



Immunosuppressants, Mobile Phase I - 4191 P IMM

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

1.1 Product identifier: Immunosuppressants, Mobile Phase I - 4191 P IMM

Other means of identification:

Non-applicable

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

Relevant uses: In vitro diagnostic. For industrial user only.

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

Diagnostix B.V.
De Plassen 4
9903 SE Appingedam - The Netherlands
Phone: +31 (0) 596 201062
info@diagnostix.com
www.diagnostix.com

1.4 Emergency telephone number: 112

SECTION 2: HAZARDS IDENTIFICATION **

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Fam. Liq. 3: Flammable liquids, Category 3, H226

STOT SE 2: Specific target organ toxicity — single exposure, Hazard Category 2, H371

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Warning



Hazard statements:

Fam. Liq. 3: H226 - Flammable liquid and vapour.

STOT SE 2: H371 - May cause damage to organs.

Precautionary statements:

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233: Keep container tightly closed.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P264: Wash thoroughly after handling.

P280: Wear protective gloves/face protection/protective clothing/respiratory protection/protective footwear.

P370+P378: In case of fire: Use ABC powder extinguisher to extinguish.

P403+P235: Store in a well-ventilated place. Keep cool.

P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

Substances that contribute to the classification

methanol

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria

** Changes with regards to the previous version

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

3.2 Mixture:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification		Concentration
CAS: 67-56-1 EC: 200-659-6 Index: 603-001-00-X REACH: 01-2119433307-44-XXXX	methanol ¹	ATP CLP00	2,5 - <10 %
	Regulation 1272/2008	Acute Tox. 3: H301+H311+H331; Flam. Liq. 2: H225; STOT SE 1: H370 - Danger	
CAS: 64-18-6 EC: 200-579-1 Index: 607-001-00-0 REACH: 01-2119491174-37-XXXX	Formic acid ²	ATP CLP00	<1 %
	Regulation 1272/2008	Skin Corr. 1A: H314 - Danger	

¹ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830
² Substance with a Union workplace exposure limit

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Induce vomiting (ONLY IF PERSON IS CONSCIOUS!) and then ingest large quantities of liquid to dilute the toxin. Keep the person affected at rest.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

If possible use polyvalent powder fire extinguishers (ABC powder), alternatively use foam or carbon dioxide extinguishers (CO₂).

Unsuitable extinguishing media:

IT IS RECOMMENDED NOT to use full jet water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

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**Immunosuppressants, Mobile Phase I - 4191 P IMM****SECTION 5: FIREFIGHTING MEASURES (continued)**

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures:****For non-emergency personnel:**

Isolate leaks provided that there is no additional risk for the people performing this task. Evacuate the area and keep out those without protection. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Above all prevent the formation of any vapour-air flammable mixtures, through either ventilation or the use of an inert medium. Remove any source of ignition. Eliminate electrostatic charges by interconnecting all the conductive surfaces on which static electricity could form, and also ensuring that all surfaces are connected to the ground.

For emergency responders:

See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling:**

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Transfer in well ventilated areas, preferably through localized extraction. Fully control sources of ignition (mobile phones, sparks,...) and ventilate during cleaning operations. Avoid the existence of dangerous atmospheres inside containers, applying inertization systems where possible. Transfer at a slow speed to avoid the creation of electrostatic charges. Against the possibility of electrostatic charges: ensure a perfect equipotential connection, always use groundings, do not wear work clothes made of acrylic fibres, preferably wearing cotton clothing and conductive footwear. Comply with the essential security requirements for equipment and systems defined in Directive 2014/34/EC (ATEX 100) and with the minimum requirements for protecting the security and health of workers under the selection criteria of Directive 1999/92/EC (ATEX 137). Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

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SECTION 7: HANDLING AND STORAGE (continued)

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

- Minimum Temp.: 2 °C
- Maximum Temp.: 8 °C
- Maximum time: 48 Months

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

Directive (EU) 2000/39, Directive 2004/37/EC, Directive (EU) 2006/15, Directive (EU) 2009/161, Directive (EU) 2017/164, Directive (EU) 2019/1831:

Identification		Occupational exposure limits		
methanol CAS: 67-56-1 EC: 200-659-6	IOELV (8h)	200 ppm	260 mg/m³	
	IOELV (STEL)			
Formic acid CAS: 64-18-6 EC: 200-579-1	IOELV (8h)	5 ppm	9 mg/m³	
	IOELV (STEL)			

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
methanol CAS: 67-56-1 EC: 200-659-6	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	20 mg/kg	Non-applicable	20 mg/kg	Non-applicable
	Inhalation	130 mg/m³	130 mg/m³	130 mg/m³	130 mg/m³
Formic acid CAS: 64-18-6 EC: 200-579-1	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	Non-applicable	9,5 mg/m³

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
methanol CAS: 67-56-1 EC: 200-659-6	Oral	4 mg/kg	Non-applicable	4 mg/kg	Non-applicable
	Dermal	4 mg/kg	Non-applicable	4 mg/kg	Non-applicable
	Inhalation	26 mg/m³	26 mg/m³	26 mg/m³	26 mg/m³
Formic acid CAS: 64-18-6 EC: 200-579-1	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	Non-applicable	Non-applicable	3 mg/m³

PNEC:

Identification				
methanol CAS: 67-56-1 EC: 200-659-6	STP	100 mg/L	Fresh water	20,8 mg/L
	Soil	100 mg/kg	Marine water	2,08 mg/L
	Intermittent	1540 mg/L	Sediment (Fresh water)	77 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	7,7 mg/kg

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Identification				
Formic acid CAS: 64-18-6 EC: 200-579-1	STP	7,2 mg/L	Fresh water	2 mg/L
	Soil	1,5 mg/kg	Marine water	0,2 mg/L
	Intermittent	1 mg/L	Sediment (Fresh water)	13,4 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	1,34 mg/kg


8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

In accordance with the order of importance to control professional exposure (Directive 98/24/EC) it is recommended to use localized extraction in the work area as a collective protection measure to avoid exceeding the occupational exposure limits. In case of using personal protective equipment it should have CE marking in accordance with Directive 2016/425/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For additional information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands





Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves (Material: Butyl, Breakthrough time: > 480 min, Thickness: 0.5 mm)		EN 420:2004+A1:2010	Replace the gloves at any sign of deterioration.

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Face shield		EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Disposable clothing for protection against chemical risks, with antistatic and fireproof properties		EN 1149-1:2,3 EN 13034:2005+A1:2009 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2013 EN ISO 6530:2005 EN ISO 13688:2013 EN 464:1994	For professional use only. Clean periodically according to the manufacturer's instructions.
 Mandatory foot protection	Safety footwear for protection against chemical risk, with antistatic and heat resistant properties		EN ISO 13287:2013 EN ISO 20345:2011 EN 13832-1:2019	Replace boots at any sign of deterioration.



F.- Additional emergency measures

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	5,05 % weight
V.O.C. density at 20 °C:	51,35 kg/m³ (51,35 g/L)
Average carbon number:	1
Average molecular weight:	32,14 g/mol

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Not available
Colour:	Not available
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	97 °C
Vapour pressure at 20 °C:	2651 Pa
Vapour pressure at 50 °C:	13610,82 Pa (13,61 kPa)
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	1016,9 kg/m³
Relative density at 20 °C:	1,017
Dynamic viscosity at 20 °C:	1,01 cP
Kinematic viscosity at 20 °C:	1 mm²/s
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	60 °C
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*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Flammability (solid, gas): Non-applicable *
 Autoignition temperature: 464 °C
 Lower flammability limit: Not available
 Upper flammability limit: Not available

Particle characteristics:

Median equivalent diameter: Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties: Non-applicable *
 Oxidising properties: Non-applicable *
 Corrosive to metals: Non-applicable *
 Heat of combustion: Non-applicable *
 Aerosols-total percentage (by mass) of flammable components: Non-applicable *

Other safety characteristics:

Surface tension at 20 °C: Non-applicable *
 Refraction index: Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Risk of combustion	Avoid direct impact	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Avoid direct impact	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.
- B- Inhalation (acute effect):
 - Acute toxicity : Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
 - Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as hazardous for skin contact. For more information see section 3.
 - Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
 - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
 - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
 - Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- F- Specific target organ toxicity (STOT) - single exposure:

Harmful effects for health in the case of ingestion, contact with the skin or inhalation after a single exposure, resulting in depression of the central nervous system causing headache, dizziness, vertigo, nausea, vomiting, confusion and, in serious cases, loss of consciousness.
- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
methanol	LD50 oral	>5000 mg/kg	Rat
CAS: 67-56-1	LD50 dermal	300 mg/kg	Rabbit
EC: 200-659-6	LC50 inhalation	3 mg/L (4 h)	Rat

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SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Acute toxicity:

Identification	Concentration	Species	Genus
methanol CAS: 67-56-1 EC: 200-659-6	LC50	15400 mg/L (96 h)	Lepomis macrochirus Fish
	EC50	12000 mg/L (96 h)	Nitrocra spinipes Crustacean
	EC50	530 mg/L (168 h)	Microcystis aeruginosa Algae
Formic acid CAS: 64-18-6 EC: 200-579-1	LC50	175 mg/L (24 h)	Lepomis macrochirus Fish
	EC50	120 mg/L (48 h)	Daphnia magna Crustacean
	EC50	26,9 mg/L (72 h)	Scenedesmus subspicatus Algae

Chronic toxicity:

Identification	Concentration	Species	Genus
methanol CAS: 67-56-1 EC: 200-659-6	NOEC	15800 mg/L	Oryzias latipes Fish
	NOEC	122 mg/L	Daphnia magna Crustacean
Formic acid CAS: 64-18-6 EC: 200-579-1	NOEC	Non-applicable	
	NOEC	100 mg/L	Daphnia magna Crustacean

12.2 Persistence and degradability:

Identification	Degradability		Biodegradability	
methanol CAS: 67-56-1 EC: 200-659-6	BOD5	Non-applicable	Concentration	100 mg/L
	COD	1,42 g O2/g	Period	14 days
	BOD5/COD	Non-applicable	% Biodegradable	92 %
Formic acid CAS: 64-18-6 EC: 200-579-1	BOD5	Non-applicable	Concentration	100 mg/L
	COD	Non-applicable	Period	14 days
	BOD5/COD	Non-applicable	% Biodegradable	110 %

12.3 Bioaccumulative potential:

Identification	Bioaccumulation potential	
methanol CAS: 67-56-1 EC: 200-659-6	BCF	3
	Pow Log	-0.77
	Potential	Low
Formic acid CAS: 64-18-6 EC: 200-579-1	BCF	3
	Pow Log	-0.54
	Potential	Low

12.4 Mobility in soil:

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SECTION 12: ECOLOGICAL INFORMATION (continued)

Identification	Absorption/desorption		Volatility	
methanol CAS: 67-56-1 EC: 200-659-6	Koc	Non-applicable	Henry	Non-applicable
	Conclusion	Non-applicable	Dry soil	Non-applicable
	Surface tension	2,355E-2 N/m (25 °C)	Moist soil	Non-applicable
Formic acid CAS: 64-18-6 EC: 200-579-1	Koc	Non-applicable	Henry	Non-applicable
	Conclusion	Non-applicable	Dry soil	Non-applicable
	Surface tension	3,862E-2 N/m (25 °C)	Moist soil	Non-applicable

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 06*	laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP3 Flammable, HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2021 and RID 2021:



- 14.1 UN number:** UN1993
- 14.2 UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (methanol)
- 14.3 Transport hazard class(es):** 3
- Labels: 3
- 14.4 Packing group:** III
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
- Special regulations: 274, 601
- Tunnel restriction code: D/E
- Physico-Chemical properties: see section 9
- Limited quantities: 5 L
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 39-18:

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SECTION 14: TRANSPORT INFORMATION (continued)



- 14.1 **UN number:** UN1993
- 14.2 **UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (methanol)
- 14.3 **Transport hazard class(es):** 3
Labels: 3
- 14.4 **Packing group:** III
- 14.5 **Marine pollutant:** No
- 14.6 **Special precautions for user**
Special regulations: 274, 223, 955
EmS Codes: F-E, S-E
Physico-Chemical properties: see section 9
Limited quantities: 5 L
Segregation group: Non-applicable
- 14.7 **Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:



- 14.1 **UN number:** UN1993
- 14.2 **UN proper shipping name:** FLAMMABLE LIQUID, N.O.S. (methanol)
- 14.3 **Transport hazard class(es):** 3
Labels: 3
- 14.4 **Packing group:** III
- 14.5 **Environmental hazards:** No
- 14.6 **Special precautions for user**
Physico-Chemical properties: see section 9
- 14.7 **Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

SECTION 15: REGULATORY INFORMATION

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

Regulation (EC) No 528/2012: contains a preservative to protect the initial properties of the treated article. Contains Formic acid.

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Formic acid (Product-type 2, 3, 4, 5, 6)

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Section	Description	Lower-tier requirements	Upper-tier requirements
P5c	FLAMMABLE LIQUIDS	5000	50000

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

- CONTINUED ON NEXT PAGE -

**Immunosuppressants, Mobile Phase I - 4191 P IMM**

SECTION 15: REGULATORY INFORMATION (continued)

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION **

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

- Pictograms
- Hazard statements

Texts of the legislative phrases mentioned in section 2:

H371: May cause damage to organs.

H226: Flammable liquid and vapour.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Acute Tox. 3: H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.

Flam. Liq. 2: H225 - Highly flammable liquid and vapour.

Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

STOT SE 1: H370 - Causes damage to organs.

Classification procedure:

STOT SE 2: Calculation method

Flam. Liq. 3: Calculation method (2.6.4.3)

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

** Changes with regards to the previous version

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -