SAFETY DATA SHEET
Alendronate Liquid Formulation

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

1.1 Product identifier
   Trade name : Alendronate Liquid 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
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Not a hazardous substance or mixture.

   Additional Labelling
   EUH210 Safety data sheet available on request.

2.3 Other hazards
   None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures
   Components
   Chemical name | CAS-No. | Classification | Concentration

1 / 14
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.

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.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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

4.2 Most important symptoms and effects, both acute and delayed

None known.

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
Alendronate Liquid Formulation

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

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. Prevent spreading over a wide area (e.g. by containment or oil barriers). 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: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. 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 deter-
mine 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
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling:
- Avoid inhalation of vapour or mist.
- 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.
- 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.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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>Alendronate</td>
<td>121268-17-5</td>
<td>TWA</td>
<td>20 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**Personal protective equipment**

**Eye protection**
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

**Material**
Chemical-resistant gloves

**Remarks**
Consider double gloving.

**Skin and body protection**

Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

**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 (P)

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Appearance**
liquid

**Colour**
clear

**Odour**
No data available

**Odour Threshold**
No data available

**pH**
6.4 - 7.2

**Melting point/freezing point**
No data available

**Initial boiling point and boiling range**
100 °C

**Flash point**
No data available

**Evaporation rate**
No data available
SAFETY DATA SHEET

Alendronate Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

- **Flammability (solid, gas)**: Not applicable
- **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**: soluble
- **Partition coefficient: n-octanol/water**: Not applicable
- **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
- **Particle size**: Not applicable

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials
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:
Alendronate:
Acute oral toxicity: LD50 (Rat): 552 - 626 mg/kg
LD50 (Mouse): 966 - 1.280 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:
Alendronate:
Species: Rabbit
Remarks: Severe skin irritation

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

Components:
Alendronate:
Species: Rabbit
Result: Severe irritation

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

Respiratory sensitisation
Not classified based on available information.
Components:

Alendronate:
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

Alendronate:
Genotoxicity in vitro:
- Test Type: Alkaline elution assay
  Test system: rat hepatocytes
  Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)
  Metabolic activation: with and without metabolic activation
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: equivocal

Genotoxicity in vivo:
- Test Type: Chromosomal aberration
  Species: Mouse
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Alendronate:
Species: Rat, male
Application Route: Oral
Exposure time: 2 Years
  - 1 mg/kg body weight
  - 3.75 mg/kg body weight
Target Organs: Thyroid
Remarks: The mechanism or mode of action may not be relevant in humans.

Reproductive toxicity
Not classified based on available information.

Components:

Alendronate:
Effects on fertility:
- Test Type: Fertility
  Species: Rat, male and female
  Application Route: Oral
Fertility: NOAEL: 5 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Effects on foetal development:

Species: Rat, female  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 - 15 mg/kg body weight  
Symptoms: Reduced number of viable fetuses, Reduced body weight, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Development  
Species: Rabbit, female  
Application Route: Oral  
Developmental Toxicity: NOAEL: 40 mg/kg body weight  
Result: No adverse effects

Reproductive toxicity - Assessment:

Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Alendronate:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

Alendronate:

Target Organs: Bone, Stomach, Kidney  
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Alendronate:

Species: Rat  
NOAEL: 2.5 mg/kg  
LOAEL: > 2.5 mg/kg  
Application Route: Intravenous  
Exposure time: 53 Weeks  
Target Organs: Stomach

Species: Dog  
NOAEL: 0.01 mg/kg  
Application Route: Intravenous
Exposure time: 3 yr
Target Organs: Stomach, Bone, Kidney
Species: Dog
NOAEL: 2 mg/kg
LOAEL: 4 mg/kg
Application Route: Oral
Exposure time: 53 Weeks
Target Organs: Kidney

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

**Components:**

**Alendronate:**
Not applicable

**Experience with human exposure**

**Product:**
Inhalation: Symptoms: respiratory tract irritation
Skin contact: Symptoms: May cause, Skin irritation
Eye contact: Symptoms: May cause, Eye irritation
Ingestion: Symptoms: Gastrointestinal disturbance, musculoskeletal pain

**Components:**

**Alendronate:**
Inhalation: Symptoms: respiratory tract irritation
Skin contact: Symptoms: Severe irritation, skin blistering
Eye contact: Symptoms: Severe irritation
Ingestion: Symptoms: Gastrointestinal disturbance, musculoskeletal pain

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Alendronate:**
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 27 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): > 1.000 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 170 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10
12.2 Persistence and degradability

Components:

Alendronate:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 70.3 %
Exposure time: 7 d

Stability in water : Degradation half life (DT50): 375 d
Method: OECD Test Guideline 111

12.3 Bioaccumulative potential

Components:

Alendronate:
Partition coefficient: n-octanol/water : log Pow: -1.73

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

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
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

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

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

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
SAFETY DATA SHEET
Alendronate Liquid Formulation

Full text of H-Statements
H302 : Harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H335 : May cause respiratory irritation.
H361d :Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure

Further information
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.

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