SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Raltegravir / Lamivudine Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 187395-00010  Date of last issue: 24.04.2019
Date of first issue: 17.06.2015

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
              Shotton Lane
              NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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
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>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td>Eye Dam. 1; H318 Repr. 2; H361d STOT SE 3; H335</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>134678-17-4</td>
<td>Repr. 2; H361d STOT RE 2; 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 products:
- Carbon oxides
- Nitrogen oxides (NOx)
- Fluorine compounds
- 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 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 spills 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 parameters

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>134678-17-0</td>
<td>TWA</td>
<td>150 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4 mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th></th>
<th>TWA (Respirable dust)</th>
<th>4 mg/m(^3)</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td>For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m(^{-3}) 8-hour TWA of inhalable dust or 4 mg.m(^{-3}) 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEL (inhalable dust)</td>
<td>20 mg/m(^3)</td>
<td>GB EH40</td>
<td></td>
</tr>
</tbody>
</table>

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
  - Equipment should conform to BS EN 166

Hand protection:
Material: Chemical-resistant gloves
Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub-
stance 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

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
 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

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
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:
Species: Rat, male and female
Application Route: Oral
General Toxicity: NOAEL: 600 mg/kg body weight
Result: negative

Effects on foetal development:
Species: Rat
Application Route: Oral
General Toxicity: NOAEL: >= 600 mg/kg body weight
Teratogenicity: LOAEL F1: 300 mg/kg body weight
Symptoms: Skeletal malformations
Result: positive

Species: Rabbit
General Toxicity Maternal: NOAEL: >= 1,000 mg/kg body weight
Teratogenicity: NOAEL: >= 1,000 mg/kg body weight
Result: negative

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:  
Species: Rabbit  
Application Route: Oral  
Symptoms: Preimplantation loss, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the offspring were detected.

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

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
  - 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

Toxicity to fish (Chronic toxicity):
- NOEC: 9.3 mg/l
  - Exposure time: 33 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 9.5 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
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 %
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
SAFETY DATA SHEET
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Raltegravir / Lamivudine Formulation

Version: 2.2  Revision Date: 09/13/2019  SDS Number: 187395-00010  Date of last issue: 24.04.2019

Date of first issue: 17.06.2015

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

REACH - Candidate List of Substances of Very High : Not applicable
Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation (Annex XIV):
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):
- Not applicable

- Not applicable

Other regulations:
- Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
- Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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
- GB EH40: UK. EH40 WEL - Workplace Exposure Limits
- GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
RALTEGRAVIR / LAMIVUDINE FORMULATION

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; 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; 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; TCIS - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Technical Rule for Hazardous Substances; TSI - Technical Rule for Inland Transport of Dangerous Goods; TCSI - Taiwan Chemical Substance Inventory; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

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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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