ELITechGroup
EMPOWERING IVD

Safety Data Sheet
acc. to OSHA HCS

Printing date 23.03.2021 Reviewed on 23.03.2021

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1 Identification

· **Product identifier**

· ***Trade name:*** **ENVOY 500 ISE DILUENT**

· *Article number:* ISDV-0850S
· ***Relevant identified uses of the substance or mixture and uses advised against***
· *Application of the substance / the mixture*
Product included in kit(s) :
- Kit composed of one reagent : 55380
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 Regulation (EC) No 1272/2008***


GHS06

Acute Tox. 3	H311	Toxic in contact with skin.


GHS08

Repr. 1B	H360FD	May damage fertility. May damage the unborn child.
STOT SE 2	H371	May cause damage to the central nervous system.
STOT RE 2	H373	May cause damage to the liver and the thymus through prolonged or repeated exposure.


GHS07

Acute Tox. 4	H302	Harmful if swallowed.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.

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


GHS06 GHS08

· *Signal word* Danger

· *Hazard-determining components of labeling:*
tetramethylammonium hydroxide
boric acid
· *Hazard statements*
Harmful if swallowed.
Toxic in contact with skin.
Causes skin irritation.
Causes serious eye irritation.
May damage fertility. May damage the unborn child.
May cause damage to the central nervous system.
May cause damage to the liver and the thymus through prolonged or repeated exposure.
· *Precautionary statements*
Do not breathe mist/vapours/spray.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not handle until all safety precautions have been read and understood.
IF exposed or concerned: Call a poison center/doctor.
Take off immediately all contaminated clothing and wash it before reuse.

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· ***Additional information:***
Restricted to professional users.

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3 Composition/information on ingredients

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

· ***Dangerous components:***

· *CAS NO. Description*		*%*
CAS: 10043-35-3 EINECS: 233-139-2 Index number: 005-007-00-2	boric acid Repr. 1B, H360FD	2.5-10%
CAS: 75-59-2 EINECS: 200-882-9	tetramethylammonium hydroxide Acute Tox. 2, H300; Acute Tox. 1, H310; STOT SE 1, H370; STOT RE 1, H372; Met. Corr.1, H290; Skin Corr. 1B, H314; Eye Dam. 1, H318; Aquatic Chronic 2, H411	≤2.5%

· ***SVHC***	
10043-35-3	boric acid

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4 First-aid measures

· **Description of first aid measures**
· ***General information:***
IF exposed or concerned: Call a poison center/doctor.
Show this safety data sheet to the doctor in attendance.
Take off immediately all contaminated clothing and wash it before reuse.
· ***After inhalation:***
Supply fresh air.
Move out of dangerous area.
If required, provide artificial respiration.
Call a poison center/doctor.
· ***After skin contact:***
Immediately wash with water and soap and rinse thoroughly.
Take off immediately all contaminated clothing and wash it before reuse.
Call a poison center/doctor.
· ***After eye contact:***
Remove contact lenses, if present and easy to do.
Rinse opened eye for several minutes under running water.
Protect unharmed eye.
Call a poison center/doctor.
· ***After swallowing:***
Rinse out mouth.
Never give anything by mouth to an unconscious person.
Call a poison center/doctor.
· *Most important symptoms and effects, both acute and delayed* The most important known symptoms and effects are described in sections 2 and 11.
· *Indication of any immediate medical attention and special treatment needed* Call a person trained in first aid / a doctor.

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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**
Dangerous decomposition products may be formed.
Carbon oxides (COx)
Boron compounds
CAS 75-59-2 : above 95°C decoposes in trimethylamine (flammable gaz) and methanol (emits flammables vapors).
· **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**
Take off immediately all contaminated clothing and wash it before reuse.
Mount respiratory protective device.
Ensure adequate ventilation
Wear protective equipment. Keep unprotected persons away.

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Pregnant women should strictly avoid inhalation and contact with the product.
Do not handle until all safety precautions have been read and understood.
Avoid physical contact with material.
Do not breathe mist/vapours/spray.
Avoid formation of vapour / mist / spray.
· **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).
Clean the affected area carefully.
Send for recovery or disposal in suitable receptacles.
· **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***
Avoid physical contact with material.
Take off immediately all contaminated clothing and wash it before reuse.
Do not eat, drink or smoke when using this product.
Ensure good ventilation/exhaustion at the workplace.
Do not handle until all safety precautions have been read and understood.
Pregnant women should strictly avoid inhalation and contact with the product.
Open and handle receptacle with care.
Do not breathe mist/vapours/spray.
Avoid formation of vapour / mist / spray.
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:*
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
· **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:***	
10043-35-3 boric acid	
TLV (USA)	Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ *as inhalable fraction

· *DNELs*		
10043-35-3 boric acid		
Dermal	DNEL (long term - systemic effects)	392 mg/kg bw/d (worker)
Inhalative	DNEL (long term - systemic effects)	8.3 mg/m3 (worker)
75-59-2 tetramethylammonium hydroxide		
Dermal	DNEL (long term - systemic effects)	0.14 mg/kg bw/d (worker)
	DNEL (long term - local effects)	6.25 µg/cm2 (worker)
Inhalative	DNEL (long term - systemic effects)	0.49 mg/m3 (worker)

· *PNECs*	
10043-35-3 boric acid	
PNEC (freshwater)	2.02 mg/l
PNEC (marine water)	2.02 mg/l
PNEC (soil)	5.4 mg/kg
PNEC (STP)	10 mg/l
PNEC (freshwater)	13.7 mg/l
75-59-2 tetramethylammonium hydroxide	
PNEC Sediment (freshwater)	30 µg/kg (-)

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PNEC Sediment (marine water)	3 µg/kg (-)
PNEC (soil)	5.7 µg/kg (-)
PNEC (STP)	5 mg/l (-)
PNEC (marine water)	0.05 µg/l (-)
PNEC Sediment (freshwater)	0.5 µg/l (-)
PNEC Rejet intermittent (eau douce)	30 µg/l (-)

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

· **Exposure controls**
· ***Personal protective equipment:***
· *General protective and hygienic measures:*
Do not eat, drink or smoke when using this product.
Store protective clothing separately.
Take off immediately all contaminated clothing and wash it before reuse.
The usual precautionary measures for handling chemicals should be followed.
Wash hands before breaks and at the end of work.
Do not handle until all safety precautions have been read and understood.
Pregnant women should strictly avoid inhalation and contact with the product.
Avoid physical contact with material.
Do not breathe mist/vapours/spray.
Avoid formation of vapour / mist / spray.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
· *Breathing equipment:*
Use suitable respiratory protective device when mist/vapour/spray is formed.
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
Under good ventilation/exhaustion at the workplace, 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:*
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.


Protective gloves

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
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:*
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).


Wear face shield/eye protection.

· *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
· *Odor threshold:*	Not determined.
· ***pH-value at 20 °C (68 °F):***	8.1
· ***Change in condition***	
Melting point:	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.

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· *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:***	
Relative density at 20 °C (68 °F)	1.0189 g/cm³ (8.5027 lbs/gal)
Vapor 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.
· **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.
Metallic aluminium
Strong acids.
Acid anhydrides
· **Hazardous decomposition products:**
Dangerous decomposition products may be formed.
Carbon oxides (COx)
Boron compounds
CAS 75-59-2 : above 95°C decoposes in trimethylamine (flammable gaz) and methanol (emits flammables vapors).
· **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.
Toxic in contact with skin.

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

ATE (Acute Toxicity Estimate)		
Oral	LD50	570-3420 mg/kg
Dermal	LD50	570-2280 mg/kg

10043-35-3 boric acid		
Oral	LD50	3450-4080 mg/kg (rat) ECHA
Dermal	LD50	>2000 mg/kg (rabbit) ECHA
75-59-2 tetramethylammonium hydroxide		
Oral	LD50	12.5-75 mg/kg ECHA
Dermal	LD50	12.5-50 mg/kg ECHA

· *Skin corrosion/irritation*
Causes skin irritation.
· *Serious eye damage/irritation*
Causes serious eye irritation.
· *Sensitization:*
Based on available data, the classification criteria are not met.
CAS : 10043-35-3 Tests on animals have shown no effect.
· ***Additional toxicological information:***
· *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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· *Germ cell mutagenicity*
CAS : 10043-35-3 Tests on animals have shown no effect.
Based on available data, the classification criteria are not met.
· *Carcinogenicity* Based on available data, the classification criteria are not met.
· *Reproductive toxicity*
Repr. 1B
May damage fertility. May damage the unborn child.
· *Specific target organ toxicity - single exposure*
May cause damage to the central nervous system.
· *Specific target organ toxicity - repeated exposure*
May cause damage to the liver and the thymus through prolonged or repeated exposure.
Information on components:

75-59-2 tetramethylammonium hydroxide		
Oral	NOAEL	5 mg/Kg bw/d
Dermal	NOAEL (local effects)	18.75 µg/cm2

· *Aspiration hazard* Based on available data, the classification criteria are not met.

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12 Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
Based on available data, the classification criteria are not met.
Information on components:

10043-35-3 boric acid		
Oral	EC50/74.5h (static)	52.4 mg/L (Pseudokirchneriella subcapitata) OCDE 201
	EC50/48h (static)	133 mg/l (Daphnia) ECOTOX Database
	LC50/96h (dynamic)	79 mg/l (Onchorhyncus mykiss) ECOTOX database
	NOEC/34d	6.4 mg/L (fish) OCDE 210
	NOEC/21d	34.2 mg/l (Daphnia) OCDE 211
75-59-2 tetramethylammonium hydroxide		
	EC50/48h	3 mg/l (Daphnia)
	LC50/96h	462 mg/l (Pimephales promelas)
	NOEC - 11d	0.025 mg/L (Daphnia)

· **Persistence and degradability** Data not available.
· **Behavior in environmental systems:**
· ***Bioaccumulative potential*** Data not available.
· *Log Pow:* CAS : 10043-35-3 Log Pow -1.09 (22 °C)
· ***Mobility in soil*** Data not available.
· **Additional ecological information:**
· ***General notes:***
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Water hazard class 1 (Self-assessment): slightly hazardous for water
At present there are no ecotoxicological assessments.
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 on hazardous wastes.

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

14 Transport information

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

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· **Transport hazard class(es)**	
· ***DOT***	
	
· *Class*	-
· ***ADR, IMDG, IATA***	
	
· *Class*	-
· **Packing group** · ***DOT, ADR, IMDG, IATA***	-
· **Environmental hazards:**	Not applicable.
· **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":**	-

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 (oral)

· *TLV (Threshold Limit Value)*		
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***	
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 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*
H290 May be corrosive to metals.
H300 Fatal if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.
H360FD May damage fertility. May damage the unborn child.
H370 Causes damage to organs.
H372 Causes damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** Product safety department
· **Contact:** Product safety department

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· **Document reference:**
· ***Abbreviations and acronyms:***
SVHC : Substances of Very High Concern
ADR: Accord relatif au transport international 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
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)
DNEL: Derived No-Effect Level (REACH)
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.
Met. Corr.1: Corrosive to metals – Category 1
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 1: Acute toxicity – Category 1
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 1: Specific target organ toxicity (single exposure) – Category 1
STOT SE 2: Specific target organ toxicity (single exposure) – Category 2
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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