Kit Components

Product code	Description
ISDI-0250 (NA)	**ISE DILUENT (Kit)**

Components:

ISDI-5220	ISE DILUENT-DIL

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/10/2013 Reviewed on 10/10/2013

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1 Identification

· **Product identifier**

· ***Trade name:*** **ISE DILUENT-DIL**

· *Article number:* ISDI-5220
· ***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:***
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
www.elitechgroup.com
MSDS.ECS-SAS@elitechgroup.com

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

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2 Hazard(s) identification

· **Classification of the substance or mixture**

· ***Classification according to Directive 67/548/EEC or Directive 1999/45/EC***

Toxic
May impair fertility. May cause harm to the unborn child.


Harmful
Harmful if swallowed.
· *Information concerning particular hazards for human and environment:*
The product has to be labeled 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:***
Observe the general safety regulations when handling chemicals.
The product has been classified and marked in accordance with directives on hazardous materials.

· *Code letter and hazard designation of product:*


Toxic

· *Hazard-determining components of labeling:*
tetramethylammonium hydroxide
boric acid

· *Risk phrases:*
May impair fertility.
May cause harm to the unborn child.
Also harmful if swallowed.

· *Safety phrases:*
Avoid exposure - obtain special instructions before use.
Wear suitable protective clothing, gloves and eye/face protection.
In case of insufficient ventilation, wear suitable respiratory equipment.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
This material and its container must be disposed of as hazardous waste.
· **Classification system:**
· ***NFPA ratings (scale 0 - 4)***

Health = 2
Fire = 0
Reactivity = 0

· ***HMIS-ratings (scale 0 - 4)***

Health = *2
Fire = 0
Reactivity = 0

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3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· ***Description:***
Mixture of substances.
Aqueous solution.

· ***Dangerous components:***

· CAS NO.	Description	%
10043-35-3	boric acid	≤ 2.5%
75-59-2	tetramethylammonium hydroxide	< 1.0%

· ***SVHC***	
10043-35-3	boric acid

· ***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).

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4 First-aid measures

· **Description of first aid measures**
· ***General information:***
In case of accident or if you feel unwell, seek medical advice immediately.
Show this safety data sheet to the doctor in attendance.
Immediately remove any clothing soiled by the product.
Wash clothing before reuse.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
· ***After inhalation:***
Supply fresh air; consult doctor in case of complaints.
If required, provide artificial respiration.
· ***After skin contact:***
Rinse with water.
If symptoms appear, seek medical advice.
· ***After eye contact:***
Protect unharmed eye.
Remove contact lenses, if present and easy to do.
Rinse opened eye for several minutes under running water. If symptoms appear, seek medical advice.
· ***After swallowing:***
Never give anything by mouth to an unconscious person.
Do not induce vomiting.
Rinse out mouth.
Seek advice from a doctor or a poison control center.
· ***Information for doctor:***
· *Most important symptoms and effects, both acute and delayed* Data not available
· *Indication of any immediate medical attention and special treatment needed* Data not available

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5 Fire-fighting measures

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

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6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective clothing.
Ensure adequate ventilation
Avoid physical contact with material.
· **Environmental precautions:** Prevent seepage into sewage system, workpits and cellars.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust).
Send for recovery or disposal in suitable receptacles.
Clean the affected area carefully.

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· **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.

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7 Handling and storage

· **Handling:**
· ***Precautions for safe handling***
Do not handle until all safety precautions have been read and understood.
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:* Unsuitable material for receptacle: aluminium.
· *Information about storage in one common storage facility:* Store away from incompatible materials (see section 10).
· *Further information about storage conditions:* Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 10-30 °C
· **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

· **Additional information about design of technical systems:**
Eyewash fountain and safety shower in the area of storage and use.
See item 7.

· **Control parameters**

· ***Components with limit values that require monitoring at the workplace:***	
10043-35-3 boric acid	
TLV	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ *as inhalable fraction

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

· **Exposure controls**
· ***Personal protective equipment:***
· *General protective and hygienic measures:*
Pregnant women should strictly avoid inhalation or skin contact.
Do not handle until all safety precautions have been read and understood.
The usual precautionary measures for handling chemicals should be followed.
Do not eat, drink, smoke or sniff while working.
Avoid physical contact with material.
Do not inhale gases / fumes / aerosols.
Take off contaminated clothing and wash before reuse.
Wash hands before breaks and at the end of work.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *Breathing equipment:*
Suitable respiratory protective device recommended.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· *Protection of hands:*


Protective gloves

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
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· *Material of gloves*
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:*
Wear face shield/eye protection.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

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· *Body protection:* Protective work clothing

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· ***General Information***	
· *Appearance:*	
Form:	Liquid
Color:	Colorless
· *Odor:*	Odorless
· ***pH-value at 20 °C (68 °F):***	8.7
· ***Change in condition***	
Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Undetermined.
Solidification point:	Not determined
· ***Flash point:***	Not applicable.
· ***Flammability (solid, gaseous):***	Not applicable.
· ***Ignition temperature:***	Not determined
· *Decomposition temperature:*	Not determined.
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Not determined
· ***Density at 20 °C (68 °F):***	1.0018 g/cm³ (8.36 lbs/gal)
· *Vapour density*	Not determined
· *Evaporation rate*	Not determined
· ***Solubility in / Miscibility with***	
Water:	Miscible
· ***Partition coefficient (n-octanol/water):***	Not determined
· ***Viscosity:***	
Dynamic:	Not determined.
· **Other information**	No further relevant information available.

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10 Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** Formation of hazardous vapours/gaz is possible during heating (> 100 °C).
· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:**
Strong oxidizing agents, strong acids
Acid anhydrides
Metallic aluminium
· **Hazardous decomposition products:**
Dangerous decomposition products may be formed.
Carbon oxides (COx)
Nitrogen oxides (NOx)
Borane / boron oxides.
· **Additional information:** Stable at the recommended storage temperature and if protected from light. Avoid exposure to heat.

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11 Toxicological information

· **Information on toxicological effects**
· ***Acute toxicity:***

· *LD/LC50 values that are relevant for classification:*		
75-59-2 tetramethylammonium hydroxide		
Oral	LD50	7.5 mg/kg (rat)
Dermal	LD50	25 mg/kg (rat)
10043-35-3 boric acid		
Oral	LD50	2660 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	>2.03 mg/l (rat)

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· *Primary irritant effect:*
· *on the skin:*
May cause irritating effect.
May be harmful if absorbed through skin.
· *on the eye:* May cause irritating effect.
· *Inhalation:*
May cause irritating effect.
May be harmful by inhalation.
· *Ingestion:* Harmful if swallowed.
· *Sensitization:* No sensitizing effects known.
· ***Additional toxicological information:***
The product shows the following dangers according to internally approved calculation methods for preparations:
Toxic
Harmful

· *Carcinogenic categories*
· *IARC (International Agency for Research on Cancer)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by IARC as a carcinogen.
· *NTP (National Toxicology Program)* None of the ingredient is listed.
· *Mutagenicity:* Data not available
· *Reproductive Effects:* May damage fertility or the unborn child.
· *Effects on development:* Data not available

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12 Ecological information

· **Toxicity**

· ***Aquatic toxicity:***	
75-59-2 tetramethylammonium hydroxide	
EC50/48h	3 mg/l (Daphnia)
EC50/72h	96 mg/l (Pseudokirchneriella subcapitata)
LC50/96h	100 mg/l (Pimephales promelas)
10043-35-3 boric acid	
EC50/48h	133 mg/l (Daphnia) ECOTOX Database
LC0/96h	> 1021 mg/l (Lepomis macrochirus)
LC50/21d	53.2 mg/L (Daphnia)
LC50/96h	50-100 mg/l (Onchorhyncus mykiss) ECOTOX database
	279 mg/l (Ptychocheilus lucius)

· **Persistence and degradability** Data not available
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available
· ***Mobility in soil*** Data not available
· **Additional ecological information:**
· ***General notes:***
At present there are no ecotoxicological assessments.
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.
· **Other adverse effects** No further relevant information available.

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13 Disposal considerations

· **Waste treatment methods**
· ***Recommendation:***
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.

· **Uncleaned packagings:**
· ***Recommendation:*** Disposal must be made according to official regulations.
· ***Primary packaging:*** Plastic vial (composed of polyethylene high density).

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14 Transport information

· **UN-Number**	Not applicable
· ***DOT, ADR, ADN, IMDG, IATA***	-
· **UN proper shipping name**	
· ***DOT, ADR, ADN, IMDG, IATA***	-

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· **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.

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15 Regulatory information

· ***SARA***
· *Section 302/304 (40CFR355.30 / 40CFR355.40):* None of the ingredients is listed.
· *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 ingredients is listed.
· *Chemicals known to cause reproductive toxicity for females:* None of the ingredients is listed.
· *Chemicals known to cause reproductive toxicity for males:* None of the ingredients is listed.
· *Chemicals known to cause developmental toxicity:* None of the ingredient is listed.

· ***Carcinogenic categories***

· *EPA (Environmental Protection Agency)*		
10043-35-3	boric acid	I

· *TLV (Threshold Limit Value established by ACGIH)*		
10043-35-3	boric acid	A4

· *NIOSH-Ca (National Institute for Occupational Safety and Health)* None of the ingredient is listed.
· *OSHA-Ca (Occupational Safety & Health Administration)* None of the ingredient is listed.

· **Product related hazard informations:**
Observe the general safety regulations when handling chemicals.
The product has been classified and marked in accordance with directives on hazardous materials.

· ***Hazard symbols:***

Toxic

· ***Hazard-determining components of labeling:***
tetramethylammonium hydroxide
boric acid

· ***Risk phrases:***
May impair fertility.
May cause harm to the unborn child.
Also harmful if swallowed.

· ***Safety phrases:***
Avoid exposure - obtain special instructions before use.
Wear suitable protective clothing, gloves and eye/face protection.
In case of insufficient ventilation, wear suitable respiratory equipment.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
This material and its container must be disposed of as hazardous waste.

· **National regulations:**

· ***Other regulations, limitations and prohibitive regulations***
US Federal Regulation:
This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.
· **U. S. State Regulations:**
· ***PA-RTK*** None of the ingredient is listed.

· ***NJ-RTK***	
75-59-2	tetramethylammonium hydroxide

· ***MA-RTK*** None of the ingredient is listed.
· ***RI-RTK*** None of the ingredient is listed.
· **US Federal Regulation** This preparation is a component of an FDA-regulated IN VITRO diagnostic medical device.

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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

· **** Data compared to the previous version altered.***