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

1.1 Product identifier

Name of product: Internal standard, DOSIMYCO[™] kit

Code: 227-40306-58

1.2 Relevant identified uses of the substance or mixture and use to be recommended

Identified use: in vitro diagnostic

Sector of use: SU20 Health Service, SU24 Scientific research and development

Chemical product category: PC21 Laboratory chemicals

Process category: PROC15 Use of substance at small scale in laboratories.

1.3 Information concerning the supplier Safety Data Sheet

Manufacturer/supplier:

ALSACHIM SAS 160 rue Tobias Stimmer 67400 ILLKIRCH - France

Tél.: +33 (0) 390 402.200 Fax: +33 (0) 390 402 199 E-Mail: contact@alsachim.com

1.4 Emergency telephone number

Alsachim: +33 (0) 390 402.200

Poison center Strasbourg: +33 (0) 388 373 737

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. This substance is not classified as dangerous according to Directive 67/548/EEC.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

Signal word: None

Hazard statements:

None

Precautionary statements

P233 - Keep container tightly closed

P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing



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2.3 Other hazards

Does not meet the criteria for PBT or vPvB pursuant to Commission Regulation (EU) N°1907/2006, Annex XIII.

SECTION 3: Composition / Information on Ingredients

3.2 Mixtures

Description: freeze dried EDTA diammonium salt.

Dangerous components

CAC. 204407F 00 7	EDTA diammonium salt	5 mM
CAS: 3044675-80-7	Eye Irrit. (cat 2), H319	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information

Never give anything by mouth to an unconscious person. Call a poison center or a doctor/physician. If possible show this safety data sheet. Remove any clothing soiled by the product. Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident is needed.

After inhalation

Supply fresh air.

Consult a doctor/medical aid in case of complaint.

After skin contact

Immediately rinse with plenty of water.

After eye contact

Rinse opened eye for several minutes. Consult a doctor if pain, blinking or redness persist.

After swallowing

Rinse mouth with water and then drink plenty of water. Consult a physician in case of complaints.

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

No further relevant information available

SECTION 5: Fire-fighting measures

5.1 Extinguishing media



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Use fire extinguishing method suitable to surrounding conditions.

5.2 Specific hazards arising from the substance or mixture

In case of fire, may produce toxic pyrolysis products.

In case of fire, the following can be released:

Nitrogen Oxide (NOx)

5.3 Advice for firefighters

Wear self-contained breathing apparatus.

Prevent fire-fighting water from entering surface water or groundwater

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

6.3 Methods and materials for containment and cleaning up

Pick up mechanically.

Dispose contaminated material as waste according to regulation.

6.4 Reference to other sections

Handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Do not drink, eat or smoke when handling this product.

Wash hands and other exposed areas before drinking, eating or smoking.

7.2 Conditions for safe storage, including any incompatibilities

Store only in the original container. Store in dry conditions below -18°C.

Storage class: 11

7.3 Specific end use (s)

The mixture is a reagent for determination of the parameters stated on the label. Comply with the instruction manual.

SECTION 8: Exposure Controls / Personal Protection

Additional information about design of technical facilities: no further data, see 7.



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8.1 Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the work place.

8.2 Exposure controls

Respiratory protection:

Not required.

Protection of hands

Wear gloves compliant with the specifications of EC Directive 89/686 EEC and the related standard EN374.

For permanent contact

Suitable material of gloves is Nitrile rubber Recommended thickness: ≥ 0.4 mm

Penetration time: > 480 min

For protection of splashes

Suitable material of gloves is Polychloroprene

Recommended thickness: ≥ 0.65 mm

Penetration time: > 120 min

Protection of eyes

Wear tightly sealed goggles

Protection of body

Wear light weight protective clothing

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Form	Solid
Color	Colorless
Odor	Odorless
pH value	Not determined
Change in condition	
Melting point:	Not determined
Boiling point:	Not determined
Flash point:	Not applicable
Flammability (solid, gaseous):	Not applicable
Ignition temperature:	
Decomposition temperature:	Not determined
Self-ignition:	Product is not self-igniting
Danger of explosion:	Product does not present an explosion hazard
Density	Not determined
Solubility/miscibility in water:	Product is miscible

9.2 Other information



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No further other relevant information available

SECTION 10: Stability and Reactivity

10.1 Reactivity

No dangerous reaction known

10.2 Chemical stability

No decomposition if used according to specifications

10.3 Possibility of hazardous reactions

No dangerous reaction known

10.4 Conditions to avoid

No further other relevant information available

10.5 Incompatible materials

No further other relevant information available

10.6 Hazardous Decomposition Products

No dangerous decomposition products known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification: (Information refers to the pure substance)

EDTA diammonium salt - CAS: 3044675-80-7		
Oral	LD50	4500 mg/kg (rat)

Primary irritant effect:

Serious eye damage/irritation.

Respiratory or skin sensitization light skin irritation.

CMR effects (carcinogecity, mutagenicity and toxicity for reproduction)

No information available

Additional toxicological information

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.



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SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No further other relevant information available

12.2 Persistence and degradability

No further other relevant information available

12.3 Bioaccumulation potential

No further other relevant information available

12.4 Mobility in soil

No further relevant information available

12.5 Results of PBT and vPvB

PBT/vPvB assessment is not available as chemical safety is not required/conducted.

12.6 Other adverse effects

No further relevant information available

SECTION 13: Disposal

13.1 Methods of waste treatment

Must not be disposed together with domestic waste. Do not circulate into the main water supply.

Product residues are to be disposed of in compliance with Directive 2008/98 EC on waste and local requirements, e.g. in a suitable incineration plant. Leave chemicals in original containers. Transfer small quantities to approved transport containers. Protect collection receptacles and containers from access by unauthorized parties.

Uncleaned packaging: to be disposed of in the same manner as the product.

SECTION 14: Transport Information

14.1 UN number

Not Applicable, not subject to the regulations.

14.2 Proper shipping name and number

Not Applicable

14.3 Classes for traffic hazards

Not Applicable



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14.4 Packing group

Not Applicable

14.5 Environmental hazards

Not Applicable

14.6 Special precautions for user

Not Applicable

14.7 Transport in bulk in accordance with Annex II of MARPOL 73/78 and the IBC Code

Not Applicable

SECTION 15: Regulatory information

15.1 Safety, health environmental Regulation/ legislation specific to the substance or mixture

No further relevant information available

15.2 Chemical safety assessment

A safety assessment has not yet been carried out

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.

16.1 Acronyms and abbreviations

ADR : Accord européen sur le transport des marchandises dangereuses par Route

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent EC: Effective concentration IC: Inhibitory concentration

NOEC: No observed effect level concentration

OECD: Organization for Economic Co-operation and Development IUCLID: International Uniform Chemical Information Database

16.2 Training hints

Users should be informed, instructed and educated appropriately.

16.3 Reasons for revision



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Change of part number. Correction in 2.