



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

1.1. Product identifier

Substance name : *E. HISTOLYTICA QUIK CHEK™*
 Product code : 5045P, 5045D, 5045C, 5045MD, MS2, MW2
 Other means of identification : This SDS is for a medical *in vitro* diagnostic (IVD) kit. The 5045P, 5045D, 5045C and MW2 components have hazards associated with them, refer to the corresponding component SDS for more information. 5045MD and MS2 are not classified as hazardous.
 Catalog No(s) : T30409

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 : The TECHLAB® *E. HISTOLYTICA QUIK CHEK™* test is a rapid membrane enzyme immunoassay for the qualitative detection of adhesin from *Entamoeba histolytica* in a single use cassette. It is intended for use with human fecal specimens from patients with diarrhea or dysentery as an aid in the diagnosis of *E. histolytica* gastrointestinal infection.

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 classification categories and 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

E. HISTOLYTICA QUIK CHEK™

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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)

The TECHLAB® *E. HISTOLYTICA QUIK CHEK™* test is a rapid membrane enzyme immunoassay for the qualitative detection of adhesin from *Entamoeba histolytica* in a single use cassette. It is intended for use with human fecal specimens from patients with diarrhea or dysentery as an aid in the diagnosis of *E. histolytica* gastrointestinal infection.

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

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.

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 and the IBC Code

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

E. HISTOLYTICA 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

: 15/07/2016

Data sources

: According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Kit Components	:	Positive Control	May cause an allergic skin reaction.
		Diluent	May cause an allergic skin reaction.
		Conjugate	May cause an allergic skin reaction.
		Membrane Device	No known hazards according to (EC) No. 1272/2008 [CLP]
		Substrate	No known hazards according to (EC) No. 1272/2008 [CLP]
		Wash Buffer	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

TECHLAB, Inc.

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