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...
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>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir</td>
<td>871038-72-1</td>
<td></td>
<td></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></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 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 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 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-</td>
<td>TWA</td>
<td>150 µg/m³ (OEB 2)</td>
<td>Internal</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 NS 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 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: No data available
SECTION 9: Physical and chemical properties

9.1 Range
Flash point: Not applicable
Evaporation rate: No data available

9.2 Flammability (solid, gas)
May form explosive dust-air mixture during processing, handling or other means.

9.3 Upper explosion limit / Upper flammability limit
No data available

9.4 Lower explosion limit / Lower flammability limit
No data available

9.5 Vapour pressure
No data available

9.6 Relative vapour density
No data available

9.7 Density
No data available

9.8 Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: No data available

9.9 Auto-ignition temperature
No data available

9.10 Decomposition temperature
No data available

9.11 Viscosity
Viscosity, kinematic: No data available

9.12 Explosive properties
Not explosive

9.13 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, han-
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Raltegravir / Lamivudine Formulation

Version 2.2 Revision Date: 09/13/2019 SDS Number: 187400-00010 Date of last issue: 24.04.2019
Date of first issue: 17.06.2015

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.

Respirator y 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  
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  
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
Raltegravir / Lamivudine Formulation

Effects on foetal development:
- Species: Rat
  - Application Route: Oral
  - General Toxicity Maternal: NOAEL: \( \geq 600 \) mg/kg body weight
  - Teratogenicity: LOAEL F1: 300 mg/kg body weight
  - Symptoms: Skeletal malformations
  - Result: positive

- Species: Rabbit
  - General Toxicity Maternal: NOAEL: \( \geq 1,000 \) mg/kg body weight
  - Teratogenicity: NOAEL: \( \geq 1,000 \) 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
SAFETY DATA SHEET
decorated to Regulation (EC) No. 1907/2006

Raltegravir / Lamivudine Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>09/13/2019</td>
<td>187400-00010</td>
<td>24.04.2019</td>
</tr>
</tbody>
</table>

- **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**: Toxicty 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

Toxicty 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
Raltegravir / Lamivudine Formulation

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)
- 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)
Raltegravir / Lamivudine Formulation

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

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

Raltegravir / Lamivudine Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 187400-00010  Date of last issue: 24.04.2019
Date of first issue: 17.06.2015

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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
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

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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; ICS0 - Half maximal inhibitory concentration; 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; 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
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

### 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>
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<td>2.2</td>
<td>09/13/2019</td>
<td>187400-00010</td>
<td>24.04.2019</td>
<td>17.06.2015</td>
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Sources of key data used to compile the Safety Data Sheet:

#### Classification of the mixture:

<table>
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<tr>
<th>Eye Dam. 1</th>
<th>Repr. 2</th>
<th>STOT SE 3</th>
<th>STOT RE 2</th>
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<tr>
<td>H318</td>
<td>H361d</td>
<td>H335</td>
<td>H373</td>
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Classification procedure:
- Calculation method
- Calculation method
- Calculation method

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