



Miltenyi Biotec

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Printdate: 01.09.2025

Product ID: FoxP3 Staining Buffer Set
Product code: 130-093-142

Statement

A safety datasheet is provided for the following component(s) :

120-004-605: Fixation Permeabilization Solution 1 25 mL
120-004-606: Fixation Permeabilization Solution 2 40 mL
120-004-607: 10x Permeabilization Buffer 40 mL

If the product contains other components, the following is valid:

It is hereby stated that the respective product poses no health risk or physical and environmental hazard. It is not classified as hazardous based on our evaluations following the standards of the European Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures. A safety data sheet is not required according to Regulation (EC) No. 1907/2006 (REACH).

Despite the classification as non-hazardous, we strongly recommend reviewing the data sheets or instructions for use as well as applying appropriate safety measures like using personal protective equipment and considering disposal legislation and local regulations when handling chemicals and reagents.

Please contact technicalsupport@miltenyi.com for any further questions or additional safety information.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 1 of 10

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

1.1. Product identifier

Fixation/Permeabilization Solution 1 25 mL

UFI: GS00-R015-R00F-S8XV

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

Use of the substance/mixture

Scientific research and development

1.3. Details of the supplier of the safety data sheet

Company name: Miltenyi Biotec B.V. & Co. KG
Street: Friedrich-Ebert-Str. 68
Place: D-51429 Bergisch Gladbach
Telephone: +49 2204 8306-0
E-mail (Contact person): technicalsupport@miltenyi.com
Internet: www.miltenyibiotec.com
Responsible Department: Technical Support
Tel.: +49 2204 8306 3803

1.4. Emergency telephone number: GBK GmbH +49 (0)6132-84463 (24h)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute Tox. 4; H302
Acute Tox. 4; H332
Skin Sens. 1; H317
Muta. 2; H341
Carc. 1B; H350

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

Formaldehyde
Methanol

Signal word: Danger

Pictograms:



Hazard statements

H302+H332 Harmful if swallowed or if inhaled.
H317 May cause an allergic skin reaction.
H341 Suspected of causing genetic defects.
H350 May cause cancer.

Precautionary statements

P201 Obtain special instructions before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing and eye protection/face protection.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 2 of 10

P302+P352 IF ON SKIN: Wash with plenty of water.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P362+P364 Take off contaminated clothing and wash it before reuse.

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Composition/information on ingredients

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
50-00-0	Formaldehyde			1 - < 5 %
	200-001-8	605-001-00-5	01-2119488953-20	
	Carc. 1B, Muta. 2, Acute Tox. 2, Acute Tox. 3, Acute Tox. 3, Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1; H350 H341 H330 H311 H301 H314 H318 H317			
67-56-1	Methanol			1 - < 5 %
	200-659-6	603-001-00-X	01-2119433307-44	
	Flam. Liq. 2, Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, STOT SE 1; H225 H331 H311 H301 H370			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
50-00-0	200-001-8	Formaldehyde	1 - < 5 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: LC50 = 462 ppm (gases); dermal: LD50 = 270 mg/kg; oral: LD50 = 100 mg/kg Skin Corr. 1B; H314: >= 25 - 100 Skin Irrit. 2; H315: >= 5 - < 25 Eye Dam. 1; H318: >= 25 - 100 Eye Irrit. 2; H319: >= 5 - < 25 Skin Sens. 1; H317: >= 0,2 - 100 STOT SE 3; H335: >= 5 - 100	
67-56-1	200-659-6	Methanol	1 - < 5 %
		inhalation: ATE = 3 mg/l (vapours); inhalation: ATE = 0,5 mg/l (dusts or mists); dermal: ATE = 300 mg/kg; oral: ATE = 100 mg/kg STOT SE 1; H370: >= 10 - 100 STOT SE 2; H371: >= 3 - < 10	

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice. In case of inhaling spray mist, consult a physician.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary. Water and soap. In case of skin irritation, seek medical treatment. Change contaminated clothing.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 3 of 10

After contact with eyes

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist. Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Observe risk of aspiration if vomiting occurs. If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Seek medical advice immediately.

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

May cause an allergic skin reaction. Harmful if inhaled.

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

Treat symptomatically. Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Not combustible. Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide, Carbon dioxide (CO₂).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

Other information

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

6.4. Reference to other sections

Safe 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

Advice on safe handling

Avoid the formation of aerosol.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work. Wear personal protection equipment. Change contaminated

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 4 of 10

clothing.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

The following must be prevented: UV-radiation/sunlight. not useable after freezing.

Further information on storage conditions

storage temperature: 2-8°C

7.3. Specific end use(s)

Scientific research and development

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
50-00-0	Formaldehyde	0.3	0.37		TWA (8 h)	
		0.6	0.738		STEL (15 min)	
67-56-1	Methanol	200	260		TWA (8 h)	

Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
67-56-1	Methanol	Methanol	15 mg/L	Urine	End of shift

DNEL/DMEL values

CAS No	Substance	DNEL type	Exposure route	Effect	Value
67-56-1	Methanol				

8.2. Exposure controls



Appropriate engineering controls

Use extractor hood (laboratory).

If local exhaust ventilation is not possible or not sufficient, the entire working area should be ventilated by technical means.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection. Personal protection equipment

Hand protection

Tested protective gloves are to be worn: Single-use gloves. German Industry Norms (DIN) / European Norms (EN): EN ISO 374

Suitable material: NBR (Nitrile rubber). Breakthrough time: 480 min. (>= 0,4 mm)

Recommended protective gloves brand: Supreno, Manufacturer. Microfex Cooperation

Or comparable articles from other companies.

Skin protection

Personal protection equipment

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 5 of 10

Wash hands before breaks and after work.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Respiratory protection necessary at: aerosol or mist generation.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid	
Colour:	colourless	
Odour:	odourless	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		100 °C
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not determined
Decomposition temperature:		not determined
pH-Value (at 21 °C):		7,3
Viscosity / kinematic:		not determined
Water solubility:		highly soluble.
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density (at 21 °C):		1 g/cm ³
Relative vapour density:		not determined
Particle characteristics:		Nanoform: none

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:	not determined
Gas:	not determined

Other safety characteristics

Evaporation rate:	not determined
Viscosity / dynamic:	not determined

Further Information

Es liegen keine Informationen vor

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 6 of 10

10.5. Incompatible materials

Oxidising substances

10.6. Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Harmful if swallowed.

Harmful if inhaled.

ATEmix calculated

ATE (oral) 1961 mg/kg; ATE (dermal) 5411 mg/kg; ATE (inhalation vapour) 11,95 mg/l; ATE (inhalation dust/mist) 1,217 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
50-00-0	Formaldehyde				
	oral	LD50 100 mg/kg	Rat	Literature reference	
	dermal	LD50 270 mg/kg	Rabbit	RTECS	
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) gas	LC50 462 ppm			
67-56-1	Methanol				
	oral	ATE 100 mg/kg			
	dermal	ATE 300 mg/kg			
	inhalation vapour	ATE 3 mg/l			
	inhalation dust/mist	ATE 0,5 mg/l			

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (Formaldehyde)

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (Formaldehyde)

May cause cancer. (Formaldehyde)

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Specific effects in experiment on an animal

No information available.

Practical experience

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 7 of 10

11.2. Information on other hazards

Endocrine disrupting properties

Not listed

SECTION 12: Ecological information

12.1. Toxicity

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
50-00-0	Formaldehyde					
	Acute fish toxicity	LC50 6,7 mg/l	96 h		ECHA	
	Acute algae toxicity	ErC50 4,89 mg/l	72 h	Desmodesmus subspicatus	ECHA	
	Acute crustacea toxicity	EC50 5,8 mg/l	48 h	Daphnia pulex (water flea)	ECHA	
	Crustacea toxicity	NOEC > 6,4 mg/l	21 d			

12.2. Persistence and degradability

CAS No	Chemical name				
	Method	Value	d	Source	
	Evaluation				
50-00-0	Formaldehyde				
	OECD 301A	99%	28	ECHA	
	Readily biodegradable (according to OECD criteria).				

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
50-00-0	Formaldehyde	0,35

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations.

Contaminated packaging

Remove according to the regulations.

SECTION 14: Transport information

Land transport (ADR/RID)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 8 of 10

14.1. UN number or ID number:	Not classified
14.2. UN proper shipping name:	Not classified
14.3. Transport hazard class(es):	Not classified
14.4. Packing group:	Not classified

Inland waterways transport (ADN)

14.1. UN number or ID number:	Not classified
14.2. UN proper shipping name:	Not classified
14.3. Transport hazard class(es):	Not classified
14.4. Packing group:	Not classified

Marine transport (IMDG)

14.1. UN number or ID number:	Not classified
14.2. UN proper shipping name:	Not classified
14.3. Transport hazard class(es):	Not classified
14.4. Packing group:	Not classified

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	Not classified
14.2. UN proper shipping name:	Not classified
14.3. Transport hazard class(es):	Not classified
14.4. Packing group:	Not classified

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No data available

14.7. Maritime transport in bulk according to IMO instruments

Not classified

SECTION 15: Regulatory information

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 40, Entry 69, Entry 72, Entry 75

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Observe employment restrictions for women of child-bearing age.

Water hazard class (D): 2 - obviously hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Indication of changes:
SECTION 1: Identification

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 9 of 10

SECTION 2. Hazards identification
SECTION 3: Composition/information on ingredients
SECTION 9. Physical and chemical properties
SECTION 11: Toxicological information
SECTION 15: Regulatory information
SECTION 16: Other information

Abbreviations and acronyms

Flam. Liq: Flammable liquid
Acute Tox: Acute toxicity
Skin Corr: Skin corrosion
Eye Dam: Eye damage
Skin Sens: Skin sensitisation
Muta: Germ cell mutagenicity
Carc: Carcinogenicity
STOT SE: Specific target organ toxicity - single exposure
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 1 25 mL

Revision date: 19.08.2024

Product code: 120-004-605

Page 10 of 10

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Sens. 1; H317	Calculation method
Muta. 2; H341	Calculation method
Carc. 1B; H350	Calculation method

Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H302+H332	Harmful if swallowed or if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H370	Causes damage to organs.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 1 of 6

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

1.1. Product identifier

Fixation/Permeabilization Solution 2 40 mL

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

Use of the substance/mixture

Scientific research and development

1.3. Details of the supplier of the safety data sheet

Company name:	Miltenyi Biotec B.V. & Co. KG
Street:	Friedrich-Ebert-Str. 68
Place:	D-51429 Bergisch Gladbach
Telephone:	+49 2204 8306-0
E-mail (Contact person):	technicalsupport@miltenyi.com
Internet:	www.miltenyibiotec.com
Responsible Department:	Technical Support
	Tel.: +49 2204 8306 3803
	GBK GmbH +49 (0)6132-84463 (24h)

1.4. Emergency telephone number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Composition/information on ingredients

Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell.

After contact with skin

Water and soap. In case of skin irritation, seek medical treatment. Change contaminated clothing.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Seek medical advice immediately.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 2 of 6

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Not combustible. Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

No information available.

5.3. Advice for firefighters

Protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe 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

Advice on safe handling

Avoid the formation of aerosol.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

The following must be prevented: UV-radiation/sunlight. not useable after freezing.

Further information on storage conditions

storage temperature: 2-8 °C

7.3. Specific end use(s)

Scientific research and development

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 3 of 6

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Personal protection equipment

Hand protection

Tested protective gloves are to be worn: Single-use gloves. German Industry Norms (DIN) / European Norms (EN): EN ISO 374

Suitable material: NBR (Nitrile rubber).

Recommended protective gloves brand: Supreno, Manufacturer. Microfex Cooperation

Or comparable articles from other companies.

Skin protection

Personal protection equipment

Wash hands before breaks and after work.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid	
Colour:	colourless - light yellow	
Odour:	odourless	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		100 °C
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not determined
Decomposition temperature:		not determined
pH-Value (at 21 °C):		7,0
Viscosity / kinematic:		not determined
Water solubility:		highly soluble.
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density (at 21 °C):		1 g/cm ³
Relative vapour density:		not determined
Particle characteristics:		Nanoform: none

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature

Solid:

not determined

Gas:

not determined

Other safety characteristics

Evaporation rate:

not determined

Viscosity / dynamic:

not determined

Further Information

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 4 of 6

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicokinetics, metabolism and distribution

Toxicological data are not available.

Acute toxicity

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

ATE_{mix} calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Specific effects in experiment on an animal

No information available.

Practical experience

No information available.

11.2. Information on other hazards

Endocrine disrupting properties

Not listed

SECTION 12: Ecological information

12.4. Mobility in soil

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 5 of 6

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations.

Contaminated packaging

Completely emptied packings can be re-cycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

-

14.2. UN proper shipping name:

Not a hazardous material with respect to these transportation regulations.

14.3. Transport hazard class(es):

-

14.4. Packing group:

-

Inland waterways transport (ADN)

14.1. UN number or ID number:

-

14.2. UN proper shipping name:

Not a hazardous material with respect to these transportation regulations.

14.3. Transport hazard class(es):

-

14.4. Packing group:

-

Marine transport (IMDG)

14.1. UN number or ID number:

-

14.2. UN proper shipping name:

Not a hazardous material with respect to these transportation regulations.

14.3. Transport hazard class(es):

-

14.4. Packing group:

-

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

-

14.2. UN proper shipping name:

Not a hazardous material with respect to these transportation regulations.

14.3. Transport hazard class(es):

-

14.4. Packing group:

-

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

none

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): - - non-hazardous to water

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Fixation/Permeabilization Solution 2 40 mL

Revision date: 07.03.2024

Product code: 120-004-606

Page 6 of 6

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Indication of changes:

SECTION 1: Identification of the substance/mixture and of the company/undertaking (Emergency telephone number)

SECTION 7: Handling and storage

SECTION 9: Physical and chemical properties

SECTION 11: Toxicological information

Abbreviations and acronyms

CLP: Classification, labelling and Packaging

REACH: Registration, Evaluation and Authorization of Chemicals

GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals

UN: United Nations

CAS: Chemical Abstracts Service

DNEL: Derived No Effect Level

DMEL: Derived Minimal Effect Level

PNEC: Predicted No Effect Concentration

ATE: Acute toxicity estimate

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

LL50: Lethal loading, 50%

EL50: Effect loading, 50%

EC50: Effective Concentration 50%

ErC50: Effective Concentration 50%, growth rate

NOEC: No Observed Effect Concentration

BCF: Bio-concentration factor

PBT: persistent, bioaccumulative, toxic

vPvB: very persistent, very bioaccumulative

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

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Regulations concerning the international carriage of dangerous goods by rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

IMDG: International Maritime Code for Dangerous Goods

EmS: Emergency Schedules

MFAG: Medical First Aid Guide

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

MARPOL: International Convention for the Prevention of Marine Pollution from Ships

IBC: Intermediate Bulk Container

SVHC: Substance of Very High Concern

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 1 of 8

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

1.1. Product identifier

10x Permeabilization Buffer 40 mL

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

Use of the substance/mixture

Scientific research and development

1.3. Details of the supplier of the safety data sheet

Company name: Miltenyi Biotec B.V. & Co. KG
Street: Friedrich-Ebert-Str. 68
Place: D-51429 Bergisch Gladbach
Telephone: +49 2204 8306-0
E-mail (Contact person): technicalsupport@miltenyi.com
Internet: www.miltenyibiotec.com
Responsible Department: Technical Support
Tel.: +49 2204 8306 3803

1.4. Emergency telephone number:

GBK GmbH +49 (0)6132-84463 (24h)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Regulation (EC) No 1272/2008

Special labelling of certain mixtures

EUH210 Safety data sheet available on request.

2.3. Other hazards

No risks worthy of mention.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Composition/information on ingredients

Hazardous components

CAS No	Chemical name	Quantity		
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
9048-46-8	Bovine Serum Albumin	15 - < 20 %		
	232-936-2			
	Acute Tox. 4; H302			
8047-15-2	Saponin	1 - < 5 %		
	232-462-6			
	Eye Irrit. 2, STOT SE 3; H319 H335			

Full text of H and EUH statements: see section 16.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 2 of 8

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
9048-46-8	232-936-2	Bovine Serum Albumin	15 - < 20 %
		oral: ATE = 500 mg/kg	
8047-15-2	232-462-6	Saponin	1 - < 5 %
		inhalation: LC50 = >0,45 mg/l (vapours); dermal: LD50 = >2000 mg/kg; oral: LD50 = >5000 mg/kg	

Further Information

Contains: Sodiumazide: <0,1%

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell.

After contact with skin

Water and soap. In case of skin irritation, seek medical treatment. Change contaminated clothing.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Seek medical advice immediately.

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Not combustible. Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

No information available.

5.3. Advice for firefighters

Protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Wear personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 3 of 8

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid the formation of aerosol.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

The following must be prevented: UV-radiation/sunlight. not useable after freezing.

Further information on storage conditions

storage temperature: 21°C

7.3. Specific end use(s)

Scientific research and development

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
8047-15-2	Saponin			
Consumer DMEL, long-term		oral	systemic	15 mg/kg bw/day

PNEC values

CAS No	Substance	Value
8047-15-2	Saponin	
Freshwater		0,0388 mg/l
Freshwater (intermittent releases)		0,388 mg/l
Marine water		0,00388 mg/l
Micro-organisms in sewage treatment plants (STP)		1 mg/l

Additional advice on limit values

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. Exposure controls

Individual protection measures, such as personal protective equipment

Eye/face protection

Personal protection equipment

Hand protection

Tested protective gloves are to be worn: Single-use gloves. German Industry Norms (DIN) / European Norms (EN): EN ISO 374

Suitable material: NBR (Nitrile rubber).

Recommended protective gloves brand: Supreno, Manufacturer: Microfex Cooperation

Or comparable articles from other companies.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 4 of 8

Skin protection

Personal protection equipment
Wash hands before breaks and after work.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls

Do not allow to enter into surface water or drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid	
Colour:	colourless - light yellow	
Odour:	odourless	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		100 °C
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not determined
Decomposition temperature:		not determined
pH-Value (at 21 °C):		6.0 - 8.0
Viscosity / kinematic:		not determined
Water solubility:		highly soluble.
Partition coefficient n-octanol/water:		not determined
Vapour pressure:		not determined
Density (at 21 °C):		1,1 g/cm ³
Relative vapour density:		not determined
Particle characteristics:		Nanoform: none

9.2. Other information

Information with regard to physical hazard classes

Self-ignition temperature	
Solid:	not determined
Gas:	not determined

Other safety characteristics

Evaporation rate:	not determined
Viscosity / dynamic:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 5 of 8

10.4. Conditions to avoid

May cause decomposition by long-term light influence.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

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

ATEmix calculated

ATE (oral) 3333 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
9048-46-8	Bovine Serum Albumin				
	oral	ATE mg/kg	500		
8047-15-2	Saponin				
	oral	LD50 mg/kg	>5000	Rat	REACH Dossier EPA OPPTS 870.1100
	dermal	LD50 mg/kg	>2000	Rat	REACH Dossier EPA OPPTS 870.1200
	inhalation (4 h) vapour	LC50 mg/l	>0,45	Rat	REACH Dossier OECD Guideline 403

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Specific effects in experiment on an animal

No information available.

Practical experience

No information available.

11.2. Information on other hazards

Endocrine disrupting properties

Not listed

SECTION 12: Ecological information

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 6 of 8

12.1. Toxicity

Data apply to the technically active substance. The product is not: Toxic to aquatic organisms.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
8047-15-2	Saponin					
	Acute fish toxicity	LC50 mg/l	38,8	96 h	Leuciscus Idus Melanotus	REACH Registration Dossier
	Acute algae toxicity	ErC50	800 mg/l	72 h	Scenedesmus subspicatus	REACH Registration Dossier
	Acute crustacea toxicity	EC50	65 mg/l	48 h	Daphia magna	REACH Registration Dossier
	Fish toxicity	NOEC	10 mg/l	48 d		
	Algae toxicity	NOEC	800 mg/l	72 d		
	Crustacea toxicity	NOEC	20 mg/l	48 d		
	Acute bacteria toxicity	(EC50 mg/l)	10000			DIN 38412 L8

12.2. Persistence and degradability

Readily biodegradable (according to OECD criteria).

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
8047-15-2	Saponin			
	OECD Guideline 301E	90,1%	28	REACH Dossier
	readily biodegradable			

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations.

Contaminated packaging

Completely emptied packings can be re-cycled.

SECTION 14: Transport information

Land transport (ADR/RID)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 7 of 8

- 14.1. UN number or ID number:** -
14.2. UN proper shipping name: Not a hazardous material with respect to these transportation regulations.
14.3. Transport hazard class(es): -
14.4. Packing group: -

Inland waterways transport (ADN)

- 14.1. UN number or ID number:** -
14.2. UN proper shipping name: Not a hazardous material with respect to these transportation regulations.
14.3. Transport hazard class(es): -
14.4. Packing group: -

Marine transport (IMDG)

- 14.1. UN number or ID number:** -
14.2. UN proper shipping name: Not a hazardous material with respect to these transportation regulations.
14.3. Transport hazard class(es): -
14.4. Packing group: -

Air transport (ICAO-TI/IATA-DGR)

- 14.1. UN number or ID number:** -
14.2. UN proper shipping name: Not a hazardous material with respect to these transportation regulations.
14.3. Transport hazard class(es): -
14.4. Packing group: -

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

none

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

National regulatory information

Water hazard class (D): 2 - obviously hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Indication of changes:

SECTION 1: Identification of the substance/mixture and of the company/undertaking (Emergency telephone number)

SECTION 7: Handling and storage

SECTION 9: Physical and chemical properties

SECTION 11: Toxicological information

Safety Data Sheet

according to Regulation (EC) No 1907/2006

10x Permeabilization Buffer 40 mL

Revision date: 07.03.2024

Product code: 120-004-607

Page 8 of 8

Abbreviations and acronyms

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).
Acute Tox: Acute toxicity
Eye Irrit: Eye irritation
STOT SE: Specific target organ toxicity - single exposure

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
EUH210	Safety data sheet available on request.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)