



Safety Data Sheet

acc. to OSHA HCS

Printing date 11/03/2016

Reviewed on 11/03/2016

1 Identification

· **Product identifier**

· **Product name: CICTAC - Ciclosporin and Tacrolimus**

· **Part number: PT-IP-CICTAC**

· **Application of the substance / the mixture** Reference material for laboratory use only

· **Manufacturer/Supplier:**

VHG Labs, Inc

LGC Standards

276 Abby Road

Manchester, NH 03103

UNITED STATES OF AMERICA

Tel : +1 (603) 622-7660

Fax : +1 (603) 622-5180

eMail : custsvc@vhglabs.com

Web : www.vhglabs.com

· **Information department:**

Product safety department

eMail : sds-request@lgcgroup.com

· **Emergency telephone number:**

INFOTRAC 24-hour Emergency telephone number:

800-535-5053 (US & Canada);

352-323-3500 (International)

2 Hazard(s) identification

· **Classification of the substance or mixture**



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

· **Label elements**

· **GHS label elements**

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

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

Human blood (unscreened)

· **Hazard statements**

H302 Harmful if swallowed.

· **Precautionary statements**

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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P330 Rinse mouth.

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

· Classification system:**· NFPA ratings (scale 0 - 4)**

Health = 1

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 1

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: Mixtures**· Description:** Also contains substances at levels not considered to be hazardous.**· Dangerous components:**

RTECS: EC6075000 Human blood (unscreened)

Acute Tox. 4, H302

> 99%

4 First-aid measures

· Description of first aid measures**· General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation: Supply fresh air; consult doctor in case of complaints.**· After skin contact:** Immediately wash with water and soap and rinse thoroughly.**· After eye contact:** Rinse opened eye for several minutes under running water.**· After swallowing:**

Rinse mouth. Do not induce vomiting.

Immediately call a doctor.

· 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.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **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** Wear protective clothing.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
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.

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:**
Store in a cool location.
Please refer to the manufacturers certificate for specific storage and transport temperature conditions.
Store only in the original receptacle.
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:** None.
- **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.

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- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
Wash hands before breaks and at the end of work.*
- **Breathing equipment:** *Not required.*
- **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** *Only use chemical-protective gloves with CE-labeling of category III.*
- **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:** *Safety glasses*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· Form:	Liquid
· Color:	Red
· Odor:	Odorless
· Odor threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

· Melting point/Melting range:	Not determined.
· Boiling point/Boiling range:	Not determined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.

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· Ignition temperature:**Decomposition temperature:** Not determined.**· Auto igniting:** Product is not selfigniting.**· Danger of explosion:** Not determined.**· Explosion limits:****Lower:** Not determined.**Upper:** Not determined.**· Vapor pressure:** Not determined.**· Density:** Not determined.**· Relative density** Not determined.**· Vapor density** Not determined.**· Evaporation rate** Not determined.**· Solubility in / Miscibility with****Water:** Fully miscible.**· Partition coefficient (n-octanol/water):** Not determined.**· Viscosity:****Dynamic:** Not determined.**Kinematic:** Not determined.**· Other information** No further relevant information available.

10 Stability and reactivity

· Reactivity Stable under normal conditions.**· 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:** No irritant effect.**· on the eye:** No irritating effect.**· Sensitization:** No sensitizing effects known.

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· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

· Carcinogenic categories**· IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

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.

· Additional ecological information:**· General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** 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.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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14 Transport information

· **UN-Number**
· **DOT, ADR, IMDG, IATA**
· **DOT**
· **ADR**
· **IMDG, IATA**

UN3373
Biological substance, Category B
3373 Biological substance, Category B
BIOLOGICAL SUBSTANCE, CATEGORY B

· **Transport hazard class(es)**

· **DOT**



· **Class**
· **Label**

6.2 Infectious substances
6.2

· **ADR, IMDG, IATA**



· **Class**
· **Label**

6.2 Infectious substances
6.2

· **Packing group**

· **DOT, ADR, IMDG, IATA** Not applicable

· **Environmental hazards:**

· **Marine pollutant:** No

· **Special precautions for user** Warning: Infectious substances

· **Danger code (Kemler):** 606

· **EMS Number:** F-A,S-T

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **UN "Model Regulation":** UN3373, Biological substance, Category B, 6.2

15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

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· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

None of the ingredients is listed.

· Proposition 65**· Chemicals known to cause cancer:**

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories**· EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

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

· Hazard pictograms

GHS07

· Signal word Warning**· Hazard-determining components of labeling:**

Human blood (unscreened)

· Hazard statements

H302 Harmful if swallowed.

· Precautionary statements

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

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

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· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI) disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

· **Date of preparation / last revision** 11/03/2016 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

LC50: Lethal concentration, 50 percent

BEI: Biological Exposure Limit

Acute Tox. 4: Acute toxicity – Category 4

· **Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.