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

1.1. Product identifier

Substance name : *C. DIFF CHEK*™ - 60

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

Catalog No(s) : T5025, T5025B, 30392, 30392B, T30392SKG

Other means of identification : This 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. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : 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.

1.2.2. 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
Skin Sens. 1	H317
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) :



GHS05 GHS07 GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H314 - Causes severe skin burns and eye damage
H317 - May cause an allergic skin reaction
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.
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.
P302+P352 - IF ON SKIN: Wash with plenty of water.
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).
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, 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 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

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

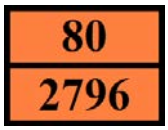
Other information : No supplementary information available.

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. DIFF CHEK*™ - 60

C. DIFF CHEK™ - 60 is not on the REACH Candidate List

15.1.2. National regulations

Refer to component Safety Data Sheets

15.2. Chemical safety assessment

Refer to component Safety Data Sheets

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	May cause an allergic skin reaction
		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
Skin Sens. 1	Sensitisation — Skin, category 1

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

EU GHS SDS

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