Section 1: Identification

Product name: Aprepitant Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
         Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification
Specific target organ toxicity - repeated exposure (Oral): STOT RE2 (Prostate, Testis)

GHS label elements
Hazard pictograms: 

Signal word: Warning

Hazard statements: H373 May cause damage to organs (Prostate, Testis) through prolonged or repeated exposure if swallowed.

Precautionary statements: Prevention:
P260 Do not breathe dust.

Response:
P314 Get medical advice/attention if you feel unwell.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.
Other hazards which do not result in classification
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Aprepitant</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
</tbody>
</table>

Section 4: 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.

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.

Most important symptoms and effects, both acute and delayed
May cause damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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).

Notes to physician
Treat symptomatically and supportively.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media
None known.

Specific hazards during fire-fighting
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)

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.

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

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.

Methods and materials for containment and 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.

Section 7: Handling and storage

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. 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.

Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents.

Section 8: Exposure controls/personal protection

Components 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>Aprepitant</td>
<td>170729-80-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (8-hr TWA)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: 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. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the...
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glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment: Safety goggles

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

Section 9: Physical and chemical properties

Appearance : powder

Colour : coloured

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

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.

Flammability (liquids) : No data available

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.

Molecular weight: No data available

Minimum ignition energy: < 3 mJ

Particle size: No data available

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

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

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes: 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

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
Result: No eye irritation
Method: Draize Test

**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

**Chronic toxicity**

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

**Components:**
Aprepitant:
Genotoxicity in vitro: Test Type: Ames test
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
## Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test system</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline elution assay</td>
<td>rat hepatocytes</td>
<td>negative</td>
</tr>
<tr>
<td>in vitro assay</td>
<td>human lymphoblastoid cells</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test system</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>oral</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Dose</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse, male</td>
<td>Oral</td>
<td>106 weeks</td>
<td>&gt;=1000 mg/kg body weight</td>
<td>positive</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Dose</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse, female</td>
<td>Oral</td>
<td>106 weeks</td>
<td>&gt;=500 mg/kg body weight</td>
<td>positive</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

| 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

**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
Application Route: Ingestion
Result: negative

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs (Prostate, Testis) through prolonged or repeated exposure if swallowed.
Componenets:

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
LOAEL: 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

**Ecotoxicity**

**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 fish (Chronic toxicity):** NOEC (Pimephales promelas (fathead minnow)): 0.195 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 0.018 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
- **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

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

**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.

### 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

### Mobility in soil

**Components:**

**Aprepitant:**  
**Distribution among environmental compartments**  
**log Koc:** 3.10

### Other adverse effects

No data available

### Section 13: Disposal considerations

**Disposal methods**

- **Waste from residues:** Dispose of in accordance with local regulations.
- **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

**International Regulations**

**UNRTDG**

<table>
<thead>
<tr>
<th>UN number</th>
<th>Proper shipping name</th>
<th>Class</th>
<th>Packing group</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN 3077</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant)</td>
<td>9</td>
<td>III</td>
</tr>
</tbody>
</table>
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Date of first issue: 09.10.2014

Labels : 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Aprepitant)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**

**NZS 5433**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Aprepitant)
- Class: 9
- Packing group: III
- Labels: 9
- Hazchem Code: 2Z

**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.

**Section 15: Regulatory information**

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

**HSNO Approval Number**
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017
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HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other Information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogenic, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 Concentration 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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
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<table>
<thead>
<tr>
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</tr>
</thead>
</table>

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.

NZ / EN