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IMPORTANT INFORMATION CONCERNING MATERIAL SAFETY DATA SHEET / SAFETY DATA SHEET

Cher client,

Le 1^{er} Janvier 2013, le nom notre société SEPPIM S.A.S. change pour devenir ELITech Clinical Systems SAS. Toute notre documentation est en cours de révision pour prendre en compte ce changement de nom. Ceci inclut les Fiches de Données de Sécurité (FDS) fournies pour nos réactifs.

Les renseignements suivants de nos FDS sont modifiés à partir du 1^{er} Janvier 2013 comme indiqué ci-après:

Producteur/fournisseur :

ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
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MSDS.ECS-SAS@elitechgroup.com

Dear customer,

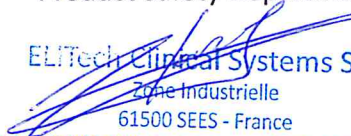
On 1st January 2013, the manufacturing company SEPPIM S.A.S. name changes to ELITech Clinical Systems SAS. All the documentation is in revision in light of the change of our company name. This includes the (Material) Safety Data Sheets ((M)SDSs) provided for our reagents.

The following contact information relative to (M)SDSs are modified from 1st January 2013 as indicated hereafter :

Manufacturer/Supplier :

ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées
France
Tel: +33 (0)2 33 81 21 00
Fax : +33 (0)2 33 28 77 51
MSDS.ECS-SAS@elitechgroup.com

Product Safety Department


ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES - France
Tél. : +33(0)2 33 81 21 00 - Fax : +33(0)2 33 28 77 51
SIRET 318 365 228 00036

27.01.2012

Kit Components

Product code	Description
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PISL-0210	ALP IFCC SL (Kit)
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Components:

PISL-5XXX	ALP IFCC SL - R1
PISL-6XXX	ALP IFCC SL - R2

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

Product identifier

Trade name: **ALP IFCC SL - R1**

Article number: PISL-5XXX

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

Application of the substance / the preparation Reagent for IN VITRO diagnostic

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SEPPIM S.A.S.

4 Rue Auguste Mottin

F-61500 Sées

FRANCE

Tel: +33 2 33 81 21 00

Fax: +33 2 33 28 77 51

seppim.msds@elitechgroup.com

Information department: Product safety department

Emergency telephone number: Contact your distributor or poison control center in your country.

2 Hazards identification

Classification of the substance or mixture

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of international guidelines.

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

Label elements

Labelling according to EU guidelines:

The product is not subject to identification regulations according to directives on hazardous materials.

Observe the general safety regulations when handling chemicals.

Classification system:

NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)



Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description:

Mixture of substances.

Aqueous solution.

Dangerous components:

CAS NO.	Description	%
124-68-5	2-amino-2-methylpropanol	2.5-10%

Additional information:

Each of the other components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).

4 First aid measures

Description of first aid measures

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

Rinse with water.

If symptoms appear, seek medical advice.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.

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Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R1

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- **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
If symptoms appear, seek medical advice.
- **Information for doctor:** Treat symptomatically.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Nitrogen oxides (NO_x)
Carbon oxides (CO_x)
- **Advice for firefighters**
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Clean the affected area carefully.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
· **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:**
Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

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Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R1

(Contd. of page 2)

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Latex or rubber.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Safety glasses

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Liquid

Color: Colorless

· **Odor:** Odorless

· **Odour threshold:** Date not available

· **pH-value at 20°C (68 °F):** 10.45

· **Change in condition**

Melting point/Melting range: Not applicable

Boiling point/Boiling range: Date not available

Solidification point: Date not available

· **Flash point:** Not applicable.

· **Ignition temperature:**

Decomposition temperature: Date not available

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure:** Date not available

· **Density at 20°C (68 °F):** 0.999 g/cm³ (8.337 lbs/gal)

· **Relative density** Date not available

· **Vapour density** Date not available

· **Evaporation rate** Date not available

· **Solubility in / Miscibility with**

Water: Miscible

· **Partition coefficient (n-octanol/water):** Date not available

· **Viscosity:**

Dynamic: Date not available

Kinematic: Date not available

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No dangerous reactions known.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** Strong oxidizing agents, acids, bases.

· **Hazardous decomposition products:**

Small quantities of dangerous decomposition products may be formed.

Carbon oxides (COx)

Nitrogen oxides (NOx)

· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

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Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 01/27/2012

Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R1

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11 Toxicological information

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:

Information on components:

124-68-5 2-amino-2-methylpropanol

Oral	LD50	2900 mg/kg (rat)
Dermal	LD50	2000 mg/kg (rabbit)

Primary irritant effect:

on the skin: May cause irritating effect.

on the eye: May cause irritating effect.

Inhalation:

May cause irritating effect.

May be harmful by inhalation.

Ingestion: May be harmful if swallowed.

Sensitization: No sensitizing effects known.

Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

Carcinogenic categories

IARC (International Agency for Research on Cancer) Available information lists no component.

NTP (National Toxicology Program) Available information lists no component.

12 Ecological information

Toxicity

Aquatic toxicity:

Information on components:

124-68-5 2-amino-2-methylpropanol

EC50/48h	193 mg/l (Daphnia)
EC50/72h	520 mg/l (Algae)
LC50/96h	190 mg/l (fish)

Persistence and degradability Date not available

Behavior in environmental systems:

Bioaccumulative potential Date not available

Mobility in soil Date not available

Additional ecological information:

General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Disposal procedures have to be respected, see Section 13.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Other adverse effects No further relevant information available.

13 Disposal considerations

Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

Primary packaging: Plastic vial (composed of polyethylene high density).

14 Transport information

UN-Number

DOT, ADR, ADN, IMDG, IATA

-

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

-

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

-

Class

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Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R1

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- **Packing group**
 - **DOT, ADR, IMDG, IATA**
 - **Environmental hazards:**
 - **Marine pollutant:**
 - **Special precautions for user**
 - **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**
- No
Not applicable.
Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**
- **Section 302/304 (40CFR355.30 / 40CFR355.40):** Available information lists none.
- **Section 313 (Specific toxic chemical listings):** Not regulated.
- **TSCA (Toxic Substances Control Act):**
This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.
- **Proposition 65**
- **Chemicals known to cause cancer:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for females:** Available information lists none.
- **Chemicals known to cause reproductive toxicity for males:** Available information lists none.
- **Chemicals known to cause developmental toxicity:** Available information lists none.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Available information lists none.
- **TLV (Threshold Limit Value established by ACGIH)** Available information lists none.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Available information lists none.
- **OSHA-Ca (Occupational Safety & Health Administration)** Available information lists none.

- **Product related hazard informations:**

The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.

- **U. S. State Regulations:**

- **PA-RTK** Available information lists none.

- **NJ-RTK**

124-68-5	2-amino-2-methylpropanol
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- **MA-RTK**

124-68-5	2-amino-2-methylpropanol
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- **RI-RTK** Available information lists none.

- **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:** Product safety department
- **Contact:** Product safety department

- USA -

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

· Product identifier

· **Trade name:** ALP IFCC SL - R2

· **Article number:** PISL-6XXX

· **Relevant identified uses of the substance or mixture and uses advised against**

· **Application of the substance / the preparation** Reagent for IN VITRO diagnostic

· Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

SEPPIM S.A.S.

4 Rue Auguste Mottin

F-61500 Sées

FRANCE

Tel: +33 2 33 81 21 00

Fax: +33 2 33 28 77 51

seppim.msds@elitechgroup.com

· **Information department:** Product safety department

· **Emergency telephone number:** Contact your distributor or poison control center in your country.

2 Hazards identification

· Classification of the substance or mixture

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Not applicable.

· **Information concerning particular hazards for human and environment:**

The product does not have to be labelled due to the calculation procedure of international guidelines.

· **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· Label elements

· **Labelling according to EU guidelines:**

The product is not subject to identification regulations according to directives on hazardous materials.

Observe the general safety regulations when handling chemicals.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization:** Mixtures

· **Description:**

Mixture of substances.

Aqueous solution.

· **Dangerous components:**

CAS NO.	Description	%
67-56-1	methanol	< 0.5%

· **Additional information:**

Each of the other components is present in less than 1% concentration for hazardous components (or 0.1% concentration for potential carcinogens, reproductive toxins, and mutagens).

4 First aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:**

Rinse with water.

If symptoms appear, seek medical advice.

· **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 01/27/2012

Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R2

(Contd. of page 1)

- **After swallowing:**
Never give anything by mouth to an unconscious person.
Rinse out mouth.
If symptoms appear, seek medical advice.
- **Information for doctor:** Treat symptomatically.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Nitrogen oxides (NO_x)
Carbon oxides (CO_x)
- **Advice for firefighters**
- **Protective equipment:** As in any fire, wear a respiratory protective device, and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Clean the affected area carefully.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Observe the warnings on the label.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
· **Requirements to be met by storerooms and receptacles:** No special requirements.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:** Protect the product from light. Avoid exposure to heat.
· **Recommended storage temperature:** 2-8 °C
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Information on components:

67-56-1 methanol

PEL	260 mg/m ³ , 200 ppm
REL	Short-term value: 325 mg/m ³ , 250 ppm Long-term value: 260 mg/m ³ , 200 ppm Skin
TLV	Short-term value: 328 mg/m ³ , 250 ppm Long-term value: 262 mg/m ³ , 200 ppm Skin; BEI

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Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R2

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26628-22-8 sodium azide (< 0.1%)

REL	Short-term value: C 0.3** mg/m ³ , C 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV	Short-term value: C 0.29** mg/m ³ , C 0.11* ppm *as HN ₃ vapor **as NaN ₃

· *Additional information:* The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· *General protective and hygienic measures:*

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

· *Breathing equipment:*

Under normal conditions, the use of these products should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

· *Protection of hands:*

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· *Material of gloves*

Latex or rubber.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· *Penetration time of glove material*

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· *Eye protection:* Safety glasses

· *Body protection:* Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· *Appearance:*

Form:	Liquid
Color:	Slightly yellow.
Odor:	Odorless
Odour threshold:	Date not available

· **pH-value at 20°C (68 °F):** ~9.0

· **Change in condition**

Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Date not available
Solidification point:	Date not available

· **Flash point:** Not applicable.

· **Ignition temperature:**

Decomposition temperature: Date not available

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure:** Date not available

· **Density at 20°C (68 °F):** 0.999 g/cm³ (8.337 lbs/gal)

· **Relative density** Date not available

· **Vapour density** Date not available

· **Evaporation rate** Date not available

· **Solubility in / Miscibility with**

Water: Miscible

· **Partition coefficient (n-octanol/water):** Date not available

· **Viscosity:**

Dynamic:	Date not available
Kinematic:	Date not available

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.

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Printing date 01/27/2012

Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R2

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- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions**
Sodium azide, contains in the product (<0.1%), can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalizations, rinse with plenty of water.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Strong oxidizing agents, acids, bases.
- **Hazardous decomposition products:**
Small quantities of dangerous decomposition products may be formed.
Carbon oxides (COx)
Nitrogen oxides (NOx)
- **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**
Information on components:

26628-22-8 sodium azide

Oral	LD50	27 mg/kg (mouse)
Dermal	LD50	20 mg/kg (rabbit)
Inhalative	LC50	37 mg/m3 (rat)

67-56-1 methanol

Oral	LD50	5628 mg/kg (rat)
Dermal	LD50	15800 mg/kg (rabbit)
Inhalative	LC50/4h	64000 ppm (rat)

- **Primary irritant effect:**
- **on the skin:** May cause irritating effect.
- **on the eye:** May cause irritating effect.
- **Inhalation:**
May cause irritating effect.
May be harmful by inhalation.
- **Ingestion:** May be harmful if swallowed.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
Ingestion of large amount of sodium azide may cause nausea, vomiting and in certain circumstances respiratory difficulties, high pulse rate and/or hypersensitivity.
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** None of the ingredient is in reportable quantity.
- **NTP (National Toxicology Program)** None of the ingredient is in reportable quantity.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:**
Information on components:

26628-22-8 sodium azide

EC50/48h	4.2 mg/l (Daphnia)
LC50/96h	0.68 mg/l (Lepomis macrochirus)

67-56-1 methanol

EC50/48h	24500 mg/l (Daphnia)
LC50/48h	36000 mg/l (Cyprinus carpio)
LC50/96h	19000 mg/l (Onchorhynchus mykiss)

- **Persistence and degradability** Date not available
- **Behavior in environmental systems:**
- **Bioaccumulative potential** Date not available
- **Mobility in soil** Date not available
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Disposal procedures have to be respected, see Section 13.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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USA

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acc. to ISO/DIS 11014

Printing date 01/27/2012

Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R2

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- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:**
Water, if necessary with cleansing agents.
Sodium azide, contained in the product (<0.1%), can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalisations, rinse with plenty of water.
- **Primary packaging:** Plastic vial (composed of polyethylene high density).

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** -
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** -
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** -
- **Packing group**
- **DOT, ADR, IMDG, IATA** -
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

26628-22-8	sodium azide
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· **Section 313 (Specific toxic chemical listings):** Not regulated.

· **TSCA (Toxic Substances Control Act):**

This product is regulated by the Food and Drug Administration; it is exempt from requirements of TSCA.

· **Proposition 65**

· **Chemicals known to cause cancer:** None of the ingredient is in reportable quantity.

· **Chemicals known to cause reproductive toxicity for females:** Available information lists none.

· **Chemicals known to cause reproductive toxicity for males:** Available information lists none.

· **Chemicals known to cause developmental toxicity:**

67-56-1	methanol
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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)** Available information lists none.

· **TLV (Threshold Limit Value established by ACGIH)**

26628-22-8	sodium azide	A4
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· **NIOSH-Ca (National Institute for Occupational Safety and Health)** Available information lists none.

· **OSHA-Ca (Occupational Safety & Health Administration)** Available information lists none.

· **Product related hazard informations:**

The product is not subject to identification regulations according to directives on hazardous materials.
Observe the general safety regulations when handling chemicals.

· **U. S. State Regulations:**

· **PA-RTK**

67-56-1	methanol
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26628-22-8	sodium azide
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· **NJ-RTK**

67-56-1	methanol
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26628-22-8	sodium azide
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· **MA-RTK**

67-56-1	methanol
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-USA-

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 01/27/2012

Reviewed on 01/27/2012

Trade name: ALP IFCC SL - R2

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26628-22-8	sodium azide
56-75-7	chloramphenicol
· <i>RI-RTK</i>	
67-56-1	methanol
26628-22-8	sodium azide

· **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:** Product safety department

· **Contact:** Product safety department

USA