

SAFETY DATA SHEET



Antibodies Reagent IVD Kit

Section 1. Identification

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
 Acealyse solution
 891B604, 892B604, 891B604CE,
 892B604CE

Validation date : 4/12/2024

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

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer : Agilent Technologies, Inc.
 5301 Stevens Creek Blvd
 Santa Clara, CA 95051, USA
 800-227-9770

1.4 Emergency telephone number

In case of emergency : CHEMTREC®: 1-800-424-9300

Section 2. Hazards identification

2.1 Classification of the substance or mixture

OSHA/HCS status : Antibody Reagents IVD
 While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Acealyse solution
 This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).


Classification of the substance or mixture

Section 2. Hazards identification

Acealyse solution

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

2.2 GHS 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 vapor. P270 - Do not eat, drink or smoke when using this product. P264 - Wash thoroughly after handling.
Response	: Antibody Reagents IVD Acealyse solution	Not applicable. P308 + P313 - IF exposed or concerned: Get medical advice or attention. P304 + P312 - IF INHALED: Call a POISON CENTER or doctor if you feel unwell. P362 + P364 - Take off contaminated clothing and wash it before reuse. P363 - Wash contaminated clothing before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water. P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: 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	:	

Section 2. Hazards identification

	Antibody Reagents IVD Acealyse solution	Not applicable. P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Antibody Reagents IVD Acealyse solution	None known. None known.
2.3 Other hazards		
Hazards not otherwise classified	: Antibody Reagents IVD Acealyse solution	None known. None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Antibody Reagents IVD Acealyse solution	Mixture Mixture
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Ingredient name	%	CAS number
Acealyse solution		
2,2' -oxybisethanol	≥25 - ≤50	111-46-6
Formaldehyde, solution	≤10	50-00-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

4.1 Description of necessary first aid measures

Eye contact	: Antibody Reagents IVD Acealyse solution	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. 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.
Inhalation	: Antibody Reagents IVD Acealyse solution	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. 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.

Section 4. First aid measures

Skin contact	: Antibody Reagents IVD Acealyse solution	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. 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 Acealyse solution	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. 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.

4.2 Most important symptoms/effects, acute and delayed

Potential acute health effects

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

Over-exposure signs/symptoms

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

Section 4. First aid measures

Ingestion	: Antibody Reagents IVD Acealyse solution	No specific data. No specific data.
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4.3 Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician	: Antibody Reagents IVD Acealyse solution	Treat symptomatically. Contact poison treatment specialist 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 Acealyse solution	No specific treatment. No specific treatment.
Protection of first-aiders	: Antibody Reagents IVD Acealyse solution	No action shall be taken involving any personal risk or without suitable training. 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.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Antibody Reagents IVD Acealyse solution	Use an extinguishing agent suitable for the surrounding fire. Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: Antibody Reagents IVD Acealyse solution	None known. None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	: Antibody Reagents IVD Acealyse solution	In a fire or if heated, a pressure increase will occur and the container may burst. In a fire or if heated, a pressure increase will occur and the container may burst.
Hazardous thermal decomposition products	: Antibody Reagents IVD Acealyse solution	No specific data. Decomposition products may include the following materials: carbon dioxide carbon monoxide metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters	: Antibody Reagents IVD Acealyse solution	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. 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. Fire-fighting 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.

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.

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 spilled material. Put on appropriate personal protective equipment. 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 spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

Acealyse solution

For emergency responders : Antibody Reagents IVD

If specialized 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". If specialized 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

6.2 Environmental precautions : Antibody Reagents IVD

Avoid dispersal of spilled 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 spilled 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 materials 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.

Section 6. Accidental release measures

disposal container. Dispose of via a licensed waste disposal contractor.

Section 7. Handling and storage

7.1 Precautions for safe handling

<p>Protective measures</p>	<p>: Antibody Reagents IVD</p> <p>Acealyse solution</p>	<p>Put on appropriate personal protective equipment (see Section 8).</p> <p>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 vapor 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.</p>
<p>Advice on general occupational hygiene</p>	<p>: Antibody Reagents IVD</p> <p>Acealyse solution</p>	<p>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.</p>
<p>7.2 Conditions for safe storage, including any incompatibilities</p>	<p>: Antibody Reagents IVD</p> <p>Acealyse solution</p>	<p>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 unlabeled 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 unlabeled containers. Use appropriate</p>

Section 7. Handling and storage

containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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

Ingredient name	Exposure limits
Acealyse solution 2,2' -oxybisethanol Formaldehyde, solution	OARS WEEL (United States, 4/2022). TWA: 10 mg/m ³ 8 hours. ACGIH TLV (United States, 1/2023). Skin sensitizer. Inhalation sensitizer. STEL: 0.3 ppm 15 minutes. TWA: 0.1 ppm 8 hours. OSHA PEL 1989 (United States, 3/1989). TWA: 0.75 ppm 8 hours. STEL: 2 ppm 15 minutes. OSHA PEL Z2 (United States, 2/2013). TWA: 0.75 ppm 8 hours. STEL: 2 ppm 15 minutes. NIOSH REL (United States, 10/2020). TWA: 0.016 ppm 10 hours. CEIL: 0.1 ppm 15 minutes. OSHA PEL (United States, 5/2018). TWA: 0.75 ppm 8 hours. STEL: 2 ppm 15 minutes. CAL OSHA PEL (United States, 5/2018). STEL: 2 ppm 15 minutes. TWA: 0.75 ppm 8 hours.

Biological exposure indices

No exposure indices known.

8.2 Exposure controls

Appropriate engineering controls	: If user operations generate dust, fumes, gas, vapor 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.
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.

Individual protection measures

Section 8. Exposure controls/personal protection

- 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.
- 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: chemical splash goggles.
- 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.

Section 9. Physical and chemical properties and safety characteristics

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

Appearance

Physical state	: Antibody Reagents IVD Acealyse solution	Liquid. Liquid.
Color	: Antibody Reagents IVD Acealyse solution	Not available. Not available.
Odor	: Antibody Reagents IVD Acealyse solution	Not available. Not available.
Odor threshold	: Antibody Reagents IVD Acealyse solution	Not available. Not available.
pH	: Antibody Reagents IVD Acealyse solution	Not available. Not available.
Melting point/freezing point	: Antibody Reagents IVD Acealyse solution	0°C (32°F) Not available.
Boiling point, initial boiling point, and boiling range	: Antibody Reagents IVD Acealyse solution	100°C (212°F) Not available.
Flash point	:	

Section 9. Physical and chemical properties and safety characteristics

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Acealyse solution						
Formaldehyde, solution	83	181.4	-	-	-	-
Citric acid, trisodium salt, dihydrate	>100	>212	-	-	-	-

Evaporation rate : Antibody Reagents IVD Not available.
Acealyse solution Not available.

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

Lower and upper explosion limit/flammability limit : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Vapor pressure :

Ingredient name	Vapor Pressure at 20°C			Vapor 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, solution	1	0.13	-	-	-	-

Relative vapor density : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Relative density : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Solubility(ies) :

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.

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Acealyse solution			
2,2' -oxybisethanol	229	444.2	DIN EN 14522-S
Formaldehyde, solution	430	806	-

Decomposition temperature : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Viscosity : Antibody Reagents IVD Not available.
Acealyse solution Not available.

Particle characteristics

Section 9. Physical and chemical properties and safety characteristics

Median particle size	: Antibody Reagents IVD Acealyse solution	Not applicable. Not applicable.
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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 oxidizing materials. May react or be incompatible with oxidizing 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 LD50 Oral	Rabbit Rat	11890 mg/kg 12000 mg/kg	- -
Formaldehyde, solution	LD50 Dermal LD50 Oral	Rabbit Rat	270 mg/kg 100 mg/kg	- -

Irritation/Corrosion

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

Section 11. Toxicological information

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Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Acealyse solution Formaldehyde, solution	+	1	Known to be a human carcinogen.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Acealyse solution Formaldehyde, solution	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Antibody Reagents IVD
Acealyse solution

Not available.
Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact : Antibody Reagents IVD
Acealyse solution

No known significant effects or critical hazards.
Causes serious eye irritation.

Inhalation : Antibody Reagents IVD
Acealyse solution

No known significant effects or critical hazards.
May cause respiratory irritation.

Skin contact : Antibody Reagents IVD
Acealyse solution

No known significant effects or critical hazards.
Causes skin irritation. May cause an allergic skin reaction.

Ingestion : Antibody Reagents IVD
Acealyse solution

No known significant effects or critical hazards.
Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Antibody Reagents IVD
Acealyse solution

No specific data.
Adverse symptoms may include the following:
pain or irritation
watering
redness

Section 11. Toxicological information

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

Delayed and immediate effects and also 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

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.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Acealyse solution					
Acealyse solution	628.9	2727.3	N/A	20.5	N/A
2,2' -oxybisethanol	500	11890	N/A	N/A	N/A
Formaldehyde, solution	100	270	N/A	3	N/A

Other information	: Acealyse solution	Adverse symptoms may include the following: May cause sensitization by inhalation.
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Section 12. Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Acealyse solution 2,2' -oxybisethanol Formaldehyde, solution	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
Acealyse solution Formaldehyde, solution	OECD 301A Ready Biodegradability - DOC Die-Away Test	99 % - Readily - 28 days	-	-

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

12.3 Bioaccumulative potential

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

12.4 Mobility in soil

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

12.5 Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

13.1 Waste treatment methods

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized 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. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. 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.

United States - RCRA Toxic hazardous waste "U" List

Ingredient	CAS #	Status	Reference number
Acealyse solution Formaldehyde	50-00-0	Listed	U122

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

The information presented below only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

Section 14. Transport information

DOT / TDG / Mexico / IMDG / IATA : Not regulated.

Additional information

DOT Classification : **Reportable quantity** 2020.2 lbs / 917.17 kg. Package sizes shipped in quantities less than the product reportable quantity are not subject to the RQ (reportable quantity) transportation requirements.

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.

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

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined

Clean Water Act (CWA) 311: Formaldehyde, solution

Clean Air Act (CAA) 112 regulated toxic substances: Formaldehyde, solution

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Section 15. Regulatory information

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed


SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Antibody Reagents IVD Sodium azide	<0.1	Yes.	500	-	1000	-
Acealyse solution Formaldehyde, solution	≤10	Yes.	500	56.3	100	11.3


SARA 304 RQ : 2020.2 lbs / 917.2 kg

SARA 311/312

Classification :  Antibody Reagents IVD
Acealyse solution

Not applicable.
ACUTE TOXICITY (oral) - Category 4
SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
SKIN SENSITIZATION - Category 1
GERM CELL MUTAGENICITY - Category 2
CARCINOGENICITY - Category 1
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

Composition/information on ingredients

Name	%	Classification
 Acealyse solution 2,2' -oxybisethanol	≥25 - ≤50	ACUTE TOXICITY (oral) - Category 4 EYE IRRITATION - Category 2B FLAMMABLE LIQUIDS - Category 4
Formaldehyde, solution	≤10	ACUTE TOXICITY (oral) - Category 3 ACUTE TOXICITY (dermal) - Category 3 ACUTE TOXICITY (inhalation) - Category 3 SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SKIN SENSITIZATION - Category 1 GERM CELL MUTAGENICITY - Category 2 CARCINOGENICITY - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	Acealyse solution Formaldehyde, solution	50-00-0	≤10
Supplier notification	Acealyse solution Formaldehyde, solution	50-00-0	≤10

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts : The following components are listed: FORMALDEHYDE

Section 15. Regulatory information

- New York** : The following components are listed: Formaldehyde
- New Jersey** : The following components are listed: FORMALDEHYDE
- Pennsylvania** : The following components are listed: ETHANOL, 2,2'-OXYBIS-; FORMALDEHYDE
- California Prop. 65**

⚠ WARNING: This product can expose you to Formaldehyde, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Ingredient name	No significant risk level	Maximum acceptable dosage level
Acealyse solution Formaldehyde	Yes.	-

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.
- 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.

Section 16. Other information

Procedure used to derive the classification

Section 16. Other information

Classification	Justification
<p>Acelyse solution ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SKIN SENSITIZATION - Category 1 GERM CELL MUTAGENICITY - Category 2 CARCINOGENICITY - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3</p>	<p>Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method</p>

History

Date of issue/Date of revision	: 04/12/2024
Date of previous issue	: 11/30/2022
Version	: 2
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available UN = United Nations

▣ Indicates information that has changed from previously issued version.

Notice to reader

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