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1 Identification of Substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: PYtest® Breath Collection Fluid

Product number: CF001, CF002, CF003

For analysis in conjunction with using AUST R 67146 & ARTG 342362

Application of the substance: Laboratory chemicals to capture human breath samples for the detection of *Helicobacter pylori*.

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Tri-Med Distributors Pty. Ltd.
Unit 6/15 Walters Drive,
Osborne Park, Western Australia, 6017.

During office hours: +61 89388 1444 (phone).

Further information obtainable from the department issuing SDS:

Operations Department of Tri-Med at info@trimed.com.au

1.3 Emergency contact:

Emergency contact telephone number +61 407385435

1.4 Other information:

Active Ingredient Manufacturer/Supplier: Perkin Elmer Life Health Sciences B.V
Rigaweg 22,
9723 TH Groningen
The Netherlands

Information department: Quality Assurance, Environment, Safety and Health at Perkin Elmer

2 Composition/Information on Ingredients

Chemical characterisation

Description:

Mixture consisting of the following components:

~ 0.5M Benzethonium hydroxide in methanol % containing 0.9% w/v thymolphthalein (CAS 125-20-2).

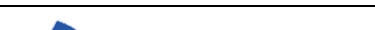
Hazardous components:

CAS#67-56-1 METHANOL	H225, H301, H311, H331, H370	40-60%
CAS#498-77-1QUATERNARY AMMONIUM HYDROXIDE	H314, H302	40-60%



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Web: www.trimed.com.au
ABN 79 010 030 857

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Additional information: For the full context of the listed H statements here-refer to section 16.

3 Hazards Identification

3.1 Classification of the substance or mixture

#Classification according to Regulation (EC) No. 1272/2008 & GHS

Flammable liquid Cat. 2, H225

Acute toxicity Cat. 3 – Oral, Dermal, Inhalation, H301, H311, H331

Skin corrosion / Irritation Cat. 1B, H314

Specific Target Organ Toxicity Cat. 1, H370

3.2 Label elements – Hazard pictograms



Signal word: Danger

Hazard-determining components of labelling:

Methanol

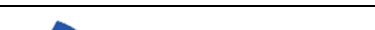
Quaternary Ammonium Hydroxide

Hazard statements

H225	Highly flammable liquid and vapour.
H301+H331	Toxic if swallowed or if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H370	Causes damage to organs, CNS and eyes.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Removes contact lenses, if present and easy to do. Continue rinsing.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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3.3 Other hazards:

Results of PBT and vPvB assessment:

PBT: Not applicable

vPvB: Not applicable

4 Section 4. First Aid Measures

4.1 Description of first aid measures

General information:

Consult a doctor. Show this safety data sheet to the doctor in attendance. Immediately remove any clothing soiled by the product. Remove breathing equipment only after contaminated clothing have been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.

If inhaled:

Move person into fresh air. Supply fresh air or oxygen; call for doctor. In case of unconsciousness place patient stably on their side for transportation.

In case of contact with skin:

Immediately wash with water and soap and rinse thoroughly.

In case of eye contact:

Rinse opened eye for several minutes (at least 15 mins) under running water. Protect unharmed eye. Then consult a doctor.

If swallowed:

DO NOT induce vomiting; call for medical help immediately. NEVER give anything by mouth to an unconscious person. Drink plenty of water and provide fresh air. Call for a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed.

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed.

No further relevant information available.

5 Section 5. Fire Fighting Measures

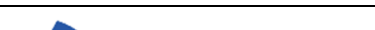
5.1 Extinguishing media

Suitable extinguishing agents:



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Web: www.trimed.com.au
ABN 79 010 030 857

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CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture.

No further relevant information available

5.3 Advice for fire-fighters

Hazardous Combustion Products: Carbon and nitrogen oxides.

Protective equipment: Mouth respiratory protective device. Wear full protective suit.

6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment and *ensure adequate ventilation. Keep unprotected persons away.

6.2 Environmental precautions:

Prevent seepage into sewage system, work pits and cellars. Dilute with plenty of water. Do not allow to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation. Contain and collect with inert absorbent material and place in a suitable container for disposal. Dispose contaminated material as waste according to local regulations.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling & Storage

7.1 Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace.

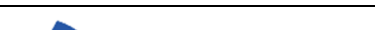
Open and handle receptacle with care.

Wear protective equipment.

Avoid contact with skin and eyes and clothing.

Avoid breath in the mist and vapour.

Keep ignition sources away – do not smoke.

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7.2 Conditions for safe storage, including incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store in a cool location.

Information about storage in one common storage facility: Not required.

Further information about storage conditions:

Keep receptacle tightly sealed. Store in cool, dry conditions in well-sealed receptacles.

Protect from exposure to direct light.

7.3 Specific end use(s)

No further relevant information available.

8 Section 8. Exposure controls / personal protection

Additional information about design of technical systems

No further data; see item 7.

8.1 Control parameters

Ingredients with workplace control parameters:

Component	CAS No.	Value	Control Parameters
Methanol	67-56-1	Short-term Exposure Limit (STEL):	328 mg/m ³ , 250ppm
		A time weighted average (TWA):	262 mg/m ³ , 200ppm

Additional information: The lists valid during the making were used as basis.

8.2 Exposure Controls

Personal protective equipment (PPE) e.g., gloves, face mask:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wear suitable gloves and protective work clothing.

Avoid contact with the eyes and skin. *Safety glasses or goggles is recommended.

Wash hands before breaks and at the end of work.

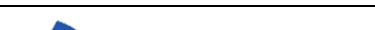
Store protective clothing separately.

Respiratory protection:

No personal respiratory protective equipment normally required.

In case of brief exposure or low pollution use normal face mask.

In case of intensive or longer exposure use self-contained respiratory protective device.

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Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

Safety glasses or goggles is recommended.

In case of intensive or longer exposure use, use tightly sealed goggles.



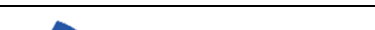
Tightly sealed goggles

9 Physical & Chemical properties

9.1 Information on basic physical and chemical properties.

General Information

a) Appearance	Form: Fluid Colour: Blue
b) Odour	Characteristic with alcohol odour
c) pH	~10
d) Melting point/melting range	Not applicable
e) Boiling point/boiling range	65°C (149°F)
f) Flash point	18°C
g) Ignition temperature	470°C (878°F)
h) Auto igniting	Product is not self-igniting

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- | | |
|--|--|
| i) Danger of explosion | Product does not present explosion hazard. However, formation of explosive air/vapour mixtures are possible. |
| j) Flammable limits in air % by volume | Lower: 5.5 vol. %
Upper: 44.0 vol. % |
| k) Vapour pressure | 97 mmHg (20°C methanol) |
| l) Solubility in / miscibility with water | Fully miscible |
| m) Solvent content | Organic solvents: more than 40% methanol |

9.2 Other information

No further relevant information available.

10 Section 10. Stability & Reactivity

10.1 Reactivity

10.2 Chemical Stability

Thermal decomposition / conditions to be avoided:
No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions:

No dangerous reactions known.

10.4 Conditions to avoid

Keep away from heat, sparks, flames, hot surfaces and all other sources of ignition.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products:

Nitrogen oxides
Carbon monoxide

11 Section 11. Toxicological Information

11.1 Information on toxicological effects

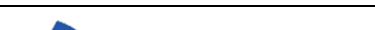
Acute toxicity:

LD/LC50 values relevant for classification:

67-56-1 methanol

Inhalation LC50 128.2mg/l/4H (rat)

Dermal LD50 5628 mg/kg (rabbit)

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Primary irritant effect:

Skin corrosion/irritation

Strong caustic effect on skin and mucous membranes.

Serious eye damage / eye irritation

Strong caustic effect.

Respiratory or skin sensitisation

No sensitising effects known.

Additional toxicological information

The product shows the following dangers according to the calculation method of the General EU.

Classification Guidelines for preparations as issued in the latest version:

Toxic

Corrosive

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of oesophagus and stomach.

Carcinogenicity Data: None of the components of this product is listed as carcinogen by IARC, NTP, US OSHA or EU CLP Annex VI.

Reproductive toxicology: There is no human information available.

12 Section 12. Ecological Information

12.1 Toxicity

Aquatic toxicity: No further relevant information available

12.2 Persistence and degradability:

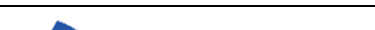
Methanol is readily biodegradable. No further relevant information is available for other ingredients.

12.3 Bioaccumulative potential:

Methanol has an estimated BCF of <10. No further relevant information available for other ingredients.

12.4 Mobility in soil:

Methanol is highly mobile in soil. No further relevant information available for other ingredients.

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12.5 Additional ecological information:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Must not reach sewage water or drainage ditch undiluted or un-neutralised.

12.6 Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

12.7 Other adverse effects:

No further relevant information available

13 Section 13. Disposal Considerations

13.1 Waste treatment methods

Recommendation: Must be specially treated adhering to official regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary, with cleansing agents.

14 Section 14. Transport Information

14.1 UN-Number

ADG, IMDG, IATA: UN2924

14.2 UN proper shipping name

ADG: 2924 FLAMMABLE LIQUID, CORROSSIVE, N.O.S.
(Methanol, quaternary ammonium hydroxide solution)

IMDG: FLAMMABLE LIQUID, CORROSIVE, N.O.S (Methanol
quaternary ammonium hydroxide solution)

IATA: FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Methanol,
quaternary ammonium hydroxide solution)

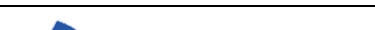
14.3 Transport Hazard class(es)

ADG



Class
Label

3(FC) Flammable liquids.
3+8

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IMDG, IATA



Class 3(FC) Flammable liquids.
Label 3+8

14.4 Packing group

ADG, IMDG, IATA: II

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

Warning: Flammable liquids
Danger code (Kemler): 368
EMS Number: F-E, S-C

14.7 Transport in bulk according to Annex II of

MARPOL 73/78 and the IBC Code Not applicable.

Transport/Additional information:

ADG

Tunnel restriction code D/E

UN "Model Regulation" UN 2924, FLAMMABLE LIQUID, CORROSIVE, N.O.S.
(Methanol, Quaternary Ammonium Hydroxide Solution), 3(8), II

14.8 Air transport ICAO-TI and IATA-DGR:

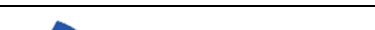
ICAO/IATA Class: 3+8

UN/ID Number: 2924

Label: 3+8

Packing group: II

Proper shipping name: FLAMMABLE LIQUID, CORROSIVE, N.O.S.
(Methanol, Quaternary Ammonium Hydroxide Solution), UN 2924 Class 3(8)

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15 Section 15. Regulations

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

Australian Inventory of Chemical Substances
67-56-1 methanol S6

National regulations:

Technical instructions (air):

Class	Share in %
I	40-60

Water hazard class: Water hazard class 1 (self-assessment): slightly hazardous for water.

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16 Section 16. Other Information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

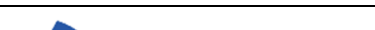
Relevant phrases

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H331	Toxic if inhaled.
H370	Causes damage to organs, CNS and eyes

Reference: #PerkinElmer 2022 Aus SDS

Key abbreviations or acronyms:

ICAO:	International Civil Aviation Organisation
ADG:	The Australian Code for the Transport of Dangerous Goods by Road and Rail.
IMDG:	International Maritime Code for Dangerous Goods.
IATA:	International Air Transport Association.
GHS:	Globally Harmonised system of Classification and Labelling of Chemicals.

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CAS: Chemical Abstracts Service (division of the American Chemical Society).

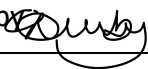
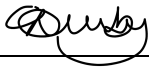
LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

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REVISION	DATE	AMENDMENTS
1.0	04/12/2023	New – copied and entered QMS
2.0	11/01/2024	Format amendments

Written By	Clare Newby 	Date	11/01/2024
Checked By	Claire Ryan 	Date	11/01/2024
Approved By	Clare Newby 	Date	11/01/2024