


# SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2020/878

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

### 1.1 Product identifier

Product name	<b>HiTrap™ MabSelect™ mild elution, 5 x 1 ml</b>	
Catalogue Number	<b>17542352</b>	 9 0 1 7 5 4 2 3 5 2
Product description	Not available.	
Product type	Liquid.	
Other means of identification	Not available.	

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

	Identified uses
Laboratory chemicals	
Liquid chromatography.	
Scientific research and development	
Consumer use	-

### 1.3 Details of the supplier of the safety data sheet

<b>Supplier</b>	Cytiva Amersham Place Little Chalfont Buckinghamshire HP7 9NA United Kingdom +44 1494 508000	<b>Hours of operation</b> 08.30 - 17.00
<b>Person who prepared the SDS :</b> sds_author@cytiva.com		

<b>Switzerland</b>	Cytiva Switzerland Europastrasse 31 CH-8152 Glattbrugg Switzerland t: 0848 8028 10	<b>1.4 Emergency telephone number</b> Call INFOTRAC 24 Hour number: 001-352-323-3500 (Call Collect).
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### National advisory body/Poison Centre

<b>Switzerland</b>	Vergiftungsnotruf Tel: 145
Aus dem Ausland oder bei technischen Problemen: +41 44 251 51 51	
<a href="https://www.toxinfo.ch/notruf-145">https://www.toxinfo.ch/notruf-145</a>	

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Product definition	Mixture
<b>Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]</b>	
Flam. Liq. 3, H226	

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

**Ingredients of unknown toxicity** 16.5 percent of the mixture consists of component(s) of unknown acute dermal toxicity

**Ingredients of unknown ecotoxicity** Not applicable.

See Section 16 for the full text of the H statements declared above.  
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms



**Signal word** Warning  
**Hazard statements** Flammable liquid and vapour.

Precautionary statements

**General** Not applicable.  
**Prevention** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
**Response** Not applicable.  
**Storage** Not applicable.  
**Disposal** Dispose of contents and container in accordance with all local, regional, national and international regulations.  
**Supplemental label elements** Not applicable.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** Not applicable.

Special packaging requirements

**Containers to be fitted with child-resistant fastenings** Not applicable.  
  
**Tactile warning of danger** Not applicable.

2.3 Other hazards

**Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII**

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

**Other hazards which do not result in classification** None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures Mixture

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
ethanol	REACH #: 01-2119457610-43 EC: 200-578-6 CAS: 64-17-5 Index: 603-002-00-5	14 - 19	Flam. Liq. 2, H225 -  See Section 16 for the full text of the H statements declared above.	[1] [2]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a physical, health or environmental hazard  
[2] Substance with a workplace exposure limit  
Occupational exposure limits, if available, are listed in Section 8.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

<b>Eye contact</b>	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing.
<b>Skin contact</b>	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
<b>Ingestion</b>	Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel.
<b>Protection of first-aiders</b>	No action shall be taken involving any personal risk or without suitable training.

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

#### Over-exposure signs/symptoms

<b>Eye contact</b>	No specific data.
<b>Inhalation</b>	No specific data.
<b>Skin contact</b>	No specific data.
<b>Ingestion</b>	No specific data.

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

<b>Notes to physician</b>	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
<b>Specific treatments</b>	No specific treatment.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

<b>Suitable extinguishing media</b>	Use dry chemical, CO <sub>2</sub> , water spray (fog) or foam.
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<b>Unsuitable extinguishing media</b>	Do not use water jet.
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### 5.2 Special hazards arising from the substance or mixture

<b>Hazards from the substance or mixture</b>	Flammable liquid and vapour. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.
<b>Hazardous combustion products</b>	Decomposition products may include the following materials: carbon dioxide carbon monoxide

### 5.3 Advice for firefighters

<b>Special precautions for fire-fighters</b>	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
<b>Special protective equipment for fire-fighters</b>	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Put on appropriate personal protective equipment.
<b>For emergency responders</b>	If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

### 6.2 Environmental precautions

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### 6.3 Methods and material for containment and cleaning up

<b>Small spill</b>	Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
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Large spill	Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.
6.4 Reference to other sections	See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by earthing and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. See Section 10 for incompatible materials before handling or use.

Seveso Directive - Reporting thresholds (in tonnes)

Danger criteria		
Category	Notification and MAPP threshold	Safety report threshold
P5c	5000	50000

7.3 Specific end use(s)

Recommendations	Analytical chemistry. Liquid chromatography. Scientific research and development.
Industrial sector specific solutions	Not available.

SECTION 8: Exposure controls/personal protection

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario (s).

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
ethanol	SUVA (Switzerland, 1/2025) Carc 1A, Repr 1A. TWA 8 hours: 500 ppm. TWA 8 hours: 960 mg/m³. STEL 15 minutes: 1000 ppm. STEL 15 minutes: 1920 mg/m³.

Biological exposure indices

No exposure indices known.

**Recommended monitoring procedures**

Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

**DNELs/DMELs****Product/ingredient name**

ethanol

**Result****DNEL - Workers - Long term - Inhalation**380 mg/m<sup>3</sup>Effects: Systemic**DNEL - General population - Long term - Oral**

87 mg/kg bw/day

Effects: Systemic**DNEL - General population - Long term - Inhalation**114 mg/m<sup>3</sup>Effects: Systemic**DNEL - General population - Long term - Dermal**

206 mg/kg bw/day

Effects: Systemic**DNEL - Workers - Long term - Dermal**

343 mg/kg bw/day

Effects: Systemic**DNEL - General population - Short term - Inhalation**950 mg/m<sup>3</sup>Effects: Local**DNEL - Workers - Short term - Inhalation**1900 mg/m<sup>3</sup>Effects: Local**PNECs**

Not available.

**8.2 Exposure controls****Appropriate engineering controls**

Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapour or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

**Individual protection measures****Hygiene measures**

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection**

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. Recommended: safety glasses with side-shields

**Skin protection****Hand protection**

Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. 1 - 4 hours (breakthrough time): butyl rubber, neoprene

**Body protection**

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves. Refer to European Standard EN 1149 for further information on material and design requirements and test methods. Recommended: lab coat

**Other skin protection**

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

**Respiratory protection**

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use. Recommended: A respirator is not needed under normal and intended conditions of product use.



Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
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SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

<b>Appearance</b>			
Physical state	Liquid.		
Colour	White. White to yellowish.		
Odour	Alcohol-like. [Slight]		
Odour threshold	180 ppm		
Melting point/freezing point	Not available.		
Boiling point or initial boiling point and boiling range	Not available.		
Flammability	Not available.		
Lower and upper explosion limit	Not available.		
Flash point	Closed cup: 38 to 43°C		
Auto-ignition temperature	Not available.		
Ingredient name	°C	Method	
ethanol	455	DIN 51794	
Decomposition temperature	Not available.		
pH	5.5 to 8.5 [Conc. (% w/w): 100%]		
Viscosity	Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C): Not available.		
Solubility			
Media	Result		
cold water	Easily soluble		
hot water	Easily soluble		
Solubility in water	Not available.		
Partition coefficient: n-octanol/ water	Not applicable.		
Vapour pressure	Not available.		

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity</b>	No specific test data related to reactivity available for this product or its ingredients.
<b>10.2 Chemical stability</b>	The product is stable.
<b>10.3 Possibility of hazardous reactions</b>	Under normal conditions of storage and use, hazardous reactions will not occur.
<b>10.4 Conditions to avoid</b>	Avoid all possible sources of ignition (spark or flame). Do not pressurise, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
<b>10.5 Incompatible materials</b>	Reactive or incompatible with the following materials: oxidising materials
<b>10.6 Hazardous decomposition products</b>	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

**Product/ingredient name**

ethanol

**Result****Rat - Oral - LD50**

7060 mg/kg

Toxic effects: Lung, Thorax, or Respiration - Other changes**Rat - Inhalation - LC50 Vapour**124700 mg/m<sup>3</sup> [4 hours]**Conclusion/Summary [Product]** Not available.**Acute toxicity estimates**

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapours) (mg/l)	Inhalation (dusts and mists) (mg/l)
ethanol	7000	N/A	N/A	124.7	N/A

**Skin corrosion/irritation**

Not available.

**Conclusion/Summary [Product]** Repeated exposure may cause skin dryness or cracking.**Serious eye damage/eye irritation**

Not available.

**Conclusion/Summary [Product]** Not available.**Respiratory corrosion/irritation**

Not available.

**Conclusion/Summary [Product]** Not available.**Respiratory or skin sensitization**

Not available.

**Skin****Conclusion/Summary [Product]** Not available.**Respiratory****Conclusion/Summary [Product]** Not available.**Germ cell mutagenicity**

Not available.

**Conclusion/Summary [Product]** Not available.**Carcinogenicity**

Not available.



**Conclusion/Summary [Product]** Not available.

**Reproductive toxicity**

Not available.

**Conclusion/Summary [Product]** Not available.

**Specific target organ toxicity (single exposure)**

Not available.

**Specific target organ toxicity (repeated exposure)**

Not available.

**Aspiration hazard**

Not available.

**Information on likely routes of exposure** Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

**Potential acute health effects**

<b>Inhalation</b>	No known significant effects or critical hazards.
<b>Ingestion</b>	No known significant effects or critical hazards.
<b>Skin contact</b>	No known significant effects or critical hazards.
<b>Eye contact</b>	No known significant effects or critical hazards.

**Symptoms related to the physical, chemical and toxicological characteristics**

<b>Inhalation</b>	No specific data.
<b>Ingestion</b>	No specific data.
<b>Skin contact</b>	No specific data.
<b>Eye contact</b>	No specific data.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Short term exposure**

**Potential immediate effects** Not available.

**Potential delayed effects** Not available.

**Long term exposure**

**Potential immediate effects** Not available.

**Potential delayed effects** Not available.

**Potential chronic health effects**

Not available.

**Conclusion/Summary [Product]** Not available.

<b>General</b>	No known significant effects or critical hazards.
<b>Carcinogenicity</b>	No known significant effects or critical hazards.
<b>Mutagenicity</b>	No known significant effects or critical hazards.
<b>Reproductive toxicity</b>	No known significant effects or critical hazards.

**11.2 Information on other hazards**

**11.2.1 Endocrine disrupting properties**

Not available.

**Conclusion/Summary [Product]** The product does not meet the criteria to be considered as having endocrine disrupting properties according to the criteria set out in either Regulation (EC) No. 1907/2006 or Regulation (EC) No 1272/2008.

**11.2.2 Other information**

Not available.





SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name

ethanol

Result

Acute - LC50 - Marine water

Fish - Bleak - *Alburnus alburnus*

Size: 8 to 10 cm

11 g/l [96 hours]

Effect: Mortality

Chronic - NOEC - Marine water

Algae - Green algae - *Ulva pertusa*

4.995 mg/l [96 hours]

Effect: Reproduction

Acute - EC50 - Fresh water

Crustaceans - Ostracod - *Cypris subglobosa*

1074 mg/l [48 hours]

Effect: Intoxication

Chronic - NOEC - Fresh water

Daphnia - Water flea - *Daphnia magna* - Neonate

Age: <24 hours

100 µl/l [21 days]

Effect: Mortality

Acute - EC50 - Marine water

Algae - Green algae - *Ulva pertusa*

Size: 9.4 mm

3306 mg/l [96 hours]

Effect: Reproduction

Conclusion/Summary [Product] Not available.

12.2 Persistence and degradability

Product/ingredient name

ethanol

Result

Aerobic

100% [20 days] - Readily

Conclusion/Summary [Product] Not available.

Product/ingredient name

ethanol

Aquatic half-life

-

Photolysis

-

Biodegradability

Readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
ethanol	-0.35	0.66	Low

12.4 Mobility in soil

Soil/water partition coefficient

Product/ingredient name

ethanol

logK<sub>oc</sub>

0.2

K<sub>oc</sub>

1.59008

Results of PMT and vPvM assessment

Product/ingredient name

ethanol

PMT

No

P

N/A

M

Yes

T

No

vPvM

N/A

vP

N/A

vM

Yes

Mobility

Not available.

Conclusion/Summary

The product does not meet the criteria to be considered as a PMT or vPvM.

12.5 Results of PBT and vPvB assessment

Regulation (EC) No. 1907/2006 [REACH]

Product/ingredient name

ethanol

PBT

No

P

N/A

B

No

T

No

vPvB

No

vP

N/A

vB

No

Regulation (EC) No. 1272/2008 [CLP]

Product/ingredient name

ethanol

PBT

No

P

N/A

B

No

T

No

vPvB

No

vP

N/A

vB

No

Conclusion/Summary

The product does not meet the criteria to be considered as a PBT or vPvB.

Regulation (EC) No. 1272/2008  
[CLP]

12.6 Endocrine disrupting properties



Not applicable.

**Conclusion/Summary [Product]** The product does not meet the criteria to be considered as having endocrine disrupting properties according to the criteria set out in either Regulation (EC) No. 1907/2006 or Regulation (EC) No 1272/2008.

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

**Methods of disposal**

Dispose of contents and container in accordance with all local, regional, national and international regulations. Avoid release to the environment. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

**Hazardous waste**

Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

European waste catalogue (EWC)

Waste code	Waste designation
07 07 99	wastes not otherwise specified

Packaging

**Methods of disposal**

The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

**Special precautions**

This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapour from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	<b>Remarks</b> IATA Special Provision A 58 - Aqueous solutions containing 24% or less alcohol by volume is not subject to these regulations.

**14.6 Special precautions for user**

**Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**14.7 Transport in bulk according to IMO instruments**

Not available.



SECTION 15: Regulatory information

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

**EU Regulation (EC) No. 1907/2006 (REACH)**

**Annex XIV - List of substances subject to authorisation**

**Annex XIV**

None of the components are listed.

**Substances of very high concern**

None of the components are listed.

**Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles**

Product/ingredient name	%	Designation [Usage]
HiTrap MabSelect mild elution, 5 x 1 ml	≥90	3
Labelling	Not applicable.	

**Synthetic polymer microparticles - Designation 78**

**Generic identity of polymer(s)** Chemically modified agarose

**Total percentage of synthetic polymer microparticles** 100%

The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

**Other EU regulations**

**Industrial emissions (integrated pollution prevention and control) - Air** Not listed

**Industrial emissions (integrated pollution prevention and control) - Water** Not listed

**Explosive precursors** Not applicable.

**Ozone depleting substances (EU 2024/590)**

Not listed.

**Prior Informed Consent (PIC) (649/2012/EU)**

Not listed.

**Persistent Organic Pollutants**

Not listed.

**Seveso Directive**

This product is controlled under the Seveso Directive.

**Danger criteria**

**Category**  
P5c

**National regulations**

**VOC content** VOC (w/w): 16.5%

**International regulations**

**Chemical Weapon Convention List Schedules I, II & III Chemicals**

Not listed.

**Montreal Protocol**

Not listed.

**Stockholm Convention on Persistent Organic Pollutants**

Not listed.

**Rotterdam Convention on Prior Informed Consent (PIC)**

Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals**

Not listed.

**Inventory list**

United States	Not determined.
Canada inventory	All components are listed or exempted.
China	All components are listed or exempted.
Japan	<b>Japan inventory (CSCL):</b> All components are listed or exempted. <b>Japan inventory (ISHL):</b> Not determined.
15.2 Chemical safety assessment	This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

 Indicates information that has changed from previously issued version.

Abbreviations and acronyms	ATE = Acute Toxicity Estimate CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008] DMEL = Derived Minimal Effect Level DNEL = Derived No Effect Level EUH statement = CLP-specific Hazard statement N/A = Not available PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number vPvB = Very Persistent and Very Bioaccumulative
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Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification		Justification
Flam. Liq. 3, H226		On basis of test data
Full text of abbreviated H statements	H225	Highly flammable liquid and vapour.
	H226	Flammable liquid and vapour.
Full text of classifications [CLP/GHS]	Flam. Liq. 2	FLAMMABLE LIQUIDS - Category 2
	Flam. Liq. 3	FLAMMABLE LIQUIDS - Category 3
Date of printing	27 October 2025	
Date of issue/ Date of revision	27 October 2025	
Date of previous issue	No previous validation	
Version	1	

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.