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

1.1 Product identifier

Name of product: Tuning Mix of labeled Mycophenolic acid and Tuning Mix of unlabeled Mycophenolic acid, DOSIMYCO™ kit

Code:

227-40340-58 or 227-40340-91 (Mix of labeled Mycophenolic acid)

227-40341-58 or 227-40341-91 (Mix of unlabeled Mycophenolic acid)

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

Product is not classified according to the CLP regulation.

2.2 Label elements

No markings according to the EC regulation. Observe the general safety regulation when handling chemicals.

2.3 Other hazards

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

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SECTION 3: Composition / Information on Ingredients

3.2 Mixtures

Mycophenolic acid diluted in EDTA and freeze dried.

Dangerous components

None.

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

Use fire extinguishing method suitable to surrounding conditions.

5.2 Specific hazards arising from the substance or mixture

May produce toxic pyrolysis products.

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5.3 Advice for firefighters

Wear self-contained breathing apparatus.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective gloves.

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 -20°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.

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.

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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. Material of gloves: Natural rubber NR or Nitrile rubber NBR

Protection of eyes

Safety glasses.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Form Color Odor	Powder White Odorless
Change in condition Melting point: Boiling point :	Not determined Not determined
Flash point:	Not applicable
Danger of explosion:	Product does not present an explosion hazard
Density:	Not determined
Solubility/miscibility in water:	Product is soluble

9.2 Other information

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

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10.6 Hazardous Decomposition Products

No dangerous decomposition products known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Primary irritant effect:

No irritating effect

Respiratory or skin sensitization:

No sensitizing effects known

CMR effects (carcinogenicity, 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.

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

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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.

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

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

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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

Change of code of product