

[13C, 2H5]-DOLUTEGRAVIR - C4671

**ALSACHIM**  
a Shimadzu Group Company

## SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

### SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product name : [13C, 2H5]-DOLUTEGRAVIR

Product code : C4671.

N° CAS 1051375-16-6 unlabeled

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

#### 1.3. Details of the supplier of the safety data sheet

Registered company name : Alsachim.

Address : 160 rue Tobias Stimmer.67400.Illkirch Graffenstaden.France.

Telephone : +33 (0) 390 402 200. Fax : +33 (0) 390 402 199 .

E-mail : [contact@alsachim.com](mailto:contact@alsachim.com)

#### 1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

### SECTION 2 : HAZARDS IDENTIFICATION

#### 2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).

This substance does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

#### 2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS09

Signal Word :

WARNING

Product identifiers :

[13C, 2H5]-DOLUTEGRAVIR

Hazard statements :

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P273 Avoid release to the environment.

Precautionary statements - Response :

P391 Collect spillage.

Precautionary statements - Disposal :

P501 Dispose of contents/container to an approved waste disposal facility.

#### 2.3. Other hazards

The substance does not fulfil the PBT or vPvP criteria in accordance with annexe XIII of the REACH regulations EC 1907/2006.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substances

N° CAS 1051375-16-6 unlabeled

Molecular weight 425,33 g/mol

[13C, 2H5]-DOLUTEGRAVIR - C4671

**Composition :**

Identification	(EC) 1272/2008	Note	%
INDEX: C4671	GHS09		100%
[13C, 2H5]-DOLUTEGRAVIR	Wng Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		

**SECTION 4 : FIRST AID MEASURES**

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

**4.1. description of first aid measures**

**In the event of splashes or contact with eyes :**

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

**In the event of splashes or contact with skin :**

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

**In the event of swallowing :**

Seek medical attention, showing the label.

**4.2. Most important symptoms and effects, both acute and delayed**

No data available.

**4.3. Indication of any immediate medical attention and special treatment needed**

No data available.

**SECTION 5 : FIREFIGHTING MEASURES**

Non-flammable.

**5.1. Extinguishing media**

**5.2. Special hazards arising from the substance or mixture**

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO<sub>2</sub>)

**5.3. Advice for firefighters**

No data available.

**SECTION 6 : ACCIDENTAL RELEASE MEASURES**

**6.1. Personal precautions, protective equipment and emergency procedures**

Consult the safety measures listed under headings 7 and 8.

**For first aid worker**

First aid workers will be equipped with suitable personal protective equipment (See section 8).

**6.2. Environmental precautions**

Prevent any material from entering drains or waterways.

**6.3. Methods and material for containment and cleaning up**

Retrieve the product by mechanical means (sweeping/vacuuming).

**6.4. Reference to other sections**

No data available.

**SECTION 7 : HANDLING AND STORAGE**

Requirements relating to storage premises apply to all facilities where the substance is handled.

**7.1. Precautions for safe handling**

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

[13C, 2H5]-DOLUTEGRAVIR - C4671

**Fire prevention :**

Prevent access by unauthorised personnel.

**Recommended equipment and procedures :**

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

**Prohibited equipment and procedures :**

No smoking, eating or drinking in areas where the substance is used.

**7.2. Conditions for safe storage, including any incompatibilities**

No data available.

**Storage**

For a prolonged period, keep at -20°C (±5°C) in a closed container, away from light and moisture.

**Packaging**

Always keep in packaging made of an identical material to the original.

**7.3. Specific end use(s)**

No data available.

---

**SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1. Control parameters**

No data available.

**8.2. Exposure controls**

**Personal protection measures, such as personal protective equipment**

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

**- Eye / face protection**

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

**- Hand protection**

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

**- Body protection**

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

**- Respiratory protection**

Avoid inhaling dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149/A1.

---

**SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on basic physical and chemical properties**

**Physical state**

Physical state : Solid.

**Colour**

Color Off white to pale orange

**Odour**

Odour threshold : Not stated.

**Melting point**

Melting point/melting range : Not relevant.

**Freezing point**

Freezing point / Freezing range : Not stated.

[13C, 2H5]-DOLUTEGRAVIR - C4671

**Boiling point or initial boiling point and boiling range**

Boiling point/boiling range : Not relevant.

**Flammability**

Flammability (solid, gas) : Not stated.

**Lower and upper explosion limit**

Explosive properties, lower explosivity limit (%) : Not stated.

Explosive properties, upper explosivity limit (%) : Not stated.

**Flash point**

Flash point interval : Not relevant.

**Auto-ignition temperature**

Self-ignition temperature : Not relevant.

**Decomposition temperature**

Decomposition point/decomposition range : Not relevant.

**pH**

pH (aqueous solution) : Not stated.

pH : Not relevant.

**Kinematic viscosity**

Viscosity : Not stated.

**Solubility**

Water solubility : Insoluble.

Fat solubility : Not stated.

Solubility : Dimethyl Sulfoxide (60 mg/mL), Acetonitrile, or slightly soluble in Methanol

**Partition coefficient n-octanol/water (log value)**

Partition coefficient: n-octanol/water : Not stated.

**Vapour pressure**

Vapour pressure (50°C) : Below 110 kPa (1.10 bar).

**Density and/or relative density**

Density : = 1

**Relative vapour density**

Vapour density : Not stated.

**9.2. Other information**

Molecular formula : C1913CH14D5F2N3O5

**9.2.1. Information with regard to physical hazard classes**

No data available.

**9.2.2. Other safety characteristics**

No data available.

**SECTION 10 : STABILITY AND REACTIVITY**

**10.1. Reactivity**

No data available.

**10.2. Chemical stability**

This substance is stable under the recommended handling and storage conditions in section 7.

**10.3. Possibility of hazardous reactions**

No data available.

**10.4. Conditions to avoid**

Avoid :

- formation of dusts

Dusts can form an explosive mixture with air.

**10.5. Incompatible materials**

No data available.

**10.6. Hazardous decomposition products**

The thermal decomposition may release/form :

- carbon monoxide (CO)

- carbon dioxide (CO2)

[13C, 2H5]-DOLUTEGRAVIR - C4671

## SECTION 11 : TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No data available.

#### 11.1.1. Substances

No toxicological data available for the substances.

## SECTION 12 : ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

### 12.1. Toxicity

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 12.6. Endocrine disrupting properties

No data available.

### 12.7. Other adverse effects

No data available.

## SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the substance and/or its container must be determined in accordance with Directive 2008/98/EC.

### 13.1. Waste treatment methods

Do not pour into drains or waterways.

#### Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

#### Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

## SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2021 - IMDG 2020 - ICAO/IATA 2021).

### 14.1. UN number or ID number

3077

### 14.2. UN proper shipping name

UN3077=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

([13c, 2h5]-dolutegravir)

### 14.3. Transport hazard class(es)

- Classification :



[13C, 2H5]-DOLUTEGRAVIR - C4671

**14.4. Packing group**

III

**14.5. Environmental hazards**

- Environmentally hazardous material :



**14.6. Special precautions for user**

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	9	M7	III	9	90	5 kg	274 335 375 601	E1	3	-

Not subject to this regulation if Q ≤ 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	9	-	III	5 kg	F-A, S-F	274 335 966 967 969	E1	Category A SW23	-

Not subject to this regulation if Q ≤ 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	956	400 kg	956	400 kg	A97 A158 A179 A197 A215	E1
	9	-	III	Y956	30 kg G	-	-	A97 A158 A179 A197 A215	E1

Not subject to this regulation if Q ≤ 5 l / 5 kg (IATA 4.4.4 - DS A197)

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

**14.7. Maritime transport in bulk according to IMO instruments**

No data available.

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**- Classification and labelling information included in section 2:**

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2020/217 (ATP 14)

**- Container information:**

The substance is packed in an interior packaging, not exceeding 10 ml, the required labelling elements appear on the outer packaging.

**- Particular provisions :**

No data available.

**15.2. Chemical safety assessment**

No data available.

**SECTION 16 : OTHER INFORMATION**

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the substance and not as a guarantee of the properties thereof.

**Wording of the phrases mentioned in section 3 :**

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

**Abbreviations :**

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

---

**[13C, 2H5]-DOLUTEGRAVIR - C4671**

---

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefährdungsklasse (Water Hazard Class).

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.