Safety Data Sheet
acc. to OSHA HCS

Printing date 01/05/2016 Reviewed on 01/05/2016

1: Identification

· **Product identifier**

· ***Trade name:*** **LIPASE SL Reagent 1**

· *Article number:* LPSL-0850R1 / LPSL-5XXX
· *Synonyms* LIPASE ENVOY R1 / LIPASE SL R1.
· ***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 two reagents : LPSL-0850 / LPSL-0230

· **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.

2: Hazard(s) identification

· **Classification of the substance or mixture**
· ***Classification according to Regulation (EC) No 1272/2008*** The product is not classified according to the CLP regulation.

· **Label elements**
· ***Labelling according to Regulation (EC) No 1272/2008*** -
· *Hazard pictograms* -
· *Signal word* -
· *Hazard statements* -

3: Composition/information on ingredients

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

· ***Dangerous components:*** No dangereous component in reportable quantity.

4: First-aid measures

· **Description of first aid measures**
· ***General information:*** 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:***
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.
Rinse out mouth.
Do not induce vomiting.
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 toxic gases is possible during heating or in case of fire.
· **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**
Ensure adequate ventilation
Wear protective clothing.
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).
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:* Store in a cool location.
· *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:* 2-8 °C
· **Specific end use(s)** Data not 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:

26628-22-8 sodium azide (< 0.1%)	
REL (USA)	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV (USA)	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3

· *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.
Avoid physical contact with material.
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).

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· *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:*
Goggles recommended during refilling.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· *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:*	Data not available.
· ***pH-value at 20 °C (68 °F):***	8
· ***Change in condition***	
Melting point/Melting range:	Data not available.
Boiling point/Boiling range:	Data not available.
· ***Flash point:***	Not applicable
· ***Flammability (solid, gaseous):***	Not applicable.
· ***Ignition temperature:***	Data not available.
· *Decomposition temperature:*	Data not available.
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Data not available
· ***Density:***	
Relative density at 20 °C (68 °F)	1.0059 g/cm³ (8.394 lbs/gal)
Vapor density	Data not available.
Evaporation rate	Data not available.
· ***Solubility in / Miscibility with***	
Water:	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Data not available.
· ***Viscosity:***	
Dynamic:	Data not available.
· **Other information**	No further relevant information available.

10: Stability and reactivity

· **Reactivity** See § Possibility of hazardous reactions.
· **Chemical stability** Stable under recommended storage conditions.
· ***Thermal decomposition / conditions to be avoided:*** Data not available.
· **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 canalisations, rinse with plenty of water.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** Sodium azide (26628-22-8) : incompatible with acids, and some metals; forms explosion-sensitive compounds.
· **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.
· **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:*** Based on available data, the classification criteria are not met.

· *LD/LC50 values that are relevant for classification:*		
ATE (Acute Toxicity Estimates)		
Oral	LD50	> 5000 mg/kg (-)
Dermal	LD50	> 5000 mg/kg (-)

26628-22-8 sodium azide		
Oral	LD50	27 mg/kg (mouse)
Dermal	LD50	20 mg/kg (rabbit)
Inhalative	LC50	37 mg/m3 (rat)

· *Primary irritant effect:*
· *on the skin:* Based on available data, the classification criteria are not met.
· *on the eye:* Based on available data, the classification criteria are not met.
· *Sensitization:* Based on available data, the classification criteria are not met.
· ***Additional toxicological information:***
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)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by IARC as a carcinogen.
· *NTP (National Toxicology Program)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by NTP as a carcinogen.

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)

· **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.

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:***
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**	Not applicable.
· ***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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· **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):*	
26628-22-8	sodium azide

· *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:*	
67-56-1	methanol

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

· *TLV (Threshold Limit Value established by ACGIH)*		
26628-22-8	sodium azide	A4

· *NIOSH-Ca (National Institute for Occupational Safety and Health)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by NIOSH as a carcinogen.
· *OSHA-Ca (Occupational Safety & Health Administration)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by OSHA as a carcinogen.
· **U. S. State Regulations:**

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

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

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

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

· **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
· ***Abbreviations and acronyms:***
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.

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

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1: Identification

· **Product identifier**

· ***Trade name:*** **LIPASE SL Reagent 2**

· *Article number:* LPSL-0850R2 / LPSL-5XXX
· *Synonyms* LIPASE ENVOY R2 / LIPASE SL R2.
· ***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 two reagents : LPSL-0850 / LPSL-0230

· **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.

2: Hazard(s) identification

· **Classification of the substance or mixture**
· ***Classification according to Regulation (EC) No 1272/2008*** The product is not classified according to the CLP regulation.

· **Label elements**
· ***Labelling according to Regulation (EC) No 1272/2008*** -
· *Hazard pictograms* -
· *Signal word* -
· *Hazard statements* -

3: Composition/information on ingredients

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

· ***Dangerous components:***		
67-68-5	dimethyl sulfoxide	10-20%

4: First-aid measures

· **Description of first aid measures**
· ***General information:*** 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:***
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.
Rinse out mouth.
Do not induce vomiting.
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 toxic gases is possible during heating or in case of fire.
· **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**
Ensure adequate ventilation
Wear protective clothing.
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, acid binders, 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:* Store in a cool location.
· *Information about storage in one common storage facility:* Not required.
· *Further information about storage conditions:*
Keep container tightly closed.
Protect the product from light. Avoid exposure to heat.
· *Recommended storage temperature:* 2-8 °C
· **Specific end use(s)** Data not 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:***	
67-68-5 dimethyl sulfoxide	
WEEL (USA)	Long-term value: 250 ppm

· *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.
Avoid physical contact with material.
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.

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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:*
Goggles recommended during refilling.
Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
· *Body protection:* Protective work clothing

9: Physical and chemical properties

· **Information on basic physical and chemical properties**	
· ***General Information***	
· *Appearance:*	
Form:	Liquid
Color:	Brown-orange
· *Odor:*	Odorless
· *Odor threshold:*	Data not available
· ***pH-value at 20 °C (68 °F):***	4,2
· ***Change in condition***	
Melting point/Melting range:	Data not available
Boiling point/Boiling range:	Data not available
· ***Flash point:***	Not applicable
· ***Flammability (solid, gaseous):***	Not applicable
· ***Ignition temperature:***	Data not available
· *Decomposition temperature:*	Data not available
· ***Auto igniting:***	Product is not selfigniting.
· ***Danger of explosion:***	Product does not present an explosion hazard.
· ***Vapor pressure:***	Data not available
· ***Density:***	
Relative density at 20 °C (68 °F)	1.0138 g/cm³ (8.46 lbs/gal)
Vapor density	Data not available
Evaporation rate	Data not available
· ***Solubility in / Miscibility with***	
Water:	Fully miscible.
· ***Partition coefficient (n-octanol/water):***	Data not available
· ***Viscosity:***	
Dynamic:	Data not available
· **Other information**	No further relevant information available.

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.
· **Possibility of hazardous reactions** No dangerous reactions if used according to specifications.
· **Conditions to avoid** Sensitive to light.
· **Incompatible materials:** Data not available.
· **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.
· **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:*** Based on available data, the classification criteria are not met.

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

ATE (Acute Toxicity Estimates)		
Oral	LD50	> 5000 mg/kg (-)
Dermal	LD50	> 5000 mg/kg (-)

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67-68-5 dimethyl sulfoxide		
Oral	LD50	14500 mg/kg (rat)
Dermal	LD50	> 5000 mg/kg (rabbit)
Inhalative	LC50/4h	40250 ppm (rat)

· *Primary irritant effect:*
· *on the skin:* Based on available data, the classification criteria are not met.
· *on the eye:* Based on available data, the classification criteria are not met.
· *Sensitization:* Based on available data, the classification criteria are not met.
· ***Additional toxicological information:***
· *Carcinogenic categories*
· *IARC (International Agency for Research on Cancer)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by IARC as a carcinogen.
· *NTP (National Toxicology Program)*
No component, contained in this product at concentration equal or greater than 0.1 %, is listed by NTP as a carcinogen.

12: Ecological information

· **Toxicity**
· ***Aquatic toxicity:***
At present there are no ecotoxicological assessments.
Information on components:

67-68-5 dimethyl sulfoxide	
LC50/96h	35000 mg/l (Onchorhyncus mykiss)
	34000 mg/l (Pimephales promelas)
EC50/96h	> 400000 mg/l (Lepomis macrochirus)
EC50	27500 mg/l (Daphnia)

· **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.

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)

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:**	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":**	-

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15: Regulatory information

· ***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)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by ACGIH as a carcinogen.
· *NIOSH-Ca (National Institute for Occupational Safety and Health)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by NIOSH as a carcinogen.
· *OSHA-Ca (Occupational Safety & Health Administration)*
No component, contained in this product at concentration equal or grater than 0.1 %, is listed by OSHA as a carcinogen.
· **U. S. State Regulations:**

· ***PA-RTK***	
67-68-5	dimethyl sulfoxide

· ***NJ-RTK***	
67-68-5	dimethyl sulfoxide

· ***MA-RTK*** Available information lists none.

· ***RI-RTK***	
67-68-5	dimethyl sulfoxide

· **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.

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
· ***Abbreviations and acronyms:***
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.