



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

### 1.1. Product identifier

Substance name : C. DIFF QUIK CHEK COMPLETE®  
 Product code : 5038MD, 5038D, 5038C, 5038P, MS2, MW2  
 Catalog No(s) : T30525C, T30550C, T30525C-J  
 Other means of identification : This SDS is for a medical *in vitro* diagnostic (IVD) kit. 5038C, 5038D and MW2 components have hazards associated with them, refer to the corresponding component SDS for more information. 5038MD, 5038P 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 the simultaneous detection of *Clostridium difficile* glutamate dehydrogenase antigen and toxins A and B in 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, USA

#### 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-phrases: see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

R43

Full text of R-phrases: 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

## C. DIFF QUIK CHEK COMPLETE®

### Safety Data Sheet

According to Regulation (EC) No. 453/2010

#### 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

Refer to component Safety Data Sheets

##### 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 the simultaneous detection of *Clostridium difficile* glutamate dehydrogenase antigen and toxins A and B in 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

##### 10.1. Reactivity

No additional information available

##### 10.2. Chemical stability

No additional information available

##### 10.3. Possibility of hazardous reactions

No additional information available

##### 10.4. Conditions to avoid

No additional information available

##### 10.5. Incompatible materials

No additional information available

##### 10.6. Hazardous decomposition products

No additional information available

#### 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

Not regulated for transport

##### 14.2. UN proper shipping name

Not applicable

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

Not applicable

##### 14.4. Packing group

Not applicable

##### 14.5. Environmental hazards

Other information : No supplementary information available.

## C. DIFF QUIK CHEK COMPLETE®

### Safety Data Sheet

According to Regulation (EC) No. 453/2010

#### 14.6. Special precautions for user

##### 14.6.1. Overland transport

No additional information available

##### 14.6.2. Transport by sea

No additional information available

##### 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. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008	C. DIFF QUIK CHEK COMPLETE®
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 COMPLETE®

C. DIFF QUIK CHEK COMPLETE® 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

: 21/05/2015

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

<b>Kit Components</b>	<b>C. DIFF QUIK CHEK COMPLETE® Membrane Device</b>	No known hazards according to (EC) No. 1272/2008 [CLP]
	<b>C. DIFF QUIK CHEK COMPLETE® Diluent</b>	May cause an allergic skin reaction.
	<b>C. DIFF QUIK CHEK COMPLETE® Conjugate</b>	May cause an allergic skin reaction.
	<b>C. DIFF QUIK CHEK COMPLETE® Positive Control</b>	No known hazards according to (EC) No. 1272/2008 [CLP]
	<b>Substrate</b>	No known hazards according to (EC) No. 1272/2008 [CLP]
	<b>Wash Buffer</b>	May cause an allergic skin reaction.

Full text of R-, H- and EUH-phrases:

Skin Sens. 1	Sensitisation — Skin, category 1
H317	May cause an allergic skin reaction
R43	May cause sensitisation by skin contact

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## C. DIFF QUIK CHEK COMPLETE®

### Safety Data Sheet

According to Regulation (EC) No. 453/2010

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*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.*