



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 1 of 6

Trade Name: CH50
Doc: MYI040-7
Ed. 05/2016

1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Trade name: CH50
Diametra Code: DKO040

1.2 Relevant identified uses of the substance or mixture and uses advised against

Components of an *in vitro* Medical-Diagnostic Device according to Directive (EC) 98/79/EC.

Kit content (name and label reference):

Reference Calibrator	DCE030/4030-0
Incubation Buffer	DCE024-0
Immunocomplex	DCE025-0
Microplate	DMZ003
ONPG Substrate	DCE026-0
Ethanediol	DCE027-0
Stop Solution	DCE028-0
Low Control	DCE045/4001-0
High Control	DCE045/4002-0

1.3 Details of the supplier of the safety data sheet

Diametra S.r.l.

www.diametra.com

- Headquarter:** 20090 Segrate – Milano – Italy
Via Calabria, 15
Tel. +39.02.21.39.184 / +39.02.26.92.15.95
Fax. +39.02.21.33.354
- R&D Manufacturing:** 06038 Spello – Perugia – Italy
Via Pozzuolo, 14
Tel. +39.0742.24.851 / +39.0742.32.04.53
Fax. +39.0742.31.61.97
- Email: massini@diametra.com

1.4 Emergency telephone number

+ 39 06-3054343 (Centro antiveneni - Policlinico Gemelli Roma)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

- Ethanediol** (label reference: DCE027-0)

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]: Acute toxicity, Oral (Category 4)

- Other components of this product**

Due to the low concentration of hazardous ingredients, no other component of this product may be classified as dangerous according to Regulation (EC) 1272/2008.

2.2 Label elements

- Ethanediol** (label reference: DCE027-0)

Labelling according Regulation (EC) No 1272/2008 [CLP]:

Pictogram:





Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 2 of 6

Trade Name: CH50
Doc: MYI040-7
Ed. 05/2016

Signal word: Warning
Hazard statement: H302 (Harmful if swallowed)
Precautionary statement: none
Supplemental Hazard Statements: none

- **Other components of this product**

The other components are not under labelling according to Regulation (EC) n. 1272/2008.

2.3 Other hazards

No other hazards.

Note: this product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

<i>Ethanediol</i>				
<i>Ingredient</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (w/v)</i>	<i>Reg. 1272/2008</i>
Ethanediol (synonym: Ethylene Glycol)	203-473-3	107-21-1	99%	H302

<i>Reference Calibrator - Immunocomplex - Controls</i>				
<i>Ingredient</i>	<i>EC No</i>	<i>CAS No</i>	<i>Conc. (%)</i>	<i>Reg. 1272/2008</i>
Sodium Azide	011-00400-7	26628-22-8	< 0,1%	H300 - H400 - H410

3.2 Mixtures

No one.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: no special measures required. Consult a physician in case of complaints.
If inhaled: supply fresh air.
In case of skin contact: wash with plenty amounts of water.
In case of eye contact: rinse opened eye for few minutes with water.
If swallowed: contact the nearest first aid.
For the component Ethanediol, always consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Ethanediol: when ingested early symptoms mimic alcohol inebriation and are followed by nausea, vomiting, abdominal pain, weakness, muscle tenderness, respiratory failure, convulsions, cardiovascular collapse, pulmonary edema, hypocalcemic tetany, and severe metabolic acidosis. Without treatment, death may occur in 8 to 24 hours. Victims who survive the initial toxicity period usually develop renal failure along with brain and liver damage. Exposure to and/or consumption of alcohol may increase toxic effects.

Other components: to the best of our knowledge, the chemical, physical a toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 3 of 6

Trade Name: CH50
Doc: MYI040-7
Ed. 05/2016

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

No restriction.

5.2 Special hazards arising from the substance or mixture

To the best of our knowledge, can not be defined special hazards known.

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use appropriate personal protective equipment.

6.2 Environmental precautions

Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Absorb with inert absorbent material and dispose of a waste (see section 13).

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use all reagents according to the Instruction For Use provided with the product.

7.2 Conditions for safe storage, including any incompatibilities

Store all reagents according to the Instruction For Use provided with the product.

7.3 Specific end use(s)

This product is intended for laboratori use by professional users only.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Component with exposure limits: it doesn't contain substances with exposure limit value.

8.2 Exposure controls

Handle in accordance with good industrial hygiene and safety practice.

Wash hands before breaks at the end of workday.

Personal protective equipment

Eye/face protection: goggles with UNI EN 166 (and subsequent updates), or other international standard certification

Skin protection: lab coats, gloves with UNI EN 374 (and subsequent updates), or other international standard certification

Body protection: lab coats

Respiratory protection: not required



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 4 of 6

Trade Name: CH50

Doc: MYI040-7

Ed. 05/2016

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Component	a) Appearance	b) Odour	d) pH
Reference Calibrator	liquid, colorless	odorless	7.4
Incubation Buffer	liquid, colorless	odorless	7.4
Immunocomplex	liquid, colorless	odorless	7.4
Microplate	solid, white	odorless	not applicable
ONPG Substrate	liquid, colorless	odorless	7.0
Ethenediol	liquid, colorless	odorless	7.0
Stop Solution	liquid, colorless	odorless	11.0
Controls	liquid, colorless	odorless	7.4

	Ethenediol (data from the supplier)	Other components
c) odour threshold	no data available	no data available
e) melting point / freezing point	- 13°C	no data available
f) initial boiling point and boiling range	196-198°C	no data available
g) flash point	111°C - closed cup	no data available
h) evaporation rate	1	no data available
i) flammability (solid, gas)	no data available	no data available
j) upper/lower flammability or explosive limits	15.3%(V) upper, 3.2%(V) lower	no data available
k) vapour pressure	0.11-0.13 hPa at 20°C	no data available
l) vapour density	2.14 - (Air=1.0)	no data available
m) relative density	1.113 g/mL at 25°C	no data available
n) solubility(ies)	completely misciblesoluble in water	no data available
o) partition coefficient: n-octanol / water	log Pow: -1.36	no data available
p) auto-ignition temperature	no data available	no data available
q) decomposition temperature	no data available	no data available
r) viscosity	no data available	no data available
s) explosive properties	no data available	no data available
t) oxidising properties	no data available	no data available

9.2 Other informations

No other information available.



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 5 of 6

Trade Name: CH50
Doc: MYI040-7
Ed. 05/2016

10. STABILITY AND REACTIVITY

10.1 Reactivity: no data available.

10.2 Chemical stability: no data available.

10.3 Possibility of hazardous reactions: no data available.

10.4 Conditions to avoid

For the functional stability and reactivity of "TMB Substrate" avoid its exposure to directed sunlight, metals or oxidants and do not freeze the solution.

10.5 Incompatible materials:

Ethanediol: strong acids, strong oxidizing agents, strong bases, aldehydes, aluminum

Other components: no data available.

10.6 Hazardous decomposition products: no data available.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

	Ethanediol (data from the supplier)	Other components
a) acute toxicity	LD50 Oral - rat - 4.700 mg/kg LD50 Dermal - rabbit - 10.626 mg/kg	no data available
b) skin corrosion/irritation	no data available	no data available
c) serious eye damage / irritation	Eyes - rabbit - Mild eye irritation - 24h	no data available
d) respiratory or skin sensitisation	no data available	no data available
e) germ cell mutagenicity	no data available	no data available
f) carcinogenicity	This product is or contains a component that is probably not carcinogenic based on its IARC, ACGIH, NTP, or EPA classification. IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.	no data available
g) reproductive toxicity	Laboratory experiments have shown teratogenic effects. Overexposure may cause reproductive disorder(s) based on tests with laboratory animals.	no data available
h) STOT-single exposure	no data available	no data available
i) STOT-repeated exposure	no data available	no data available
j) aspiration hazard	no data available	no data available

Potential health effects

	Ethanediol	Other components
Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.	no data available
Ingestion	Harmful if swallowed.	no data available
Skin	May be harmful if absorbed through skin. May cause skin irritation.	no data available
Eyes	Causes eye irritation.	no data available



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 6 of 6

Trade Name: CH50

Doc: MYI040-7

Ed. 05/2016

Signs and Symptoms of Exposure

Ethanediol: When ingested early symptoms mimic alcohol inebriation and are followed by nausea, vomiting, abdominal pain, weakness, muscle tenderness, respiratory failure, convulsions, cardiovascular collapse, pulmonary edema, hypocalcemic tetany, and severe metabolic acidosis. Without treatment, death may occur in 8 to 24 hours. Victims who survive the initial toxicity period usually develop renal failure along with brain and liver damage., Exposure to and/or consumption of alcohol may increase toxic effects.

Other components: To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Additional Informations

No one.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Ethanediol:

Toxicity to fish: LC50 - *Oncorhynchus mykiss* (rainbow trout) - 18.500 mg/l - 96 h
LC50 - *Leuciscus idus* (Golden orfe) - > 10.000 mg/l - 48 h
NOEC - *Pimephales promelas* (fathead minnow) - 32.000 mg/l - 7 d
NOEC - *Pimephales promelas* (fathead minnow) - 39.140 mg/l - 96 h

Toxicity to daphnia and other aquatic invertebrates:

EC50 - *Daphnia magna* (Water flea) - 74.000 mg/l - 24 h
NOEC - *Daphnia* - 24.000 mg/l - 48 h
LC50 - *Daphnia magna* (Water flea) - 41.000 mg/l - 48 h

Other components: no data available.

12.2 Persistence and degradabilità: no data available.

12.3 Bioaccumulative potential:

Ethanediol: Does not bioaccumulate.
Bioaccumulation other fish - 61 d -50 mg/l
Bioconcentration factor (BCF): 0,60

Other components: no data available.

12.4 Mobility in soil: no data available.

12.5 Results of PBT and vPvB assessment: no data available.

12.6 Other adverse effects: no data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Reagents must be disposed of in accordance with local regulations. Do not disposed of in wastewater. If appropriate, contact a licensed disposal company.



Safety Data Sheet

According to Regulation (EC) n. 1907/2006 (REACH)
and Regulation (EC) n. 453/2010

Mod: MYIXXX-2
Pag. 7 of 6

Trade Name: CH50
Doc: MYI040-7
Ed. 05/2016

14. TRANSPORT INFORMATION

The product is not under transport regulations.

- 14.1 **UN number:** no data available
- 14.2 **UN proper shipping name:** no data available
- 14.3 **Transport hazard class(es):** no data available
- 14.4 **Packing group:** no data available
- 14.5 **Environmental hazards:** no data available
- 14.6 **Special precautions for user:** no data available
- 14.7 **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** no data available

15. REGULATORY INFORMATION

This Safety Data Sheet is according to Regulation (CE) n. 1907/2006 (REACH) and Regulation (EC) n. 453/2010; this product is classified and labelled according the Regulation (EC) n. 1272/2008 (CLP).

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

15.2 Chemical safety assessment
No data available.

16. OTHER INFORMATION

- "H code" used in this Safety data sheet

<i>Reg. 1272/2008</i>	
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

- **Changing against the last version:**

Rev. 5: updating to Regulation (CE) n. 1907/2006, Regulation (EC) n. 453/2010, and according to Regulation (EC) n. 1272/2008 (CLP).

Rev. 6: change in Headquarter address

Rev. 7: sodium carbonate substance deleted following a change in Stop Solution formulation

- **Note:**

The information in this document is believed to be accurate and represents the best information currently available to us. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.