

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Code:** 30005
Product Name: cGMP Entecavir
Synonyms: 2-amino-1,9-dihydro-9-[(1S,3R,4S)-4-hydroxy-3-(hydroxymethyl)-2-methylenecyclopentyl]-6H-purin-6-one, monohydrate; BMS 200475; Baraclude; SQ 34,676;
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant identified uses: API intended for use in a product approved in an NDA, ANDA, or equivalent.
- 1.3 Details of the Supplier of the Safety Data Sheet:**
Company Name: Cayman Chemical Company
 1180 E. Ellsworth Rd.
 Ann Arbor, MI 48108
Web site address: www.caymanchem.com
Information: Cayman Chemical Company +1 (734)971-3335
- 1.4 Emergency telephone number:**
Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300
 CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
- 2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:**
Acute Toxicity: Oral, Category 1
Skin Corrosion/Irritation, Category 2
Serious Eye Damage/Eye Irritation, Category 1
Toxic To Reproduction, Category 2
Target Organ Systemic Toxicity (repeated exposure), Category 2
- 2.1.2 Classification according to Directive 1999/45/EC:**
T+: Very Toxic
Reproductive Hazard: 3
Risk Phrases: R28, R38, R41, R48, R62, R63
For full text of R- phrases: see SECTION 15.
- 2.2 Label Elements:**
- 2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:**



GHS Signal Word: Danger

GHS Hazard Phrases:

- H300: Fatal if swallowed.
 H315: Causes skin irritation.
 H318: Causes serious eye damage.
 H361: Suspected of damaging fertility or the unborn child.
 H373: May cause damage to organs through prolonged or repeated exposure.

GHS Precaution Phrases:

- P264: Wash {hands} thoroughly after handling.
- P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
- P362+364: Take off contaminated clothing and wash it before reuse.
- P201: Obtain special instructions before use.
- P202: Do not handle until all safety precautions have been read and understood.
- P281: Use personal protective equipment as required.
- P260: Do not breathe {dust/fume/gas/mist/vapours/spray}.

GHS Response Phrases:

- P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- P330: Rinse mouth.
- P302+352: IF ON SKIN: Wash with plenty of soap and water.
- P332+313: If skin irritation occurs, get medical advice/attention.
- P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310: Immediately call a {POISON CENTER/doctor/...}.
- P308+313: IF exposed or concerned: Get medical attention/advice.
- P314: Get medical attention/advice if you feel unwell.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.2.2 Labeling according to Directive 1999/45/EC:



T+

Reproductive Hazard: 3

2.3 Adverse Human Health Causes skin irritation.

Effects and Symptoms: Causes serious eye damage.

- Contains a potent pharmaceutically active ingredient; Substance not fully tested, handle with care.
- Fatal if swallowed.
- Material may be irritating to the mucous membranes and upper respiratory tract.
- May be harmful by inhalation or skin absorption.
- May cause respiratory system irritation.
- May cause damage to organs through prolonged or repeated exposure.
- Suspected of damaging fertility or the unborn child.
- To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	Risk Phrases/ GHS Classification
209216-23-9 NA	Entecavir (hydrate)	100.0 %	606-668-5 NA	T+, Rp:3, R28-38-41-48-62-63 Acute Tox.(O) 2: H300 Skin Corr. 2: H315 Eye Damage 1: H318 TOST (RE) 2: H373

Toxic Repro. 2: H361

Section 4. First Aid Measures

- 4.1 Description of First Aid Measures:**
- In Case of Inhalation:** Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
- In Case of Skin Contact:** Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- In Case of Eye Contact:** Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
- In Case of Ingestion:** Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Media: Use water spray to cool fire-exposed containers.
Unsuitable Extinguishing Media: A solid water stream may be inefficient.
- 5.2 Flammable Properties and Hazards:** No data available.
Flash Pt: No data.
Explosive Limits: LEL: No data. UEL: No data.
Autoignition Pt: No data.
- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

- 6.1 Protective Precautions, Protective Equipment and Emergency Procedures:** Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
- 6.2 Environmental Precautions:** Take steps to avoid release into the environment, if safe to do so.
- 6.3 Methods and Material For Containment and Cleaning Up:** Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

- 7.1 Precautions To Be Taken in Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
- 7.2 Precautions To Be Taken in Storing:** Keep container tightly closed. Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
209216-23-9	Entecavir (hydrate)	No data.	No data.	No data.
CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
209216-23-9	Entecavir (hydrate)	No data.	No data.	No data.

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices: Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.

Wash thoroughly after handling.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: [] Gas [] Liquid [X] Solid

Appearance and Odor: A crystalline solid

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mm Hg): No data.

Vapor Density (vs. Air = 1): No data.

Specific Gravity (Water = 1): No data.

Solubility in Water: No data.

Solubility Notes: ~0.5 mg/ml in 1:1 DMF:PBS (pH 7.2); ~0.1 mg/ml in EtOH; ~12 mg/ml in DMSO; ~14 mg/ml in DMF;

Autoignition Pt: No data.

9.2 Other Information

Percent Volatile: No data.
Molecular Formula & Weight: C₁₂H₁₅N₅O₃ • H₂O 295.3

Section 10. Stability and Reactivity

- 10.1 Reactivity:** No data available.
10.2 Stability: Unstable [] Stable [X]
10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.
Polymerization: Will occur [] Will not occur [X]
10.4 Conditions To Avoid: No data available.
**10.5 Incompatibility -
Materials To Avoid:** No data available.
**10.6 Hazardous
Decomposition Or
Byproducts:** No data available.

Section 11. Toxicological Information

- 11.1 Information on
Toxicological Effects:** The toxicological effects of this product have not been thoroughly studied.
Carcinogenicity: NTP? No IARC Monographs? No OSHA Regulated? No

Section 12. Ecological Information

- 12.1 Toxicity:** Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

Section 13. Disposal Considerations

- 13.1 Waste Disposal
Method:** Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information**14.1 LAND TRANSPORT (US DOT):**

DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

**Additional Transport
Information:** Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
209216-23-9	Entecavir (hydrate)	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
209216-23-9	Entecavir (hydrate)	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

European Community Hazard Symbol codes:



T+

Reproductive Hazard: 3

European Community Risk and Safety Phrases:

- R28 Very toxic if swallowed.
- R38 Irritating to skin.
- R41 Risk of serious damage to the eyes.
- R48 Danger of serious damage to health by prolonged exposure.
- R62 Risk of impaired fertility.
- R63 Possible risk of harm to the unborn child.
- S22 Do not breathe dust.
- S24/25 Avoid contact with skin and eyes.
- S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S28 After contact with skin, wash immediately with plenty of soap-suds.
- S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label whenever possible.)

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200, Regulation (EC) No.1272/2008, and European Directive 67/548/EEC as amended.

Section 16. Other Information

Revision Date: 12/04/2013

Additional Information About This Product: No data available.

Company Policy or Disclaimer: This product was manufactured in accordance with applicable current Good Manufacturing Practice regulations including, ICH Q7 and Cayman standard operating procedures.
DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.

N.A.=Not available, N.P.=Not applicable, N.D.=Not determined, N.E.=Not established,

N.R.=Not required