

Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH)
Classifications according to Regulation (EC) No 1272/2008.
Printdate 24 Feb 2026

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product name:

Entecavir monohydrate

1.1. Catalog No.:

693458

1.2. Relevant identified uses of the substance or mixture

Identified: Laboratory chemical
uses: R&D

1.3. Uses advised against:

HPC Standards GmbH
An der Laakenwiese 7

04838 Jesewitz
Deutschland

Tel. +49 34241 54 990
Fax. +49 34241 54 9999
contact@hpc-standards.com

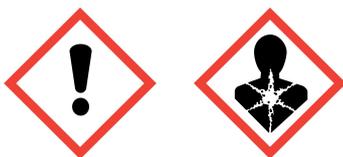
1.4. Emergency telephone number

HPC Standards Tel. +49 34291 3372-36
This number is only available during office hours.

2. HAZARDS IDENTIFICATION

2.2. Label elements

2.2.1. Pictogram



2.2.2.

Label elements

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

Signal word Warning

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer.

H361-H362 Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

· Precautionary statements

P260 Do not breathe dusts or mists.

P263 Avoid contact during pregnancy/while nursing.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system:

· NFPA ratings (scale 0 - 4)

2 0 0

Health = 2

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH

FIRE

REACTIVITY

2

0

0

Health = 2

Fire = 0

Reactivity = 0

· Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Substances

· CAS No. Description

209216-23-9 Entecavir Monohydrate

· Identification number(s) -

· EC number: 606-668-5

RTECS: -

3.1.1. Formula

C₁₂H₁₇N₅O₄

3.1.2. Molecular Weight (g/mol)

295.29

3.1.3. CAS-No.

209216-23-9

4. FIRST AID MEASURES

Description of first aid measures

· After inhalation: Supply fresh air; consult doctor in case of complaints.

· After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing: Rinse mouth. Do not induce vomiting.

· Information for doctor:

· Most important symptoms and effects, both acute and delayed No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available

5. FIRE-FIGHTING MEASURES

Extinguishing media

· Suitable extinguishing agents: Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

· Advice for firefighters

· Protective equipment: Wear self-contained respiratory protective device

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Avoid formation of dust.

· Environmental precautions: Do not allow to enter sewers/ surface or ground water.

· Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· Protective Action Criteria for Chemicals

· PAC-1: Substance is not listed.

· PAC-2: Substance is not listed.

· PAC-3: Substance is not listed

7. HANDLING AND STORAGE

Handling:

- Precautions for safe handling Store in cool, dry place in tightly closed receptacles.
- Information about protection against explosions and fires: No special measures required.
- Conditions for safe storage, including any incompatibilities

Storage:

- Requirements to be met by storerooms and receptacles:

Please refer to the manufacturers certificate for specific storage and transport temperature conditions.

Store only in the original receptacle unless other advice is given on the CoA.

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.

- Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: Keep receptacle tightly sealed.
- Specific end use(s) No further relevant information available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical systems: No further data; see item 7.

- Control parameters
- Components with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists that were valid during the creation were used as basis.
- Exposure controls
- Personal protective equipment:

- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- Breathing equipment:

Not required.

Use suitable respiratory protective device in case of insufficient ventilation.

- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374

Protective gloves

- Material of gloves Butyl rubber, BR
- Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed

Eye protection:

Tightly sealed goggles

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

- General Information

- Appearance:

Form: Solid

Color: Off white

- Odor: Odorless

- Odor threshold: Not determined.

- pH-value: Not applicable.

- Change in condition

Melting point/Melting range: >220 °C (>428 °F)

Boiling point/Boiling range: Not determined.

- Flash point: Not applicable.

- Flammability (solid, gaseous): Not determined.

- Ignition temperature: Not determined

- Decomposition temperature: Not determined.
- Auto igniting: Not determined.
- Danger of explosion: Not determined.
- Explosion limits:
Lower: Not determined.
Upper: Not determined.
- Vapor pressure: Not applicable.
- Density: Not determined.
- Relative density Not determined.
- Vapor density Not applicable.
- Evaporation rate Not applicable.
- Solubility in / Miscibility with
Water: Not determined.
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
Dynamic: Not applicable.
(Contd. on page 6)
US
Kinematic: Not applicable.
- Other information No further relevant information available

10. STABILITY AND REACTIVITY

Reactivity

Stable under normal conditions.

No further relevant information available.

- Chemical stability Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:
Formation of toxic gases is possible during heating or in case of fire.
- Possibility of hazardous reactions No dangerous reactions known.
- Conditions to avoid Heat.
- Incompatible materials: Strong oxidizing agents.
- Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

- Acute toxicity:
- Primary irritant effect:
 - on the skin: Irritant to skin and mucous membranes.
 - on the eye: Causes serious eye irritation.
- Sensitization: Based on available data, the classification criteria are not met.
- Additional toxicological information:
 - Carcinogenic categories
 - IARC (International Agency for Research on Cancer) Substance is not listed.
 - NTP (National Toxicology Program) Substance is not listed.
 - OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.
 - Carcinogenicity Suspected of causing cancer.
 - Reproductive toxicity
Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

12. ECOLOGICAL INFORMATION

Toxicity

- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behavior in environmental systems:
- Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

- Recommendation:
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packagings:
· Recommendation: Dispose in accordance with national regulations.

14. TRANSPORT INFORMATION

UN-Number

- DOT, ADR, IMDG, IATA Not applicable
- DOT, ADR, IMDG, IATA Not applicable
- Transport hazard class(es)
- DOT, ADR, ADN, IMDG, IATA
- Class Not applicable
- Packing group
- DOT, ADR, IMDG, IATA Not applicable
- Environmental hazards: Not applicable.
- Special precautions for user Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.
- UN "Model Regulation": Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

- Sara
- Section 355 (extremely hazardous substances): Substance is not listed.
- Section 313 (Specific toxic chemical listings): Substance is not listed.
- TSCA (Toxic Substances Control Act): Substance is not listed.
- Hazardous Air Pollutants Substance is not listed.
- Proposition 65
- Chemicals known to cause cancer: Substance is not listed.
- Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- Chemicals known to cause developmental toxicity: Substance is not listed.
- Carcinogenic categories
- EPA (Environmental Protection Agency) Substance is not listed.
- TLV (Threshold Limit Value) Substance is not listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed
- Signal word Warning
- Hazard statements
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 - P405 Store locked up.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. For lab use only!