

SAFETY DATA SHEET



Antibodies Reagent IVD Kit

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

1.1 Product identifier

Product name : Antibodies Reagent IVD Kit
Part no. (chemical kit) : None assigned.
Part no. : Antibody Reagents IVD 8920008, 8930008, 8920197, 8920250, 8930250, 8920251, 8920250CE, 8930250CE, 8920251CE, 8920008CE, 8930008CE, 8920197CE, 891B604, 892B604, 891B604CE, 892B604CE
 Acealyse solution

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

Identified uses : For In Vitro Diagnostic Use
 8920008, 8920008CE CD3/CD8/CD45/CD4 antibody kit 1 ml
 8930008, 8930008CE CD3/CD8/CD45/CD4 antibody kit 2 ml
 8920197, 8920197CE FITC HLA-B27 / PerCP CD3 antibody Kit 1 ml
 8920250, 8920250CE CD3/CD16+CD56/CD45/CD19 antibody kit 1 ml
 8930250, 8930250CE CD3/CD16+CD56/CD45/CD19 antibody kit 2 ml
 8920251, 8920251CE CD3/CD16+CD56/CD45/CD4/CD19 /CD8 kit 1 ml
 891B604, 891B604CE 5 ml
 892B604, 892B604CE 10 ml

Uses advised against : None known.

1.3 Details of the supplier of the safety data sheet

Agilent Technologies Deutschland GmbH
 Hewlett-Packard-Str. 8
 76337 Waldbronn
 Germany
 0800 603 1000
e-mail address of person responsible for this SDS : pdl-msds_author@agilent.com

1.4 Emergency telephone number

Emergency telephone number (with hours of operation) : CHEMTREC®: +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Antibody Reagents IVD Mixture
 Acealyse solution Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Acealyse solution

H302	ACUTE TOXICITY (oral)	Category 4
H315	SKIN CORROSION/IRRITATION	Category 2
H319	SERIOUS EYE DAMAGE/EYE IRRITATION	Category 2
H317	SKIN SENSITISATION	Category 1
H341	GERM CELL MUTAGENICITY	Category 2
H350	CARCINOGENICITY	Category 1B
H335	SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation)	Category 3

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SECTION 2: Hazards identification

Antibody Reagents IVD	The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.
Acealyse solution	The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity : Acealyse solution Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 1 - 10%

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 : Acealyse solution



Signal word : Antibody Reagents IVD
Acealyse solution No signal word.
Danger

Hazard statements : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards.
H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H341 - Suspected of causing genetic defects.
H350 - May cause cancer.

Precautionary statements

Prevention : Antibody Reagents IVD
Acealyse solution Not applicable.
P201 - Obtain special instructions before use.
P280 - Wear protective gloves, protective clothing and eye or face protection.
P261 - Avoid breathing vapour.

Response : Antibody Reagents IVD
Acealyse solution Not applicable.
P308 + P313 - IF exposed or concerned: Get medical advice or attention.

Storage : Antibody Reagents IVD
Acealyse solution Not applicable.
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.

Disposal : Antibody Reagents IVD
Acealyse solution Not applicable.
P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazardous ingredients : Acealyse solution 2,2'-oxybisethanol and formaldehyde

Supplemental label elements : Antibody Reagents IVD
Acealyse solution Not applicable.
Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Antibody Reagents IVD
Acealyse solution Not applicable.
Restricted to professional users.

Special packaging requirements

Tactile warning of danger : Antibody Reagents IVD
Acealyse solution Not applicable.
Not applicable.

2.3 Other hazards

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SECTION 2: Hazards identification

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : Antibody Reagents IVD This mixture does not contain any substances that are assessed to be a PBT or a vPvB.
 Acealyse solution 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 : Antibody Reagents IVD None known.
 Acealyse solution None known.

SECTION 3: Composition/information on ingredients

3.1 Substances : Antibody Reagents IVD Mixture
 Acealyse solution Mixture

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
Acealyse solution					
2,2' -oxybisethanol	EC: 203-872-2 CAS: 111-46-6 Index: 603-140-00-6	≥25 - ≤50	Acute Tox. 4, H302	ATE [Oral] = 500 mg/kg	[1] [2]
formaldehyde	EC: 200-001-8 CAS: 50-00-0 Index: 605-001-00-5	≤10	Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 STOT SE 3, H335	ATE [Oral] = 100 mg/kg ATE [Dermal] = 270 mg/kg ATE [Inhalation (vapours)] = 3 mg/l Skin Corr. 1B, H314: C ≥ 25% Skin Irrit. 2, H315: 5% ≤ C < 25% Eye Dam. 1, H318: C ≥ 25% Eye Irrit. 2, H319: 5% ≤ C < 25% Skin Sens. 1, H317: C ≥ 0.2% STOT SE 3, H335: C ≥ 5%	[1] [2]
			See Section 16 for the full text of the H statements declared above.		

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type
 Acealyse solution [1] Substance classified with a 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

Eye contact : Antibody Reagents IVD 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.
 Acealyse solution Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

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SECTION 4: First aid measures

Inhalation	: Antibody Reagents IVD	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
	Acealyse solution	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin contact	: Antibody Reagents IVD	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
	Acealyse solution	Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Ingestion	: Antibody Reagents IVD	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. Get medical attention if symptoms occur.
	Acealyse solution	Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Protection of first-aiders	: Antibody Reagents IVD	No action shall be taken involving any personal risk or without suitable training.
	Acealyse solution	No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact	: Antibody Reagents IVD	No known significant effects or critical hazards.
	Acealyse solution	Causes serious eye irritation.
Inhalation	: Antibody Reagents IVD	No known significant effects or critical hazards.
	Acealyse solution	May cause respiratory irritation.
Skin contact	: Antibody Reagents IVD	No known significant effects or critical hazards.
	Acealyse solution	Causes skin irritation. May cause an allergic skin reaction.

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SECTION 4: First aid measures

Ingestion : Antibody Reagents IVD : No known significant effects or critical hazards.
 Acealyse solution : Harmful if swallowed.

Over-exposure signs/symptoms

Eye contact : Antibody Reagents IVD : No specific data.
 Acealyse solution : Adverse symptoms may include the following:
 pain or irritation
 watering
 redness

Inhalation : Antibody Reagents IVD : No specific data.
 Acealyse solution : Adverse symptoms may include the following:
 respiratory tract irritation
 coughing

Skin contact : Antibody Reagents IVD : No specific data.
 Acealyse solution : Adverse symptoms may include the following:
 irritation
 redness

Ingestion : Antibody Reagents IVD : No specific data.
 Acealyse solution : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Antibody Reagents IVD : Treat symptomatically. Contact poison treatment specialist
 Acealyse solution : immediately if large quantities have been ingested or inhaled.
 Treat symptomatically. Contact poison treatment specialist
 immediately if large quantities have been ingested or inhaled.

Specific treatments : Antibody Reagents IVD : No specific treatment.
 Acealyse solution : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Antibody Reagents IVD : Use an extinguishing agent suitable for the surrounding fire.
 Acealyse solution : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : Antibody Reagents IVD : None known.
 Acealyse solution : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : Antibody Reagents IVD : In a fire or if heated, a pressure increase will occur and the
 Acealyse solution : container may burst.
 In a fire or if heated, a pressure increase will occur and the
 container may burst.

Hazardous combustion products : Antibody Reagents IVD : No specific data.
 Acealyse solution : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 metal oxide/oxides

5.3 Advice for firefighters

Special precautions for fire-fighters : Antibody Reagents IVD : Promptly isolate the scene by removing all persons from the
 Acealyse solution : vicinity of the incident if there is a fire. No action shall be
 taken involving any personal risk or without suitable training.
 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.

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SECTION 5: Firefighting measures

Special protective equipment for fire-fighters	: Antibody Reagents IVD	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.
	Acealyse solution	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

For non-emergency personnel	: Antibody Reagents IVD	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. Put on appropriate personal protective equipment.
	Acealyse solution	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. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	: Antibody Reagents IVD	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".
	Acealyse solution	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	: Antibody Reagents IVD	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).
	Acealyse solution	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

Methods for cleaning up	: Antibody Reagents IVD	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
	Acealyse solution	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

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**7.1 Precautions for safe handling**

Protective measures	: Antibody Reagents IVD Acealyse solution	Put on appropriate personal protective equipment (see Section 8). Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
Advice on general occupational hygiene	: Antibody Reagents IVD Acealyse solution	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. 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

Storage	: Antibody Reagents IVD Acealyse solution	Storage temperature: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. 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. 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. See Section 10 for incompatible materials before handling or use. Store in accordance with local regulations. 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. Store locked up. 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. See Section 10 for incompatible materials before handling or use.
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7.3 Specific end use(s)

Recommendations	: Antibody Reagents IVD Acealyse solution	Industrial applications, Professional applications. Industrial applications, Professional applications.
Industrial sector specific solutions	: Antibody Reagents IVD Acealyse solution	Not available. Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
Acealyse solution 2,2' -oxybisethanol formaldehyde	NAOSH (Ireland, 5/2021). Notes: Advisory Occupational Exposure Limit Values (OELVs) OELV: 23 ppm 8 hours. OELV: 100 mg/m ³ 8 hours. NAOSH (Ireland, 5/2021). Skin sensitiser. Inhalation sensitiser. Notes: EU derived Occupational Exposure Limit Values OELV: 0.3 ppm 8 hours. OELV: 0.6 ppm 15 minutes. OELV: 0.738 mg/m ³ 15 minutes. OELV: 0.37 mg/m ³ 8 hours.

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	Type	Exposure	Value	Population	Effects
Acealyse solution 2,2' -oxybisethanol	DNEL	Long term Inhalation	44 mg/m ³	Workers	Systemic
	DNEL	Long term Inhalation	12 mg/m ³	General population	Local
	DNEL	Long term Inhalation	12 mg/m ³	General population	Systemic
	DNEL	Long term Dermal	21 mg/kg bw/day	General population	Systemic
	DNEL	Long term Dermal	43 mg/kg bw/day	Workers	Systemic
	DNEL	Long term Inhalation	60 mg/m ³	Workers	Local

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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SECTION 8: Exposure controls/personal protection

- 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.

- 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.

- 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.

- 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.

- 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.

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

Appearance

- Physical state** : Antibody Reagents IVD Liquid.
Acealyse solution Liquid.

- Colour** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

- Odour** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

- Odour threshold** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

- Melting point/freezing point** : Antibody Reagents IVD 0°C
Acealyse solution Not available.

- Initial boiling point and boiling range** : Antibody Reagents IVD 100°C
Acealyse solution Not available.

- Flammability** : Antibody Reagents IVD Not applicable.
Acealyse solution Not applicable.

- Upper/lower flammability or explosive limits** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Flash point :

	Closed cup		Open cup	
	°C	Method	°C	Method
Ingredient name				
Acealyse solution				
formaldehyde	83	-	-	-

Auto-ignition temperature :

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SECTION 9: Physical and chemical properties

Ingredient name	°C	Method
Acealyse solution		
2,2' -oxybisethanol	229	DIN EN 14522-S
formaldehyde	430	-

- Decomposition temperature** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- pH** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- Viscosity** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Media	Result
Antibody Reagents IVD water	Soluble
Acealyse solution water	Soluble

- Partition coefficient: n-octanol/water** : Antibody Reagents IVD Not applicable.
Acealyse solution Not applicable.

Ingredient name	Vapour Pressure at 20°C			Vapour pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Antibody Reagents IVD						
water	17.5	2.3	-	92.258	12.3	-
Acealyse solution						
water	17.5	2.3	-	92.258	12.3	-
formaldehyde	1	0.13	-	-	-	-

- Evaporation rate** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- Relative density** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- Vapour density** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- Explosive properties** : Antibody Reagents IVD Not available.
Acealyse solution Not available.
- Oxidising properties** : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Particle characteristics

- Median particle size** : Antibody Reagents IVD Not applicable.
Acealyse solution Not applicable.

9.2 Other information

No additional information.

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SECTION 10: Stability and reactivity

10.1 Reactivity	: Antibody Reagents IVD Acealyse solution	No specific test data related to reactivity available for this product or its ingredients. No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: Antibody Reagents IVD Acealyse solution	The product is stable. The product is stable.
10.3 Possibility of hazardous reactions	: Antibody Reagents IVD Acealyse solution	Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: Antibody Reagents IVD Acealyse solution	No specific data. No specific data.
10.5 Incompatible materials	: Antibody Reagents IVD Acealyse solution	May react or be incompatible with oxidising materials. May react or be incompatible with oxidising materials.
10.6 Hazardous decomposition products	: Antibody Reagents IVD Acealyse solution	Under normal conditions of storage and use, hazardous decomposition products should not be produced. Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Acealyse solution 2,2' -oxybisethanol	LD50 Dermal	Rabbit	11890 mg/kg	-
	LD50 Oral	Rat	12000 mg/kg	-
formaldehyde	LD50 Dermal	Rabbit	270 mg/kg	-
	LD50 Oral	Rat	100 mg/kg	-

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)
Acealyse solution	628.9	2727.3	N/A	30.3	N/A
Acealyse solution	500	11890	N/A	N/A	N/A
2,2' -oxybisethanol	100	270	N/A	3	N/A
formaldehyde					

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Acealyse solution 2,2' -oxybisethanol	Eyes - Mild irritant	Rabbit	-	50 mg	-
	Skin - Mild irritant	Rabbit	-	500 mg	-
formaldehyde	Eyes - Severe irritant	Rabbit	-	24 hours 750 ug	-
	Eyes - Severe irritant	Rabbit	-	750 ug	-
	Skin - Moderate irritant	Rabbit	-	24 hours 50 mg	-
	Skin - Severe irritant	Rabbit	-	0.8 %	-
	Skin - Severe irritant	Rabbit	-	24 hours 2 mg	-

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SECTION 11: Toxicological information

Sensitiser

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Acealyse solution formaldehyde	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Antibody Reagents IVD
Acealyse solution Not available.
Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Inhalation : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards.
May cause respiratory irritation.

Ingestion : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards.
Harmful if swallowed.

Skin contact : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards.
Causes skin irritation. May cause an allergic skin reaction.

Eye contact : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards.
Causes serious eye irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation : Antibody Reagents IVD
Acealyse solution No specific data.
Adverse symptoms may include the following:
respiratory tract irritation
coughing

Ingestion : Antibody Reagents IVD
Acealyse solution No specific data.
No specific data.

Skin contact : Antibody Reagents IVD
Acealyse solution No specific data.
Adverse symptoms may include the following:
irritation
redness

Eye contact : Antibody Reagents IVD
Acealyse solution No specific data.
Adverse symptoms may include the following:
pain or irritation
watering
redness

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

Short term exposure

Potential immediate effects : Not available.

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SECTION 11: Toxicological information

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary : Not available.

General : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards. May cause cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards. Suspected of causing genetic defects.

Reproductive toxicity : Antibody Reagents IVD
Acealyse solution No known significant effects or critical hazards. No known significant effects or critical hazards.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Acealyse solution Adverse symptoms may include the following: May cause sensitisation by inhalation.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
<input checked="" type="checkbox"/> Acealyse solution 2,2' -oxybisethanol formaldehyde	Acute LC50 75200000 µg/l Fresh water	Fish - <i>Pimephales promelas</i>	96 hours
	Acute EC50 3.48 mg/l Fresh water	Algae - <i>Desmodesmus subspicatus</i>	72 hours
	Acute EC50 3.05 mg/l Marine water	Algae - <i>Isochrysis galbana</i> - Exponential growth phase	96 hours
	Acute EC50 3.26 mg/l Fresh water	Daphnia - <i>Daphnia magna</i> - Embryo	48 hours
	Acute LC50 11.41 mg/l Fresh water	Crustaceans - <i>Ceriodaphnia dubia</i>	48 hours
	Acute LC50 1.41 ppm Fresh water	Fish - <i>Oncorhynchus mykiss</i>	96 hours
	Chronic NOEC 3000 ppm Fresh water	Crustaceans - <i>Astacus astacus</i> - Egg	21 days
Chronic NOEC 0.81 to 1.07 mg/l	Daphnia - <i>Daphnia magna</i>	21 days	
Chronic NOEC 1.56 mg/l Fresh water	Fish - <i>Oreochromis niloticus</i> - Fingerling	12 weeks	

12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
<input checked="" type="checkbox"/> Acealyse solution formaldehyde	OECD 301A Ready Biodegradability - DOC Die-Away Test	99 % - Readily - 28 days	-	-

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SECTION 12: Ecological information

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Acealyse solution formaldehyde	-	-	Readily

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Acealyse solution 2,2' -oxybisethanol formaldehyde	-1.98 0.35	100 -	Low Low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

Not available.

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

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. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

Antibodies Reagent IVD Kit

SECTION 14: Transport information

	ADR/RID	IMDG	IATA
14.1 UN number or ID number	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.

Additional information

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	Identifiers	Designation [Usage]
<input checked="" type="checkbox"/> Acealyse solution Acealyse solution formaldehyde		3 28 28 72

Label : Antibody Reagents IVD
Acealyse solution

Not applicable.
Restricted to professional users.

Other EU regulations

Ozone depleting substances (1005/2009/EU)

Not listed.

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

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

Antibodies Reagent IVD Kit

SECTION 15: Regulatory information

This product is not controlled under the Seveso Directive.

National regulations

Product/ingredient name	List name	Name on list	Classification	Notes
Acealyse solution formaldehyde	Ireland Occupational Exposure Limits	formaldehyde	Carc..1B	-

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

- Australia** : Not determined.
- Canada** : Not determined.
- China** : Not determined.
- Eurasian Economic Union** : **Russian Federation inventory**: Not determined.
- Japan** : **Japan inventory (CSCL)**: Not determined.
Japan inventory (ISHL): Not determined.
- New Zealand** : Not determined.
- Philippines** : Not determined.
- Republic of Korea** : Not determined.
- Taiwan** : Not determined.
- Thailand** : Not determined.
- Turkey** : Not determined.
- United States** : Not determined.
- Viet Nam** : Not determined.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments might still be 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

Antibodies Reagent IVD Kit

SECTION 16: Other information

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Acealyse solution Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Muta. 2, H341 Carc. 1B, H350 STOT SE 3, H335	Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method

Full text of abbreviated H statements

Acealyse solution H301 H302 H311 H314 H315 H317 H318 H319 H331 H335 H341 H350	Toxic if swallowed. Harmful if swallowed. Toxic in contact with skin. Causes severe skin burns and eye damage. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. Causes serious eye irritation. Toxic if inhaled. May cause respiratory irritation. Suspected of causing genetic defects. May cause cancer.
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Full text of classifications [CLP/GHS]

Acealyse solution Acute Tox. 3 Acute Tox. 4 Carc. 1B Eye Dam. 1 Eye Irrit. 2 Muta. 2 Skin Corr. 1B Skin Irrit. 2 Skin Sens. 1 STOT SE 3	ACUTE TOXICITY - Category 3 ACUTE TOXICITY - Category 4 CARCINOGENICITY - Category 1B SERIOUS EYE DAMAGE/EYE IRRITATION - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 GERM CELL MUTAGENICITY - Category 2 SKIN CORROSION/IRRITATION - Category 1B SKIN CORROSION/IRRITATION - Category 2 SKIN SENSITISATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE - Category 3
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