Date of issue: 11/06/2018 Revision date: 17/02/2020 Version: 2

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product Identifier

Product form: mixture.

Trade name: Chemdye® KPRO2-E69; Chemdye® KPRO2-E250.

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

1.2.1. Relevant identified uses of the substance or mixture:

Chemdye® KPRO2-E69 was designed to detect proteins on surfaces of surgical equipment after the cleaning process and in hard to reach areas. / Chemdye® KPRO2-E250 was designed to detect proteins on endoscopes and other reusable instruments with hard to reach internal channels or cannulated instruments.

1.2.2. Uses advised against:

Do not use for purposes other than stated in the indications for use.

1.3. Details of the supplier of the safety sheet

Manufacturer: Terragene S.A.

Address: Ruta Nacional Nº 9, Km 280 - CP 2130 - Parque Industrial Micropi - Alvear - Santa Fe - Argentina

Produced by: QA&RA Department

Info Telephone: +54 341 5587007 | 5587008 | 5587009

E-mail: info@terragene.com.ar

Web Page: www.terragene.com.ar

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1.4. Emergency telephone

Telephone number: +54 341 5587010

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture.

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008 (CLP).

CLASSIFICATION:

N/A

Adverse physicochemical, human health and environmental effects:

No information available.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP)

2.2.1. Hazard pictograms

N/A

2.2.2 Signal word

N/A

2.2.3. Hazard statements

N/A

2.2.4. Precautionary statements

N/A

2.2.5 Supplemental Hazard information (EU):

Not applicable

2.3. Other hazards

PBT: not yet assessed.

VPvB: not yet assessed.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable.

3.2 Mixture

Substances presenting a health or environmental hazard within the meaning of the Dangerous Substances Regulation (EC) No. 1272/2008 (CLP)

Ingredients	CAS Number	Content %	EC Number	Classification according to Regulation (EC) No. 1272/2008 (CLP)
Hydrogen Chloride	7647-01-0	<3%	231-595-7	Skin Corr. 1B; H314 STOT SE 3; H335
Tricloacetic acid	76-03-9	<1%	200-927-2	Skin Corr. 1A; H314 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Ethanol	64-17-5	<1%	200-578-6	Flam. Liq. 2; H225

Comments: Exact concentrations are withheld as trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

4.1.1. General:

No need for first aid is anticipated.

4.1.2. In case of ingestion:

No need for first aid is anticipated.

4.1.3. In case of eye contact:

No need for first aid is anticipated.

4.1.4. In case of skin contact:

No need for first aid is anticipated.

4.1.5. In case of inhalation:

No need for first aid is anticipated.

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

No additional information available.

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

No additional information available.

Section 5: FIREFIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

Unsuitable extinguishing media: None known.

5.2. Special hazards arising from the substance or mixture

N/A

5.3. Advice for firefighter

No additional information available.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

N/A

6.1.1 For non-emergency personnel

N/A

6.1.2 For emergency responders

N/A

6.2. Environmental precautions

N/A

6.3. Methods for containment and cleaning up

Methods for cleaning up: Comply with applicable local and national regulations. Spills may be picked up with a mop and followed by a water rinse. Residue may be washed down with water. Smalls spills may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state or national legislation.

Released material in dry form may be swept up using a broom and dust pan or picked up by hand if wearing protective gloves. Clean up residue. Seal container. Dispose of collected material according to country's healthcare and safety regulations.

6.4 Reference to other sections

Section 8 and 13.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautionary for safe handling: Read label before use. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation.

Hygiene measures: Take care for general good hygiene and housekeeping. Do not drink, eat, smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in dark, dry conditions before and after use. Do not freeze. Ensure adequate ventilation. Avoid dust formation.

Incompatible products: Do not store near sterilizing agents or other chemical products.

Keep away from sources of ignition.

Temperatures: 2 - 25 °C.

Relative humidity: 30 - 80 %.

7.3 Specific end use(s)

Designed to detect and quantify proteins, allergens and reducing agents with high sensitivity on surfaces and difficult-to-access areas after the cleaning process.

Section 8: EXPOSURE CONTROL / PERSONAL PROTECTION

8.1. Control parameters

8.1.1 Occupational Exposure Limits

This product, as supplied, does not contain any hazardous material with occupational exposure limits established by the region specific regulatory bodies.

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls are necessary.

8.2.2. Personal protective equipment

The use of gloves, moisture impervious aprons, and other protective clothing must be dictated by the standard operational procedures of each individual laboratory. Wash hands thoroughly after handling.

8.2.3. Environmental exposure controls

No additional information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State:	Varies			
Appearance:	System with liquid			
Color:	Light brown solution			
Odour:	N/A			
Odour threshold:	N/A			
pH:	N/A			
Relative evaporation rate:	N/A			
Melting point/Freezing point:	N/A			
Boiling point:	N/A			
Flash point:	N/A			
Flammability:	N/A			
Vapour pressure:	N/A			
Relative vapour density at 20°C:	N/A			
Relative density:	N/A			
Log Pow:	N/A			
Explosive properties:	N/A			
Oxidising properties:	N/A			
Solids:	1-5%			
Viscosity (for Cup n° 3):	N/A			
Decomposition Temp.:	N/A			
Explosive Limits:	N/A			
Auto-ignition Temp.:	N/A			
Solubility:	N/A			

9.2 Other information

VOC's (ASTM D 2369-87): N/A

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Stable under recommended storage conditions (see section 7).

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous Decomposition Products: N/A

Hazardous Polymerization: N/A

10.4. Conditions to avoid

Avoid excessive heat and pressure. Avoid dust formation.

10.5. Incompatible materials

Sterilizing agents or other chemical products.

10.6. Hazardous decomposition products

None under normal conditions of use.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Signs and symptoms of exposure

Acute toxicity: Not available.

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory or skin sensitization: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Specific target organ toxicity (single exposure): Not available.

Specific target organ toxicity (repeated exposure): Not available.

Aspiration hazard: Not available.

Additional Information: These products, when used under reasonable conditions and in accordance with the instructions for use, should not present any risk to health. However, the use or processing of the product in a manner not in accordance with the product's instructions for use could affect the performance of the product and could present a potential risk to health and safety.

Section 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

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12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects.

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Waste must be disposed of in accordance with federal, state, and local environmental control regulations. Ensure all national/local regulations are observed.

Avoid release to the environment.

Section 14: TRANSPORT INFORMATION

14.1. UN number

Not considered a dangerous good according to IATA, IMDG, ADN, ADR, RID Dangerous Goods Regulations.

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14.2 UN proper shipping name
N/A
14.3 Transport hazard class(es)
N/A
14.4 Packing group
N/A
14.5 Environmental hazards
N/A
14.6 Special precaution for users
No additional information available.
14.7 Transport in bulk according to Annex II MARPOL 73/78 and the IBC CODE
N/A
Section 15: REGULATORY INFORMATION
15.1 Safety, Health and environmental regulation/legislation specific for the substance or mixture
Contains no substance on the REACH Candidate List.
Contains no REACH Annex XIV substances.

Contains no REACH substances with Annex XVII restrictions.

15.2 Chemical safety assessment

No chemical safety assessment is required.

Section 16: OTHER INFORMATION

According to Regulation (EU) 2015/830

Indication of changes: N/A.

Abbreviations and acronyms:

CLP: Classification, Labelling and Packaging.

CAS number: Chemical Abstracts Service number.

Data sources:

https://echa.europa.eu/information-on-chemicals/cl-inventory-database

https://echa.europa.eu/es/information-on-chemicals

Regulation 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.

16.1. Legal disclaimer

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The company shall not be held liable for any damage resulting from handling or from contact with the above product.

16.2. Date of issue/Date of revision

17-02-2020

16.3 Revision number

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