

Developed and Manufactured by:

Distributed by:



Material Safety Data Sheet

Conforms to regulation (EC) No 1907/2006 (REACH) and 29 CFR 1910.1200(g)

Ref: 30525C/30550C/T30525C/T30550C

Issue Date: 2013-10

1. Identification of the substance / preparation and of the company / undertaking

1.1. Identification of the substance or preparation

Product Name: *C. DIFF QUIK CHEK COMPLETE*[®]
Cat. Number: 30525C/30550C/T30525C/T30550C
Composition: *Conjugate*
Diluent
Positive Control
Wash Buffer
Substrate
Membrane Device

1.2. Use of the substance / preparation

The *C. DIFF QUIK CHEK COMPLETE*[®] test is a rapid immunoassay for the simultaneous detection of *C. difficile* glutamate dehydrogenase antigen and toxins A and B in fecal specimens.
 FOR *IN VITRO* DIAGNOSTIC USE.

1.3. Company / undertaking identification

Manufactured by:	Distributed by:
TECHLAB [®] , Inc.	Alere North America, LLC.
2001 Kraft Drive	30 South Keller Road
Blacksburg, VA 24060	Orlando, Florida 32810

1.4. Emergency telephone: 1-800-222-1222 (Poison Control)

2. Hazard Identification

All kit components have been classified as non-hazardous according to EC Directive 67/548 EC and 1999/45/EEC.

The **Conjugate**, **Diluent**, and **Positive Control** contain material of animal origin:
Animal proteins are potentially infectious

3. Composition / information on ingredients

<u>Product</u>	<u>Hazardous Chemicals</u>	<u>CAS No.</u>	<u>%</u>	<u>EC No.</u>	<u>Classification</u>
Positive Control	Animal proteins	N/A	N/A	N/A	N/A
Diluent	Animal proteins	N/A	N/A	N/A	N/A

Conjugate	Animal proteins	N/A	N/A	N/A	N/A
Conjugate, Wash Buffer, Diluent:	ProClin300*	N/A	<0.05	N/A	T; R23/24/25 C; R34 R43 N; R50/53

*Active ingredient of ProClin300 is 3:1 mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one approximately 0.0014%.

For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures

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

- **After inhalation:** Remove person to fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:** Rinse immediately with water for 15 minutes. If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse open eye with water for 15 minutes under running water. Then consult doctor.
- **After swallowing:** Induce vomiting, only if person affected is fully conscious. Wash out mouth with water. Drink large quantities of water. Seek medical attention immediately.
- **The following symptoms may occur:** Headache, cramps, dizziness, nausea, diarrhea.

5. Fire Fighting Measures

- **Suitable extinguishing agents:**
Product itself does not burn. Use fire fighting measures that suit the environment.
- **Special hazards caused by the material, its products of combustion or flue gases:**
No data available.
- **Protective equipment:**
No special measures required. In case of burning of a larger amount: Wear breathing equipment and protective suit to avoid contact with skin and eyes.

6. Accidental Release Measures

- **Person-related safety precautions:**
Do not inhale vapors. Prevent contact with skin and eyes.
- **Measures for environmental protection:**
Do not allow product to reach sewage system or water bodies.
- **Measures for cleaning / collecting:**
Ensure adequate ventilation. Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to item 13.

7. Handling and Storage

7.1. Handling

- **Information for safe handling:**
Open and handle container with care. Prevent formation of aerosols.
- **Information about protection against explosions and fires:**
In cases of fire formation of dangerous fumes possible.

7.2. Storage

- **Requirements to be met by storerooms and containers:**
No special requirements.
- **Information about storage in one common storage facility:**
Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store refrigerated (2-8 °C).
- **Storage class:**
Not inflammable liquids – storage according to the national regulations.

7.3. Specific Use(s):
N/A

8. Exposure Controls and Personal Protection

8.1. Exposure limit values
Not available for this preparation.

8.2. Exposure controls

8.2.1. Occupational exposure controls

8.2.1.1. Respiratory protection

Not required

8.2.1.2. Hand protection

Compatible chemical-resistant gloves.

For the selection of glove material, breakthrough times and other test results are not available for this specific preparation.

8.2.1.3. Eye protection

Safety goggles.

8.2.1.4. Skin protection

Protective work clothing.

8.2.2. Environmental exposure controls

No data available.

9. Physical and Chemical Properties

▪ General information

Form: Liquid preparations

Color: Various

Smell: Characteristic

▪ Important health, safety and environmental information

Melting point/Melting range: N/A

Boiling point(Boiling range): N/A

Flash point: N/A

Self-inflammability: Not self-inflammable

Danger of explosion: Not explosive

Solubility in/Miscibility with water: Fully miscible

pH-value: N/A

10. Stability and Reactivity:

▪ Conditions to be avoided:

No decomposition if used according to specifications.

▪ Materials to avoid:

- N/A
 - **Hazardous decomposition products:**
N/A
-

11. Toxicological Information

Active ingredient of ProClin 300:

Acute toxicity

LD50 Oral - rat - 862 mg/kg

LD50 Dermal - rabbit - 2.800 mg/kg

Irritation and corrosion

On the skin: rabbit - Corrosive

On the eye: rabbit - Corrosive

Sensitization: May cause allergic skin reaction.

Subacute to chronic toxicity: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Potential Health Effects

Inhalation May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.

Skin May be harmful if absorbed through skin. Causes skin burns.

Eyes Causes eye burns.

Ingestion Harmful if swallowed. Causes burns.

Aggravated Medical Condition May provoke asthmatic response in persons with asthma who are sensitive to airway irritants

Target Organs Liver

12. Ecological Information

12.1. Ecotoxicological effects

No data available

12.2. Mobility

No data available

12.3. Persistence and degradability

No data available

12.4. Bioaccumulative potential

Log Pow = no data available

BCF = no data available

12.5. Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal Considerations

- **Product**

Recommendation:

Must not be disposed of together with household garbage.

Do not allow product to reach sewage system.

Residues of chemicals and preparations are generally considered hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies, which will give advice on how to dispose of hazardous waste.

- **Uncleaned packagings**

Recommendation: Disposal must be made according to official regulations.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14. Transport Information

- **Land transport ADR / RID and GGVS / GGVE (cross-border/domestic)**

ADR / RID-GGV / E Class: N/A

- **Maritime transport IMDG / GGVSea**

IMDG/ GGVSea Class: N/A

Marine pollutant: Yes

- **Air Transport ICAO-TI and IATA-DGR**

ICAO / IATA Class: N/A

- **Transport / Additional information:**

Because of small volumes no classification as dangerous goods according to above regulations.

15. Regulatory Information

- **Designation according to EC guidelines:**

The product has been classified as non-hazardous and labeled in accordance with EC Directives / Ordinance on Hazardous Materials.

Code letter and hazard designation of product: N/A

Hazard-determining components of labeling: N/A

- **National regulations:**

Please ask your national/regional authorities.

16. Other Information

The above information and recommendations are believed to be correct as of the date of this Material Safety Data Sheet but shall not be taken to be all-inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. TECHLAB[®], Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

Ingredients of animal origin are sourced from countries/areas with no-risk or low-risk status for bovine spongiform encephalopathy (BSE).

- **Relevant R-phrases:**

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitization by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- **Abbreviations:**
N/A = not applicable

Effective: 10/2013

Replaces version from: 10/2011

Modification versus previous version: Change in distributor information and update animal origin statement.

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