



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

1.1. Product identifier

Substance name : C. DIFF QUIK CHEK®
 Product code : 5029MD, 5029C, 5029P, 5029D, MS2, MW2
 Catalog No(s) : T5029, 30390
 Other means of identification : This SDS is for a medical *in vitro* diagnostic (IVD) kit. The 5029C, 5029D and MW2 components have hazards associated with them, refer to the corresponding component SDS for more information. 5029MD, 5029P, and MS2 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 : A rapid membrane 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 Sens. 1 H317

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) :



GHS07

Signal word (CLP) : Warning
 Hazard statements (CLP) : H317 - May cause an allergic skin reaction
 Precautionary statements (CLP) : P261 - Avoid breathing vapors, mist, or spray.
 P272 - Contaminated work clothing should not be allowed out of the workplace.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P302+P352 - IF ON SKIN: Wash with plenty of water.
 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.
 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

C. DIFF QUIK CHEK®

Safety Data Sheet

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

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)

A rapid membrane 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

Refer to component Safety Data Sheets

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 QUIK CHEK®
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C. DIFF QUIK CHEK® 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 : 24/09/2015

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

Kit Components :	Membrane Device	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]
	Diluent	May cause an allergic skin reaction.

C. DIFF QUIK CHEK®

Safety Data Sheet

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

Substrate
Wash Buffer

No known hazards according to (EC) No. 1272/2008 [CLP]
May cause an allergic skin reaction.

Full text of H- and EUH-statements:

Skin Sens. 1	Sensitisation — Skin, category 1
H317	May cause an allergic skin reaction

EU GHS SDS

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