

Product Blue Eye™ Submucosal Injection Agent.
 Revision date 24 Jan. 2024
 Revision 5



Safety Data Sheet (SDS)

1. Product and Company Information

Product name Blue Eye™ Submucosal Injection Agent
Company The Standard Co. Ltd.
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Telephone +82 2 838 5533
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Website www.thestandard.co.kr
Recommended use of the chemical and restrictions on use
 Recommended use Materials for medical treatment
 Restrictions on use No data available

2. Hazards Identification

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Physical hazard Not applicable
 Health hazard Not applicable
 Environment hazard Not applicable

Lable elements including precautionary statements

Symbol / Signal word Not applicable
 Hazard statements Not applicable
 Precautionary statement Not applicable

NFPA Rating

Health 0
 Flammability 0
 Reactivity 0
 Water reactivity 0

3. Composition / Information on Ingredients

Ingredients	CAS No.	EINECS No.	Conc. %
Water for injection	7732-18-5 From *US NLM	231-791-2 From **ECHA	> 98.5 %
Sodium chloride	7647-14-5	231-598-3	0.5 - 1.0 %
Hyaluronate Sodium	9067-32-7	618-620-0	0.1 - 0.5 %
1% Methylene Blue trihydrate	7220-79-3	615-731-6	0.1 - 0.5 %

* UC NLM : U.S. National Library of Medicine, <http://chem.sis.nlm.nih.gov/chemidplus/>

** ECHA : European chemical agency, <http://echa.europa.eu/>

4. First aid measures

In case of eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
In case of skin contact	No data available
If inhaled	If breathed in, move person into fresh air.
If swallowed	Never give anything by mouth to an unconscious person.
Other medical attention	Medical personnel should be aware of the protective measure of the substance.

5. Fire-Fighting measures

Flammable properties	
Flash point	No flash occurred under 250°C (Cleveland open cup)
Autoignition temperature	No spontaneous combustion under 200°C
Suitable extinguisher	Water spray, alcohol-resistant foam, dry chemical, carbon dioxide
Specific hazards arising from the chemical	No data available
Special protective equipment for fire-fighters	Wear self contained breathing apparatus for fire fighting if necessary.

6. Accidental release measures

Personal precautions	Avoid contact with eyes.
Environmental precautions	No data available
Methods and materials for containment and cleaning up	Keep in suitable, closed for disposal.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes.
Condition for safe storage	Keep container tightly closed.

8. Exposure control / Personal protection

Components with workplace control parameter	
KOSHA	No data available
ACCIH	No data available
Appropriate engineering controls	No data available
Personal protective equipment	
Respiratory protection	No data available
Eye protection	Protective goggles
Hand protection	No data available
Skin and body protection	No data available

9. Physical and Chemical properties

State	Liquid at 20 °C
Flash Point	No flash occurred under 250 °C (Cleveland open cup)
Autoignition temperature	No spontaneous combustion under 200 °C
pH	6.5 ~ 7.5 at 20 °C ※ Sample : H ₂ O = 1:5 (v/v)

Water solubility	Soluble at 20 °C	
Relative density	1.0 at 20 °C	
Oxidizing properties	No oxidizing hazard	※ UN TDG test & criteria – Test O1
Flammable properties	No data available	
Explosive properties	No data available	
Melting range	No data available	
Boiling point (Initial)	> 97 °C	
Evaporation rate	No data available	
Vapour pressure	No data available	
Decomposition temperature	No data available	
Partition coefficient (n-octanol/water)	No data available	
Viscosity	< 100 mPa · s (cP)	at 20 °C
Lower explosion limit / Upper explosion limit	No data available	
Freezing Point	-0.5 °C	

10. Stability and Reactivity

Chemical stability	Stable under recommended storage conditions.
Conditions to avoid	No data available
Materials to avoid	Strong oxidizing agents
Hazardous decomposition products	Carbon oxides

11. Toxicological Information

Acute toxicity				
Oral	rat	LD50	> 2,000 mg/kg	※ From US NLM / ECHA
Inhalation	rat	LD50	> 2,000 mg/kg	
Skin	rabbit	LD50	No data available	
Skin Irritation				No data available
Eye Irritation				No data available
Respiratory sensitization				No data available
Skin sensitization				No data available
Germ cell mutagenicity				No data available
Carcinogenicity				Not classifiable ※ From CCRIS / IARC
Reproductive toxicity				Suspected of damaging fertility Or the unborn child (Methylene Blue trihydrate) ※ From US NLM / ECHA
Specific target organ toxicity – single exposure (GHS)				No data available
Specific target organ toxicity – repeated exposure (GHS)				No data available
Aspiration hazard				No data available

12. Ecological Information

Toxicity					
Fish	LC50	> 100 mg/L,	96h		※ From US NLM / ECHA
Crustacean	EC50	> 100 mg/L,	48h		
Algae	EC50	No data available			
Persistence and degradability		No data available			
Bioaccumulative potential		No data available			
Mobility in soil		No data available			
Other adverse effects		No data available			

13. Disposal Considerations

Disposal consideration	Observe all environmental regulations.
Disposal precaution	Keep in suitable, closed containers for disposal.

14. Transport Information

UN TDG	Not dangerous goods
IATA	Not dangerous goods
IMDG	Not dangerous goods
Marine pollution	Not applicable
Special precaution	
Fire EmS Guide	F-A (Recommendation)
Spillage EmS Guide	Not dangerous goods

15. Regulatory Information

Korea Industrial Safety and Health Act	
GHS	Not applicable
Material(s) applied by workplace exposure limits	Not applicable
Korea Chemicals Control Act	Not toxic chemical
Korea Hazardous Materials Safety Control Act	Not hazardous material
Korea Persistent Organic Pollutants Control Act	Not applicable
US OSHA Hazards (GHS)	Not applicable

16. REACH Compliance

This product does not require to provide a REACH test result in compliance with Chapter 1, Aim, Scope and application Article 2, Section 6. (c) of REGULATION(EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (2006-12-18)

16. Other Information

Issued Data	29 August 2019
Revision No.	5
Revision Date	24 January 2024
References	

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| - GHS Classification | Korea MSDS Testing Lab Certificate (Report No. 2019-03-003567), US NLM |
| - Physical and chemical properties | Korea MSDS Testing Lab Certificate |
| - Transport information | Korea MSDS Testing Lab Certificate |
| - Toxic & ecological information | OECD SIDS, ECHA, US NLM, HSDB, IARC, CCRIS, JP NITE |

Acronyms and Websites

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| - ECHA | European chemical agency, | http://echa.europa.eu/ |
| - US NLM | U.S. National Library of Medicine, | http://chem.sis.nlm.nih.gov/chemiplus/ |
| - HSDB | US Hazardous Substances Data Bank, | http://toxnet.nlm.nih.gov/ |
| - CCRIS | US Chemical Carcinogenesis Research Information System. | http://toxnet.nlm.nih.gov |
| - IARC | International Agency for Research on Cancer, | http://monographs.iarc.fr/ |
| - JP NITE | Japan National Institute of Technology and Evaluation, | http://www.safe.nite.go.jp/ |

※ **Hazards Testing and Classification**

Korea MSDS Testing Laboratory

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This SDS' composition/information on ingredient(s) and recommended use are provided by the mentioned Company in this SDS' section 1.
This SDS is composed in line with Korea Occupational Safety and Health Act (KOSHA) Article 41, to protect the health of the employees, and for documentation.
This SDS is composed with reference to criteria provided by KOSHA.