

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

1 Identification of substance:

- **Product details:**
- **Trade name:** Anti-CCP Calibrator L04
- **Catalog or product number:** 663-3204
- **Application of the substance / the preparation** In-vitro laboratory reagent or component
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
4000 Alfred Nobel Drive
Hercules, California 94547
1(510)724-7000
- **Information department:** Technical services, customer support.
- **Emergency information:**
1(800) 424-9300 Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.

2 Composition/Information on components:

- **Chemical characterization**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

• **Listing of dangerous and non-hazardous components:**

7732-18-5	water		35-50%
	Comprehensive Negative Serum (Human)		35-50%
50-70-4	D-glucitol		10-20%
9048-46-8	Bovine Serum Albumin		1.0-2.5%
	Anti-CCP Positive Serum (Human)		0.1-1.0%
26628-22-8	sodium azide	T+, N; R 28-32-50/53	0.01-0.1%
6132-04-3	Citric acid, trisodium salt dihydrate	Xi; R 36/37	0.1-1.0%
77-92-9	citric acid	Xi; R 36/37	0.01-0.1%
	ProClin 300	C, Xn, N; R 20/21/22-34-43-51/53	0.1-1.0%
532-32-1	sodium benzoate		0.01-0.1%

- **Additional information**
Contains human sourced and/or potentially infectious components.
For the wording of the listed risk phrases refer to section 15.

3 Hazards identification

- **Emergency overview:**
Irritant to skin.
Irritant to eyes.
Sensitizer by dermal contact.
Irritant to respiratory system and skin.
Xi Irritant
- **Routes of exposure:**
Ingestion
Skin
- **Information pertaining to particular dangers for man and environment**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
R 43 May cause sensitization by skin contact.

(Contd. on page 2)

DUS

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

Trade name: Anti-CCP Calibrator L04

(Contd. of page 1)

- **Classification system**

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

The classification was made according to OSHA 29CFR 1910.1200 and 1910.1030, and is expanded upon from company and/or literature information.

4 First aid measures

- **General information** Immediately remove any clothing soiled by the product.
- **After inhalation** In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for doctor**
- **The following symptoms may occur:**
 - Headache
 - Allergic reactions

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:** Handle as potentially infectious.
- **Measures for environmental protection:** Do not allow product to reach sewage system or any water course.
- **Measures for cleaning/collecting:**
Disinfectant effective against agent of concern.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.

7 Handling and storage

- **Handling**
- **Information for safe handling:**
Keep receptacles tightly sealed.
No special precautions are necessary if used correctly.
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** According to product specification
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Keep receptacle tightly sealed.

DUS

(Contd. on page 3)

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

Trade name: Anti-CCP Calibrator L04

(Contd. of page 2)

* 8 Exposure controls and personal protection

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

· **Components with limit values that require monitoring at the workplace:**

26628-22-8 sodium azide

REL (United States) Short-term value: C 0.3** mg/m³, C 0.1* ppm

*as HN₃ vapor; **as NaN₃; Skin

TLV (United States) Short-term value: C 0.29** mg/m³, C 0.11* ppm

*as HN₃ vapor **as NaN₃

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Personal protective equipment**

· **General protective and hygienic measures**

Follow the usual biosafety practices for handling potentially infectious materials.

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.

· **Protection of hands:** Protective gloves.

· **Material of gloves** Synthetic gloves

· **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

· **Body protection:** Protective work clothing.

* 9 Physical and chemical properties:

· **General Information**

Form: Liquid

Color: Amber colored

Odor: Odorless

· **Change in condition**

Melting point/Melting range: undetermined

Boiling point/Boiling range: undetermined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**

Water: Fully miscible

· **pH-value at 20°C:** 7-8

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

Trade name: Anti-CCP Calibrator L04

(Contd. of page 3)

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Materials to be avoided:**
- **Dangerous reactions**
This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds of lead azide and copper azide.
- **Dangerous products of decomposition:** No dangerous decomposition products known

11 Toxicological information

- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritant effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- **Target organs:**
Skin.
Eye.

12 Ecological information:

- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.

13 Disposal considerations

- **Product:**
- **Recommendation**
Dispose of waste in accordance to applicable national, regional, or local regulations.
Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **DOT regulations:**
- **Hazard class:** -

(Contd. on page 5)

DUS

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

Trade name: Anti-CCP Calibrator L04

(Contd. of page 4)

· Land transport ADR/RID (cross-border)

· ADR/RID class: -

· Maritime transport IMDG:

· IMDG Class: -

· Marine pollutant: No

· Air transport ICAO-TI and IATA-DGR:

· ICAO/IATA Class: -

· Transport/Additional information: Not dangerous according to the above specifications.

15 Regulations

· SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

· Section 302/304 (40CFR355.30 / 40CFR355.40):

26628-22-8 sodium azide

· Section 313 (40CFR372.65):

26628-22-8 sodium azide

· TSCA (Toxic Substances Control Act):

7732-18-5 water

50-70-4 D-glucitol

9048-46-8 Bovine Serum Albumin

26628-22-8 sodium azide

77-92-9 citric acid

532-32-1 sodium benzoate

6132-04-3 Citric acid, trisodium salt dihydrate

· 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.

· Markings according to EU guidelines:

Observe the general safety regulations when handling chemicals

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:

Xi Irritant

· Risk phrases:

43 May cause sensitization by skin contact.

· Safety phrases:

24 Avoid contact with skin.

56 Dispose of this material and its container at hazardous or special waste collection point

(Contd. on page 6)

Material Safety Data Sheet

Printing date 04/02/2010

Reviewed on 03/25/2010

Trade name: Anti-CCP Calibrator L04

(Contd. of page 5)

37 Wear suitable gloves.

· **National regulations**· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.**16 Other information:**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** Environmental Health and Safety.· **Contact:**

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· *** Data compared to the previous version altered.**

DUS