



C. DIFF CHEK™ - 60

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Revision Date: 10/05/2018 Date of Issue: 06/18/2015 Supersedes Date: 08/19/2015 Version: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: C. DIFF CHEK™ - 60

Product Code: 5025M, 5025C, 5025P, I2, S, W, D6

Cat. Number: T5025, T5025B, 30392, 30392B, T30392SKG

Other Means of Identification: This kit SDS is for a medical *in vitro* diagnostic (IVD) kit. 5025C, I2 and W components have hazards associated with them, refer to the corresponding component SDS for more information. D6, 5025P, 5025M, and S are not classified as hazardous.

1.2. Intended Use of the Product

An enzyme immunoassay for use as a screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase, in fecal specimens from persons suspected of having *C. difficile* disease.

1.3. Name, Address, and Telephone of the Responsible Party

Company, Manufacturer

TECHLAB, Inc.
2001 Kraft Drive
Blacksburg, VA 24060

Distributor

Alere North America, LLC
30 South Keller Road
Orlando, Florida 32810, USA

1.4. Emergency Telephone Number

Emergency Number : + (207) 730-5750

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Skin Corr. 1A	H314
Eye Dam. 1	H318
Skin Sens. 1	H317
STOT RE 2	H373

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements (GHS-US/CA)

: P260 - Do not breathe vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.

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P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

2.3. Other Hazards

No additional information available

2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Refer to component Safety Data Sheets

SECTION 4: FIRST AID MEASURES

Refer to component Safety Data Sheets

SECTION 5: FIRE-FIGHTING MEASURES

Refer to component Safety Data Sheets

SECTION 6: ACCIDENTAL RELEASE MEASURES

Refer to component Safety Data Sheets

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling Not available

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store closed in a dry, cool and well-ventilated place. Store refrigerated (2 - 8 °C).

7.3. Specific End Use(s)

An enzyme immunoassay for use as a screening test to detect *Clostridium difficile* antigen, glutamate dehydrogenase, in fecal specimens from persons suspected of having *C. difficile* disease.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Refer to component Safety Data Sheets

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Refer to component Safety Data Sheets

SECTION 10: STABILITY AND REACTIVITY

Refer to component Safety Data Sheets

SECTION 11: TOXICOLOGICAL INFORMATION

Refer to component Safety Data Sheets

SECTION 12: ECOLOGICAL INFORMATION

Refer to component Safety Data Sheets

SECTION 13: DISPOSAL CONSIDERATIONS

Refer to component Safety Data Sheets

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : SULFURIC ACID with not more than 51% acid

Hazard Class : 8

Identification Number : UN2796

Label Codes : 8

Packing Group : II

ERG Number : 157

14.2. In Accordance with IMDG

Proper Shipping Name : SULPHURIC ACID with not more than 51% acid



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Hazard Class : 8
Identification Number : UN2796
Label Codes : 8
Packing Group : II
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-B



14.3. In Accordance with IATA

Proper Shipping Name : SULPHURIC ACID with 51% or less acid
Hazard Class : 8
Identification Number : UN2796
Label Codes : 8
Packing Group : II
ERG Code (IATA) : 8L



14.4. In Accordance with TDG

Proper Shipping Name : SULFURIC ACID with not more than 51% acid
Hazard Class : 8
Identification Number : UN2796
Label Codes : 8
Packing Group : II



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Serious eye damage or eye irritation Health hazard - Skin corrosion or Irritation

Refer to component Safety Data Sheets for additional Federal Regulation information.

15.2. US State Regulations

Refer to component Safety Data Sheets

15.3. Canadian Regulations

Refer to component Safety Data Sheets

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest : 10/05/2018

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

Kit Components:	Microassay Plate	No known OSHA/WHMIS hazards
	Conjugate	May cause an allergic skin reaction
	Positive Control	No known OSHA/WHMIS hazards
	Stop Solution	Causes severe skin burns and eye damage.
	Substrate	No known OSHA/WHMIS hazards
	Wash Buffer	May cause damage to organs through prolonged or repeated exposure.
	Diluent	No known OSHA/WHMIS hazards

GHS Full Text Phrases:

Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1

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STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H373	May cause damage to organs through prolonged or repeated exposure

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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NA GHS SDS 2015 (Can, US)