SAFETY DATA SHEET

Alendronate / Vitamin D Formulation

Version 6.0  Revision Date: 2020/03/23  SDS Number: 22054-00016  Date of last issue: 2019/09/13  Date of first issue: 2014/10/15

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Alendronate / Vitamin D Formulation

Supplier’s company name, address and phone number

Company name of supplier : Organon & Co.

Address : 30 Hudson Street, 33rd floor  Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

E-mail address : EHSSTEWARD@organon.com

Emergency telephone number : 215-631-6999

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Acute toxicity (Oral) : Category 4

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2 (Bone, Stomach, Kidney)

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.
Precautionary statements:

Prevention:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
- P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
- P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
- P308 + P313 IF EXPOSED OR CONCERNED: Get medical advice/attention.
- P332 + P313 IF SKIN IRRITATION OCCURS: Get medical advice/attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
- P405 Store locked up.

Disposal:
- P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification:
- Important symptoms and outlines of the emergency assumed: May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
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Alendronate / Vitamin D Formulation

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 40 - &lt; 50</td>
<td></td>
</tr>
<tr>
<td>Alendronate</td>
<td>121268-17-5</td>
<td>&gt;= 25 - &lt; 30</td>
<td></td>
</tr>
<tr>
<td>Colecalciferol</td>
<td>67-97-0</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td>9-1054</td>
</tr>
</tbody>
</table>

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.

In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

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

Most important symptoms and effects, both acute and delayed:
Harmful if swallowed.
Causes skin irritation.
Causes serious eye damage.
May cause respiratory irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.

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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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
Nitrogen oxides (NOx)
Phosphorus compounds
Metal oxides

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.

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.

7. HANDLING AND STORAGE

Handling
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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
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.

Avoidance of contact:
Oxidizing agents

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.

Storage
Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

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

Packaging material:
Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Alendronate</td>
<td>121268-17-5</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Colecaciferol</td>
<td>67-97-0</td>
<td>TWA</td>
<td>5 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>50 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:
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 con-
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Decomposition temperature : No data available
pH : No data available
Evaporation rate : Not applicable
Auto-ignition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : Not applicable
Density and / or relative density
   Relative density : No data available
Density : No data available
Relative vapour density : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle characteristics
   Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure : Inhalation
   Skin contact
   Ingestion
   Eye contact
Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,965 mg/kg
Method: Calculation method

Components:

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

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

Colecalciferol:
Acute oral toxicity: LD50 (Rat, male): 35 mg/kg
Acute inhalation toxicity: Acute toxicity estimate: 0.05 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgement
Acute dermal toxicity: Acute toxicity estimate: 50 mg/kg
Method: Expert judgement

Skin corrosion/irritation
Causes skin irritation.

Components:

Alendronate:
Species: Rabbit
Remarks: Severe skin irritation

Serious eye damage/eye irritation
Causes serious eye damage.
Components:

Alendronate:
Species: Rabbit
Result: Severe irritation

Coledcalciferol:
Species: Rabbit
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:

Alendronate:
Remarks: No data available

Coledcalciferol:
Test Type: Maurer optimisation test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

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

Colecalciferol:
Genotoxicity in vitro:
: Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: equivocal

  Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative

  Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative

Genotoxicity in vivo:
: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 474
  Result: negative

  Test Type: In vivo mammalian alkaline comet assay
  Species: Rat
  Application Route: Ingestion
  Result: positive

Germ cell mutagenicity - Assessment:
  Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Components:

Cellulose:
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative
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Alendronate:
Species: Rat, male
Application Route: Oral
Exposure time: 2 Years
Target Organs: Thyroid
Remarks: The mechanism or mode of action may not be relevant in humans.

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

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

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: Test Type: 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
May cause respiratory irritation.
Components:

Alendronate:
- **Assessment**: May cause respiratory irritation.

STOT - repeated exposure
May cause damage to organs (Bone, Stomach, Kidney) through prolonged or repeated exposure.

Components:

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

Colecalciferol:
- **Exposure routes**: Ingestion
- **Target Organs**: Kidney, Blood, Bone
- **Assessment**: Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Cellulose:
- **Species**: Rat
- **NOAEL**: \( \geq 9,000 \text{ mg/kg} \)
- **Application Route**: Ingestion
- **Exposure time**: 90 Days

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

Species:
- **Species**: Dog
- **LOAEL**: 0.01 mg/kg
- **Application Route**: Intravenous
- **Exposure time**: 3 yr
- **Target Organs**: Stomach, Bone, Kidney

Species:
- **Species**: Dog
- **NOAEL**: 2 mg/kg
- **LOAEL**: 4 mg/kg
- **Application Route**: Oral
- **Exposure time**: 53 Weeks
- **Target Organs**: Kidney
Colecalciferol:
Species: Rat  
NOAEL: 0.06 mg/kg  
LOAEL: 0.3 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Method: OECD Test Guideline 408  

Aspiration toxicity
Not classified based on available information.

Components:

Alendronate:
Not applicable

Experience with human exposure

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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 plants:
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
- NOEC (Pimephales promelas (fathead minnow)): 1.1 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210

- LOEC (Pimephales promelas (fathead minnow)): 1.9 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)): 4.7 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Coledcalciferol:
- Toxicity to fish:
  - LL50 (Danio rerio (zebra fish)): > 100 mg/l
    Exposure time: 96 h
    Method: OECD Test Guideline 203

- Toxicity to daphnia and other aquatic invertebrates:
  - EL50 (Daphnia magna (Water flea)): > 100 mg/l
    Exposure time: 48 h
    Method: OECD Test Guideline 202

- Toxicity to algae/aquatic plants:
  - EL50 (Scenedesmus capricornutum (fresh water algae)): > 100 mg/l
    Exposure time: 96 h
    Method: OECD Test Guideline 201

Persistence and degradability:

Components:

**Cellulose:**
- Biodegradability: Result: Readily biodegradable.

**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

**Coledcalciferol:**
Biodegradability

Result: Not readily biodegradable.
Biodegradation: <= 7 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Bioaccumulative potential

Components:

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

- Colecalciferol:
  Partition coefficient: n-octanol/water: log Pow: > 6.2
  Method: OECD Test Guideline 107

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available

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.

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 for product as supplied.

National Regulations
Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
17. OTHER INFORMATION

Further information

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 other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, 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 - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with
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