SAFETY DATA SHEET

Raltegravir / Lamivudine Formulation

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

1.1 Product identifier
   Trade name : Raltegravir / Lamivudine 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)
   - Serious eye damage, Category 1 : H318: Causes serious eye damage.
   - Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
   - Specific target organ toxicity - single exposure, Category 3 : H335: May cause respiratory irritation.
   - Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : 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.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- 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.

Hazardous components which must be listed on the label:
- Raltegravir
- Lamivudine

**2.3 Other hazards**
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**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td></td>
<td>Eye Dam.1; H318 Repr.2; H361d STOT SE3; H335</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td></td>
<td>Repr.2; H361d STOT RE2; H373</td>
<td>&gt;= 20 - &lt; 30</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.

**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
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.

4.2 Most important symptoms and effects, both acute and delayed
Risks
Causes serious eye damage.
May cause respiratory irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.

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 prod-
Carbon oxides
SAFETY DATA SHEET

Raltegravir / Lamivudine 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>
<tbody>
<tr>
<td>2.3</td>
<td>23.03.2020</td>
<td>184751-00011</td>
<td>13.09.2019</td>
<td>17.06.2015</td>
</tr>
</tbody>
</table>

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 and personal protective equipment recommendations.

6.2 Environmental precautions

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.

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

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 breathe dust. Do not swallow. Do not get in 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.

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.

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 locked up. Keep tightly closed. Keep in a cool, well-ventilated place. 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: Exposure limits

Occupational Exposure Limits

<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>Raltegravir</td>
<td>871038-72-1</td>
<td>TWA</td>
<td>1.000 µg/m3</td>
<td>Internal</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>TWA</td>
<td>150 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m3</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m3</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Recommended Limit
8.2 Exposure controls

Engineering measures
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).
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment
Eye protection
- Wear the following personal protective equipment:
  Chemical resistant goggles must be worn.
  If splashes are likely to occur, wear:
  Face-shield

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. Change gloves often! 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
Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance: powder
Colour: green
Odour: No data available
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
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Version 2.3  Revision Date: 23.03.2020  SDS Number: 184751-00011  Date of last issue: 13.09.2019  Date of first issue: 17.06.2015

Flash point : Not applicable
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
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
Particle size : No data available

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:

Raltegravir:
Acute oral toxicity : LD50 (Mouse, male and female): > 2.000 mg/kg

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

LD50 (Mouse): 4.000 mg/kg
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): > 2.000 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:

Raltegravir:
Species : Rabbit
Result : No skin irritation

Lamivudine:
Species : Rabbit
Result : Mild skin irritation

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

**Raltegravir:**
- Species: Bovine cornea
- Result: Severe irritation

**Lamivudine:**
- 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:**

**Raltegravir:**
- Test Type: Local lymph node assay (LLNA)
- Species: Mouse
- Result: negative

**Lamivudine:**
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Not a skin sensitizer.

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

**Components:**

**Raltegravir:**
- Genotoxicity in vitro:
  - Test Type: reverse mutation assay
  - Result: negative
  - Test Type: Alkaline elution assay
  - Test system: rat hepatocytes
  - Result: negative
  - Test Type: Chromosomal aberration
  - Method: OECD Test Guideline 473
  - Result: negative

- Genotoxicity in vivo:
  - Test Type: In vivo micronucleus test
  - Species: Mouse
  - Result: negative
  - Test Type: Chromosomal aberration
  - Method: OECD Test Guideline 475
Lamivudine:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Mouse Lymphoma
  Result: equivocal

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Rat
  Application Route: Oral
  Result: negative
- Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
  Species: Rat
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:
Raltegravir:
Species: Mouse, male and female
Exposure time: 104 weeks
Result: negative

Lamivudine:
Species: Rat
Exposure time: 2 Years
Result: negative
Species: Mouse
Exposure time: 2 Years
Result: negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:
Raltegravir:
Effects on fertility:
- Test Type: Fertility/early embryonic development
  Species: Rat, male and female
  Application Route: Oral
  General Toxicity - Parent: NOAEL: 600 mg/kg body weight
  Result: negative

Effects on foetal development:
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: \( \geq 600 \text{ mg/kg body weight} \)

Teratogenicity: LOAEL F1: 300 mg/kg body weight

Symptoms: Skeletal malformations

Result: positive

Species: Rabbit

General Toxicity Maternal: NOAEL: \( \geq 1.000 \text{ mg/kg body weight} \)

Teratogenicity: NOAEL: \( \geq 1.000 \text{ mg/kg body weight} \)

Result: negative

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**Lamivudine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Fertility: NOAEL: 900 mg/kg body weight

Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

Symptoms: Preimplantation loss, Skeletal malformations

Result: Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 45 mg/kg body weight

Symptoms: Effects on foetal development

Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

May cause respiratory irritation.

**Components:**

**Raltegravir:**

Exposure routes : Inhalation

Target Organs : Respiratory Tract

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.
## Components:

**Lamivudine:**
- **Exposure routes**: Ingestion
- **Target Organs**: Blood
- **Assessment**: May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

**Raltegravir:**
- **Species**: Dog
  - NOAEL: 90 mg/kg
  - Application Route: Oral
  - Exposure time: 371 d
  - Symptoms: Vomiting

- **Species**: Rat
  - NOAEL: 30 mg/kg
  - LOAEL: 120 mg/kg
  - Application Route: Oral
  - Exposure time: 189 d
  - Target Organs: Stomach

- **Species**: Mouse
  - NOAEL: 50 mg/kg
  - LOAEL: 500 mg/kg
  - Application Route: Oral
  - Exposure time: 14 Weeks
  - Target Organs: Stomach

- **Species**: Rat
  - NOAEL: 50 mg/kg
  - LOAEL: 200 mg/kg
  - Application Route: Oral
  - Exposure time: 8 Weeks
  - Target Organs: Stomach

**Lamivudine:**
- **Species**: Rat
  - NOAEL: 425 mg/kg
  - Application Route: Oral
  - Exposure time: 6 Months
  - Target Organs: Blood
  - Symptoms: Gastrointestinal discomfort, Breathing difficulties, Fatality
  - Remarks: Significant toxicity observed in testing

- **Species**: Dog
  - LOAEL: 90 mg/kg
  - Application Route: Oral
  - Exposure time: 12 Months
  - Target Organs: Blood, spleen, Liver
Symptoms: Salivation, Diarrhoea, Changes in the blood count, Liver disorders, Gastrointestinal disturbance

Species: Mouse
NOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 1 Months
Target Organs: Blood

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Raltegravir:
Ingestion: Symptoms: Nausea, Diarrhoea, Headache, Fever, Rash, Skin irritation

Lamivudine:
Ingestion: Symptoms: Headache, Fatigue, Respiratory disorders, Diarrhoea, Cough

SECTION 12: Ecological information

12.1 Toxicity

Components:

Raltegravir:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 66 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 3,8 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
### Toxicity to fish (Chronic toxicity)

Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
NOEC: 1.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
NOEC: 9.3 mg/l  
Exposure time: 33 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210  
NOEC: 9.5 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Lamivudine:

#### Toxicity to fish

LC50 (Pimephales promelas (fathead minnow)): > 97.7 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

#### Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

#### Toxicity to algae/aquatic plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 96.9 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
NOEC (Pseudokirchneriella subcapitata (green algae)): 96.9 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

### 12.2 Persistence and degradability

#### Components:

**Raltegravir:**

Biodegradability: Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 9 d  
Method: OECD Test Guideline 302B

Stability in water: Hydrolysis: < 10 % (5 d)  
Method: OECD Test Guideline 111

**Lamivudine:**

Biodegradability: Result: Not readily biodegradable.  
Biodegradation: 4 %
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Version 2.3 Revision Date: 23.03.2020 SDS Number: 184751-00011 Date of last issue: 13.09.2019 Date of first issue: 17.06.2015

Exposure time: 28 d

12.3 Bioaccumulative potential

Components:

Raltegravir:
Partition coefficient: n-octanol/water : log Pow: -0.328

Lamivudine:
Partition coefficient: n-octanol/water : log Pow: -1.44

12.4 Mobility in soil

Components:

Lamivudine:
Distribution among environmental compartments : log Koc: 2.03

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.

Full text of H-statements

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 if swallowed.

Full text of other abbreviations

Eye Dam.: Serious eye damage
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

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; AICS - Australian Inventory of Chemical Substances; 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; IECS - 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; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Stot Re 2</th>
<th>H373</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stot SE 3</td>
<td>H335</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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