

Printing date 10/01/2015

Reviewed on 09/30/2015

1: Identification

· Product identifier

- · Trade name: SYSTEM CLEANING SOLUTION
- · Article number: SLNA-5XXX
- · Relevant identified uses of the substance or mixture and uses advised against
- Application of the substance / the mixture Reagent for IN VITRO diagnostic
- Cleaning solution for ELITech Clinical Systems equipments.

• Details of the supplier of the safety data sheet • Manufacturer/Supplier: ELITech Clinical Systems SAS

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· Information department: Product safety department

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

2: Hazard(s) identification

· Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008



Met. Corr.1 H290 May be corrosive to metals.

- Skin Corr. 1A H314 Causes severe skin burns and eye damage.
- Eye Dam. 1 H318 Causes serious eye damage.

· Label elements

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

Hazard pictograms

GHS05

· Signal word Danger

- Hazard-determining components of labeling: sodium hydroxide
- sodium hypochlorite • *Hazard statements*
- May be corrosive to metals.

Causes severe skin burns and eye damage.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

Do not breathe mist/vapours/spray.

If swallowed: Rinse mouth. Do NOT induce vomiting.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Absorb spillage to prevent material damage.

Chemical characterization: Mixtures Description: Mixture of substances. Aqueous solution.		
Aqueous solution.		
· Dangerous components:		
Dangerous components: CAS NO. Description %		
с .	Met. Corr.1, H290; Skin Corr. 1A, H314 2.	5-10%

(Contd. on page 2)

Printing date 10/01/2015

Trade name: SYSTEM CLEANING SOLUTION

4: First-aid measures

- · Description of first aid measures
- · General information:
- Take off immediately all contaminated clothing and wash it before reuse. Show this safety data sheet to the doctor in attendance. *After inhalation:* Supply fresh air.
- Move out of dangerous area.
- If required, provide artificial respiration.
- If symptoms appear, seek medical advice.
- After skin contact:
- Take off immediately all contaminated clothing and wash it before reuse.
- Immediately rinse with water.
- Immediately call a POISON CENTER/doctor.
- After eye contact:
- Protect unharmed eye.
- Remove contact lenses, if present and easy to do. Rinse opened eye for several minutes under running water.
- Immediately call a POISON CENTER/doctor.
- After swallowing:
- Never give anything by mouth to an unconscious person. Rinse out mouth.
- Do not induce vomiting.
- Seek immediate advice from a doctor or a poison control center.
- Information for doctor:
- Most important symptoms and effects, both acute and delayed Irritation and corrosion. Danger to the sight.

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.

Hydrogen chloride (HCl)

- · 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 equipment. Keep unprotected persons away.
- Ensure adequate ventilation
- Take off immediately all contaminated clothing and wash it before reuse.
- Avoid physical contact with material.
- Avoid formation of gas/mist/vapours.
- Do not breathe mist/vapours/spray.
- Environmental precautions:

Dilute with plenty of water.

Prevent seepage into sewage system, workpits and cellars.

· Methods and material for containment and cleaning up:

Absorb spillage to prevent material damage.

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.

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.
- Do not breathe mist/vapours/spray.

(Contd. of page 1)

Reviewed on 09/30/2015

• Indication of any immediate medical attention and special treatment needed Data not available

Printing date 10/01/2015

Trade name: SYSTEM CLEANING SOLUTION

Reviewed on 09/30/2015

(Contd. of page 2)

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:
- May be corrosive to metals.
- Keep only in original container.
- · Information about storage in one common storage facility: Store away from incompatible materials (see section 10).
- \cdot Further information about storage conditions:
- Store receptacle in a well ventilated area.
- Keep receptacle tightly sealed.
- Protect the product from light. Avoid exposure to heat.
- Recommended storage temperature: 15-25 °C
- · Specific end use(s) Data not available

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:

1310-73-2 sodium hydroxide (2.5-10%)

Long-term value: 2 mg/m3 PEL

REL Ceiling limit value: 2 mg/m3

TLV

Ceiling limit value: 2 mg/m3

7681-52-9 sodium hypochlorite (≤2.5%)

WEEL Short-term value: 2 mg/m3

· 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.

Take off immediately all contaminated clothing and wash it before reuse.

Avoid physical contact with material.

Avoid formation of gas/mist/vapours.

Do not breathe mist/vapours/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:

- 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:



Color:

Odour threshold:

Odor:

Protective gloves

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

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

Use equipement 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).

Colorless to light yellow

Not determined.

Odorless to faint chlorine-like.

· Body protection: Protective work clothing

	9: Physical and ch	emical properties	
	· Information on basic p · General Information	hysical and chemical properties	
	· Appearance:		
I	Form:	Liquid	

(Contd. on page 4)

US

Safety Data Sheet acc. to OSHA HCS

Printing date 10/01/2015

Trade name: SYSTEM CLEANING SOLUTION

Reviewed on 09/30/2015

		(Contd. of page 3
• pH-value at 20 •C (68 •F):	≥13	
· 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.	
· Vapor pressure:	Not determined	
· Density:		
Relative density at 20 °C (68 °F)	1.064 g/cm ³ (8.879 lbs/gal)	
Vapour density	Not determined	
Evaporation rate	Not determined	
· Solubility in / Miscibility with		
Water:	Miscible	
· Partition coefficient (n-octanol/wate	r): Not determined	
· Viscosity:		
Dynamic:	Not determined	
· Other information	No further relevant information available.	

10: Stability and reactivity

- **Reactivity** May be corrosive to metals.
- · Chemical stability Stable under recommended storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions
- Caution! Do not use in conjunction with other products. Dangerous gases (chlorine) may be given off.
- Violent reactions possible with:
- Oxidizable substances.

Acids.

Ammonium compounds.

Organics.

- Metals, light metals : reacts with metals, light metals to form hydrogen (Danger of explosion)
- Conditions to avoid No further relevant information available.
- · Incompatible materials:
- Oxidizable substances.
- Acids.
- Ammonium compounds.
- Metals.
- Light metals.
- Organics.
- Hazardous decomposition products: Dangerous decomposition products may be formed.
- Hydrogen chloride (HCl)
- 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:	
ATE (Acute Toxicity Estimates)	
Oral LD50 > 5000 mg/kg (-)	
1310-73-2 sodium hydroxide	
Oral LD50 2000 mg/kg (rat)	
7681-52-9 sodium hypochlorite	
Oral LD50 5800 mg/kg (mouse)	
8200 mg/kg (rat)	
	(Contd. on page 5)

Printing date 10/01/2015

Trade name: SYSTEM CLEANING SOLUTION

· Primary irritant effect:

- \cdot on the skin:
- Causes severe skin burns and eye damage.
- \cdot on the eye:
- Causes serious eye damage.
- · Inhalation:
- May be harmful by inhalation.

May cause irritations or burns of mucous.

- Ingestion:
- May be harmful if swallowed.

May cause irritations or burns of mucous.

Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

- · 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:

- 1310-73-2 sodium hydroxide
- EC50/48h 76 mg/l (Daphnia)

LC50/96h 45.4 mg/l (Onchorhyncus mykiss)

7681-52-9 sodium hypochlorite

LC50/96h 0.023-0.0528 mg/l (Oncorhyncus gorbuscha)

chlore

• Persistence and degradability Anorganic product, is not eliminable from water by means of biological cleaning processes.

- · Behavior in environmental systems:
- · Bioaccumulative potential Data not available
- Mobility in soil Data not available
- · Ecotoxical effects:
- · Remark: Can lead to changes in pH and deterioration of aquatic life.
- · Additional ecological information:
- · General notes:
- At present there are no ecotoxicological assessments.
- Water hazard class 1 (Self-assessment): slightly hazardous for water

Avoid transfer into the environment.

Must not reach bodies of water or drainage ditch undiluted or unneutralized.

Disposal procedures have to be respected, see Section 13.

 \cdot 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)

· UN-Number · DOT, ADR, IMDG, IATA	UN3266
· UN proper shipping name	
$\cdot DOT$	Corrosive liquid, basic, inorganic, n.o.s. (Sodium hydroxide solution,
	Hypochlorite solutions)
·ADR	3266 Corrosive liquid, basic, inorganic, n.o.s. (Sodium hydroxide solution,
	Hypochlorite solutions)
· IMDG, IATA	CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S. (SODIUM HYDROXID
	SOLUTION, HYPOCHLORITE SOLUTION)

Reviewed on 09/30/2015

(Contd. of page 4)

Printing date 10/01/2015

Reviewed on 09/30/2015

Trade name: SYSTEM CLEANING SOLUTION

	(Contd. of pag
Transport hazard class(es)	
DOT	
~	
- Class	8 Corrosive substances
Label	8
ADR, IMDG, IATA	
the second secon	
8	
· Class	8 Corrosive substances
Label	8
Packing group	
DOT, ADR, IMDG, IATA	III
Environmental hazards: Marine pollutant:	No
Special precautions for user Danger code (Kemler):	Warning: Corrosive substances 88
• EMS Number:	F-A,S-B
· Segregation groups	Alkalis
Transport in bulk according to Annex II of MARP	
IBC Code	Not applicable.
• Transport/Additional information:	
ADR	
Excepted quantities (EQ)	Code: E1
	Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
 IMDG	
Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
-	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
UN "Model Regulation":	UN3266, Corrosive liquid, basic, inorganic, n.o.s. (Sodium hydroxide solution
	Hypochlorite solutions), 8, III

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
- \cdot 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) None of the ingredient is listed.
- · 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

	sodium hydroxide
7681-52-9	sodium hypochlorite
· NJ-RTK	
	sodium hydroxide
7681-52-9	sodium hypochlorite
· MA-RTK	
1010 50 0	

1310-73-2 sodium hydroxide 7681-52-9 sodium hypochlorite

(Contd. on page 7)

US

Printing date 10/01/2015

Trade name: SYSTEM CLEANING SOLUTION

(Contd. of page 6)

Reviewed on 09/30/2015

· RI-RTK

1310-73-2 sodium hydroxide 7681-52-9 sodium hypochlorite

US Federal Regulation

This preparation is an accessorie of an FDA-regulated medical device.

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.

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. H314 Causes severe skin burns and eye damage.

· 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
- 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)

- CAS: Chemical Abstracts Service (division of the American Chemic LC50: Lethal concentration, 50 percent DJ50: 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, Hazard Category 1 Skin Corr. 18: Skin corrosion/irritation, Hazard Category 1A Skin Corr. 18: Skin corrosion/irritation, Hazard Category 1B Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

 \cdot * Data compared to the previous version altered.