ALSACHIM

a Shimadzu Group Company

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name : RITONAVIR-13C-D3 Product code : C2963. N° CAS 155213-67-5 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

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.

Acute oral toxicity, Category 4 (Acute Tox. 4, H302).

Eye irritation, Category 2 (Eye Irrit. 2, H319).

Carcinogenicity, Category 2 (Carc. 2, H351).

Reproductive toxicity, Category 2 (Repr. 2, H361).

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

This substance does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use. **2.2. Label elements**

2.2. Laber elements

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

Hazard pictograms :



GHS07 GHS08 Signal Word :

WARNING Product identifiers :

[13C,2H3]-RITONAVIR

Hazard statements :	
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer .
H361	Suspected of damaging fertility or the unborn child .
Precautionary statements - Prevention :	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves, protective clothing, eye protection.
Precautionary statements - Response :	
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P330	Rinse mouth.
P337 + P313	If eye irritation persists: Get medical advice/attention.
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	155213-67-5 unlabeled 724,96 g/mol		
Molecular weight			
Composition :			
Identification	(EC) 1272/2008	Note	%
INDEX: C2963	GHS07, GHS08	[2]	100%
	Wng		
[13C,2H3]-RITONAVIR	Acute Tox. 4, H302		
	Eye Irrit. 2, H319		
	Carc. 2, H351		
	Repr. 2, H361		

Information on ingredients :

[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

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 :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor.

Seek medical attention, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show 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 (CO2)

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 non first aid worker

Avoid any contact with the skin and eyes.

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. Avoid exposure to pregnant women and warn women of child-bearing age of the possible risks

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

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.

Avoid eye contact with this substance.

Avoid exposure - obtain special instructions before use.

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

Keep away from food and drink, including those for animals.

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

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



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.

Prescription glasses are not considered as protection.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

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.

Recommended properties :

- Impervious gloves in accordance with standard EN374

- 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 breathing dust.

Type of FFP mask :

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

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :	
Physical state :	Solid.
Molecular formula :	C37H48N6O5S2 - C3613CH45D3N6O5
Color	White
Important health, safety and environmental information	
pH :	Not relevant.
Boiling point/boiling range :	Not relevant.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Below 110 kPa (1.10 bar).
Density :	= 1
	Method for determining the density :
Solubility	Methanol or Chloroform
Water solubility :	Insoluble.
Melting point/melting range :	120 °C.
Self-ignition temperature :	Not relevant.
Decomposition point/decomposition range :	Not relevant.
0.2 Other information	

9.2. Other information

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)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Harmful if swallowed.

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

Suspected human carcinogen.

Suspected human reproductive toxicant.

11.1.1. Substances

No toxicological data available for the substances.

SECTION 12 : ECOLOGICAL INFORMATION

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. 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

Exempt from transport classification and labelling.

14.1. UN number

14.2. UN proper shipping name

- -
- 14.3. Transport hazard class(es)
- 14.4. Packing group

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14.5. Environmental hazards

14.6. Special precautions for user

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. 2018/1480 (ATP 13)
- EU Regulation No. 1272/2008 amended by EU Regulation No. 2019/521 (ATP 12)

- 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 :

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
H361	Suspected of damaging fertility or the unborn child .

Abbreviations :

CMR: Carcinogenic, mutagenic or reprotoxic.

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

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 : Wassergefahrdungsklasse (Water Hazard Class).

GHS07 : Exclamation mark

GHS08 : Health hazard

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.