Safety Data Sheet
acc. to OSHA HCS

Printing date 10/02/2015 Reviewed on 10/02/2015

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1: Identification

· **Product identifier**

· ***Trade name:*** **ISE DILUENT**

· *Article number:* ISDI-5XXX
· *Synonyms* ISE DILUENT - DIL
· ***Relevant identified uses of the substance or mixture and uses advised against***
· *Application of the substance / the mixture*
Reagent for IN VITRO diagnostic
Product included in kit(s) :
- Kit composed of one reagent : ISDI-0250

· **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 Regulation (EC) No 1272/2008***


GHS07

Acute Tox. 4 H302 Harmful if swallowed.

· **Label elements**
· ***Labelling according to Regulation (EC) No 1272/2008*** The product is classified and labeled according to the CLP regulation.
· *Hazard pictograms*


GHS07

· *Signal word* Warning

· *Hazard-determining components of labeling:*
tetramethylammonium hydroxide
· *Hazard statements*
Harmful if swallowed.
· *Precautionary statements*
IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
Rinse mouth.

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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 Repr. 1B, H360FD	≤ 2.5%
75-59-2	tetramethylammonium hydroxide Acute Tox. 2, H300; Acute Tox. 1, H310; STOT SE 1, H370; STOT RE 1, H372; Skin Corr. 1B, H314	< 1.0%

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4: First-aid measures

· **Description of first aid measures**
· ***General information:***
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
Show this safety data sheet to the doctor in attendance.
· ***After inhalation:***
Supply fresh air.

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Move out of dangerous area.
If required, provide artificial respiration.
If symptoms appear, seek medical advice.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
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.
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:***
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 hazardous vapours/gases is possible during heating or in case of fire.
Carbon oxides (COx)
Nitrogen oxides (NOx)
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**
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
· **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.
· **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***
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
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:*
Store receptacle in a well ventilated area.
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 10-30 °C

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· **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.

· **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.

10043-35-3 boric acid (≤2.5%)	
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:*
The usual precautionary measures for handling chemicals should be followed.
Do not eat, drink, smoke or sniff while working.
Wash hands before breaks and at the end of work.
Avoid physical contact with material.
Avoid formation of gas/mist/vapours.
Avoid breathing gas/mist/vapours.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *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 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:*
Safety glasses
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· *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:	Fluid
Color:	Colorless
· *Odor:*	Odorless
· *Odour threshold:*	Not determined.
· ***pH-value at 20 °C (68 °F):***	8.7
· ***Change in condition***	
Melting point/Melting range:	Not applicable.
Boiling point/Boiling range:	Not determined.
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.

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· ***Vapor pressure:***	Not determined.
· ***Density:***	
Relative density at 20 °C (68 °F)	1.002 g/cm³ (8.362 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:***
No decomposition if used according to specifications.
Formation of hazardous vapours/gaz is possible during heating.
· **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)
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:***
Harmful if swallowed.

· *LD/LC50 values that are relevant for classification:*

ATE (Acute Toxicity Estimates)		
Oral	LD50	1042 mg/kg (rat)
Dermal	LD50	3473 mg/kg (rat)
Inhalative	LC50/4 h	116 mg/l (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)
75-59-2 tetramethylammonium hydroxide		
Oral	LD50	7.5 mg/kg (rat)
Dermal	LD50	25 mg/kg (rat)

· *Primary irritant effect:*
· *on the skin:*
May cause irritating effect.
· *on the eye:*
May cause irritating effect.
· *Inhalation:*
May be harmful by inhalation.
May cause irritating effect.
· *Ingestion:* Harmful if swallowed.
· *Sensitization:* Based on available data, the classification criteria are not met.
· ***Additional toxicological information:***
· *Carcinogenic categories*
· *IARC (International Agency for Research on Cancer)* None of the ingredient is listed.
· *NTP (National Toxicology Program)* None of the ingredient is listed.

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12: Ecological information

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

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)
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)

· **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:*** 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** · ***DOT, ADR, ADN, IMDG, IATA***	Not applicable. -
· **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.
· **UN "Model Regulation":**	-

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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.

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· *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 (oral)

· *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.
· **U. S. State Regulations:**
· ***PA-RTK*** None of the ingredient is listed.
· ***NJ-RTK*** None of the ingredient is listed.
· ***MA-RTK*** None of the ingredient is listed.
· ***RI-RTK*** None of the ingredient is listed.
· **US Federal Regulation** This mixture is a component of an FDA-regulated IN VITRO diagnostic medical device.

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

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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.

· *Relevant phrases*
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H370 Causes damage to organs.
H372 Causes damage to organs through prolonged or repeated exposure.

· **Department issuing SDS:** Product safety department
· **Contact:** Product safety department
· ***Abbreviations and acronyms:***
SVHC : Substances of Very High Concern
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOEC : No Observed Effect Concentration
EC50: Effective concentration, 50 percent
IC50 : Inhibitory concentration, 50 percent.
Acute Tox. 2: Acute toxicity, Hazard Category 2
Acute Tox. 4: Acute toxicity, Hazard Category 4
Acute Tox. 1: Acute toxicity, Hazard Category 1
Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
Repr. 1B: Reproductive toxicity, Hazard Category 1B
STOT SE 1: Specific target organ toxicity - Single exposure, Hazard Category 1
STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1

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