</td>
<td>Further information: Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ZOAD/TWA (Respirable dust)</td>
<td>5 mg/m3</td>
<td>TR OEL DU</td>
</tr>
<tr>
<td></td>
<td>Further information: Allowable occupational exposure limit values of chemicals in dust form</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.
Apply measures to prevent dust explosions.
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).

Personal protective equipment

Eye protection: Wear the following personal protective equipment:
Safety goggles
Equipment should conform to TS EN 166

Hand protection

Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer.
Wash hands before breaks and at the end of workday.

Skin and body protection: Skin should be washed after contact.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to TS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: coloured
Odour: odourless
Odour Threshold: No data available
pH: No data available
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Melting point/freezing point: No data available

Initial boiling point and boiling range:

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas):

May form explosive dust-air mixture during processing, handling or other means.

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: No data available

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, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids): No data available

Molecular weight: No data available

Minimum ignition energy: < 3 mJ

Particle size: No data available
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SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure: Inhalation Skin contact Ingestion Eye contact

Acute toxicity
Not classified based on available information.

Components:

Aprepitant:
Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 2.000 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 800 - 2.000 mg/kg Application Route: Intraperitoneal
LD50 (Mouse): > 2.000 mg/kg Application Route: Intraperitoneal

Sucrose:
Acute oral toxicity: LD50 (Rat): 29.700 mg/kg
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**Cellulose:**
- **Acute oral toxicity** : LD50 (Rat): > 5.000 mg/kg
- **Acute inhalation toxicity** : LC50 (Rat): > 5.8 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- **Acute dermal toxicity** : LD50 (Rabbit): > 2.000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Aprepitant:**
- **Species** : Rabbit
- **Method** : Draize Test
- **Result** : No skin irritation

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

**Components:**

**Aprepitant:**
- **Species** : Rabbit
- **Method** : Draize Test
- **Result** : No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Aprepitant:**
- **Remarks** : No data available

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Aprepitant:**
- **Genotoxicity in vitro** : Test Type: Ames test
Genotoxicity in vitro

Result: negative
Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Alkaline elution assay
Test system: rat hepatocytes
Result: negative

Test Type: in vitro assay
Test system: human lymphoblastoid cells
Result: negative

Genotoxicity in vivo

Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Sucrose:

Genotoxicity in vitro

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Cellulose:

Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo

Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Aprepitant:

Species
Application Route
Exposure time
Dose
Result
Remarks
Species

Mouse, male
Oral
106 weeks
>=1000 mg/kg body weight
positive
The mechanism or mode of action is not relevant in humans.
Mouse, female
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**Application Route**: Oral  
**Exposure time**: 106 weeks  
**Dose**: \( \geq 500 \text{ mg/kg body weight} \)  
**Result**: positive  
**Remarks**: The mechanism or mode of action is not relevant in humans.

**Species**: Mouse  
**Application Route**: Oral  
**Exposure time**: 105 weeks  
**Dose**: 2000 mg/kg body weight  
**Result**: positive  
**Remarks**: The mechanism or mode of action is not relevant in humans.

**Cellulose**:  
**Species**: Rat  
**Application Route**: Ingestion  
**Exposure time**: 72 weeks  
**Result**: negative

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

**Components**:  

**Aprepitant**:  
**Effects on fertility**  
Test Type: Fertility  
Species: Rat, male and female  
Fertility: NOAEL: 2.000 mg/kg body weight  
Result: No effects on fertility

**Effects on foetal development**  
Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 2.000 mg/kg body weight  
Result: No effects on foetal development

**Test Type**: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: No effects on foetal development

**Cellulose**:  
**Effects on fertility**  
Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Effects on foetal development**  
Test Type: Fertility/early embryonic development  
Species: Rat
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</tbody>
</table>

Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

Aprepitant:
- Target Organs: Prostate, Testis
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Aprepitant:
- Species: Dog
- LOAEL: >= 50 mg/kg
- Application Route: Oral
- Exposure time: 39 Weeks
- Target Organs: Prostate, Testis

- Species: Rat
- NOAEL: 125 mg/kg
- Application Route: Oral
- Exposure time: 27 Weeks
- Target Organs: Liver, Thyroid

- Species: Monkey
- NOAEL: 0.240 mg/kg
- Application Route: Intravenous
- Exposure time: 7 d
- Remarks: No significant adverse effects were reported

- Species: Rat, female
- LOAEL: 125 mg/kg
- Application Route: Oral
- Exposure time: 106 Weeks
- Target Organs: Kidney

Cellulose:
- Species: Rat
- NOAEL: >= 9.000 mg/kg
- Application Route: Ingestion
- Exposure time: 90 Days
Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Aprepitant:
Ingestion:
Symptoms: Headache, Fatigue, hiccups, constipation, anorexia, liver function change, Rash, Nausea, Diarrhoea, hypotension

SECTION 12: Ecological information

12.1 Toxicity

Components:

Aprepitant:
Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): > 0.462 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 0.345 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
NOEC (Pseudokirchneriella subcapitata (green algae)): 0.184 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.184 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms:
EC50: > 100 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity):
NOEC: 0.195 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 0.018 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1

**Cellulose:**
Toxicity to fish:
LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

12.2 Persistence and degradability

**Components:**

Aprepitant:
Biodegradability: Result: not rapidly degradable
Biodegradation: 50 %
Exposure time: 66 Days
Method: OECD Test Guideline 314

Cellulose:
Biodegradability: Result: Readily biodegradable.

12.3 Bioaccumulative potential

**Components:**

Aprepitant:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 50.1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4.75

Sucrose:
Partition coefficient: n-octanol/water: Pow: < 1

12.4 Mobility in soil

**Components:**

Aprepitant:
Distribution among environmental compartments: log Koc: 3.10

12.5 Results of PBT and vPvB assessment
Not relevant
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12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

| Product | Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

SECTION 14: Transport information

14.1 UN number

| ADN | UN 3077 |
| ADR | UN 3077 |
| RID | UN 3077 |
| IMDG | UN 3077 |
| IATA | UN 3077 |

14.2 UN proper shipping name

| ADN | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant) |
| ADR | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant) |
| RID | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant) |
| IATA | Environmentally hazardous substance, solid, n.o.s. (Aprepitant) |

14.3 Transport hazard class(es)

| ADN | 9 |
| ADR | 9 |
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</tbody>
</table>

**14.4 Packing group**

### ADN
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

### ADR
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

### RID
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

### IMDG
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

### IATA (Cargo)
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

### IATA (Passenger)
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

## 14.5 Environmental hazards

### ADN
- Environmentally hazardous: yes

### ADR
- Environmentally hazardous: yes

### RID
- Environmentally hazardous: yes

### IMDG
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Marine pollutant: yes

IATA (Passenger)
Environmentally hazardous: yes

IATA (Cargo)
Environmentally hazardous: yes

14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable
Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable
Regulation on prevention of major industrial accidents. Reg number 30702 Quantity 1 Quantity 2
E1 ENVIRONMENTAL HAZARDS
100 t 200 t

Other regulations:
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.
Regulation on Dust Control (No: 28812, 2013). Occupational Dust Exposure Limit Values (Annex 1)

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16: Other information

Other information: The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Cer-
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According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Aprepitant Formulation

Version 4.1 Revision Date: 27.08.2021 SDS Number: 2548481-00009 Date of last issue: 09.04.2021 Date of first issue: 23.02.2018

Certificate Date: 22 September 2020; Valid Until: 22 September 2025
Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H410 : Very toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
STOT RE : Specific target organ toxicity - repeated exposure
TR OEL DU : Turkey. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
TR OEL DU / ZOAD/TWA : Time Weighted Average Value

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Dose to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Aprepitant Formulation

Version 4.1 Revision Date: 27.08.2021 SDS Number: 2548481-00009 Date of last issue: 09.04.2021 Date of first issue: 23.02.2018

Further information

Classification of the mixture:
<table>
<thead>
<tr>
<th>Classification procedure:</th>
<th>STOT RE 2</th>
<th>Aquatic Chronic 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>H373</td>
<td>H410</td>
<td></td>
</tr>
</tbody>
</table>

- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

TR / EN