



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 <i>in vitro</i> 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 <i>Clostridium difficile</i> Toxins A and B in human fecal specimens.
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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).

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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.

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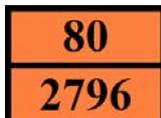
According to regulation (EU) No. 2015/830 and regulation (EC) No. 1272/2008

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

C. DIFFICILE TOX A/B II™

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	No known hazards according to (EC) No. 1272/2008 [CLP]
	Conjugate	No known hazards according to (EC) No. 1272/2008 [CLP]
	Positive Control	No known hazards according to (EC) No. 1272/2008 [CLP]
	Stop Solution	Causes severe skin burns and eye damage.
	Substrate	No known hazards according to (EC) No. 1272/2008 [CLP]
	Wash Buffer	May cause damage to organs through prolonged or repeated exposure.
	Diluent	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

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

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