



## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Substance name : C. DIFFICILE TOX A/B II™  
 Product code : 5015M, 5015C, 5015P, I2, S, W, D6  
 Catalog No(s) : T5015, T5015B, 30397, 30397B, T30397SKG  
 Other means of identification : This SDS is for a medical *in vitro* diagnostic (IVD) kit. The I2 and W components have hazards associated with them, refer to the corresponding component SDS for more information. 5015C, D6, 5015P, 5015M, and S are not classified as hazardous.

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### 1.2.1. Relevant identified uses

Use of the substance/mixture : An ELISA for the detection of *Clostridium difficile* Toxins A and B in human fecal specimens.

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

#### Company, Manufacturer

TECHLAB, Inc.  
 2001 Kraft Drive  
 Blacksburg, VA 24060

#### Distributed by:

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

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

Full text of H-statements: see section 16

#### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Danger

Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage  
 H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements (CLP) : P260 - Do not breathe vapors, mist, or spray.  
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.  
 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/shower.  
 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.  
 P314 - Get medical advice/attention if you feel unwell.  
 P321 - Specific treatment (see section 4 on this SDS).

## C. DIFFICILE TOX A/B II™

### Safety Data Sheet

According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

P405 - Store locked up.

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

#### 2.3. Other hazards

No additional information 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: Firefighting 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

No additional information 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 ELISA for the detection of *Clostridium difficile* Toxins A and B in human fecal specimens.

### 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

In accordance with ADR / RID / IMDG / IATA / ADN

#### 14.1. UN number

UN-No. (ADR) : 2796

#### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : SULPHURIC ACID

Transport document description (ADR) : UN 2796 SULPHURIC ACID, 8, II

#### 14.3. Transport hazard class(es)

Class (ADR) : 8

Danger labels (ADR) : 8



#### 14.4. Packing group

Packing group (ADR) : II

#### 14.5. Environmental hazards

Other information : No supplementary information available.

## C. DIFFICILE TOX A/B II™

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According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

#### 14.6. Special precautions for user

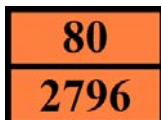
##### 14.6.1. Overland transport

Classification code (ADR)

: C1

Orange plates

:



Transport category (ADR)

2

EAC code

: 2R

##### 14.6.2. Transport by sea

EmS-No. (1)

: F-A

EmS-No. (2)

: S-B

##### 14.6.3. Air transport

No additional information available

#### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3.b. Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

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C. DIFFICILE TOX A/B II™ is not on the REACH Candidate List

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

Revision date

: 30/07/2015

Data sources

: According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

#### Kit Components

: Microassay Plate

Conjugate

Positive Control

Stop Solution

Substrate

Wash Buffer

Diluent

No known hazards according to (EC) No. 1272/2008 [CLP]

No known hazards according to (EC) No. 1272/2008 [CLP]

No known hazards according to (EC) No. 1272/2008 [CLP]

Causes severe skin burns and eye damage.

No known hazards according to (EC) No. 1272/2008 [CLP]

May cause damage to organs through prolonged or repeated exposure.

No known hazards according to (EC) No. 1272/2008 [CLP]

Full text of H- and EUH-statements:

Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H373	May cause damage to organs through prolonged or repeated exposure

## **C. DIFFICILE TOX A/B II™**

### Safety Data Sheet

According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

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