

Safety Data Sheet

1. PRODUCT AND COMPANY INFORMATION

Product name : CRYSTAL[®] Products
 Company : Koru Pharmaceuticals
 Address : 8F, 14-6, Teheran-ro 78-gil,
 Gangnam-gu, Seoul, Korea
 Telephone : + 82-70-8630-3089
 Fax : + 82-70-8630-3003
 Website : www.korupharma.com

Recommended use of the chemical and restrictions on use

Recommended use : Graft / Prosthesis, Biomaterial (Dermal Filler)

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

Label elements including precautionary statements

Symbol / Signal word : Not applicable

Hazard statements / Precautionary statements : Not applicable

NFPA Rating

Health : 0

Flammability : 0

Reactivity : 0

Water reactivity : 0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	EINECS No.	Conc. %
Hyaluronate Sodium	9067-32-7	232-678-0	2.0 %
Water	7732-18-5	231-791-2	96.8 %
Lidocaine hydrochloride monohydrate	6108-05-0	200-803-8	0.3 %

Sodium phosphate, dibasic, dihydrate	10028-24-7	231-448-7	
Sodium phosphate, monobasic, dihydrate	13472-35-0	231-449-2	0.9 %
Sodium chloride	7647-14-5	231-598-3	

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 not breathing, give artificial respiration.

If swallowed

Never give anything by mouth to an unconscious person.

Potential health effect

May be harmful if swallowed.

Other medical attention.

Medical personnel should be aware of the protective measures of the substance.

5. FIRE-FIGHTING MEASURES

Flammable properties

Flash point : No flash occurred under 93 °C (Rapid equilibrium method)

Autoignition temperature : No spontaneous combustion under 200 °C

Burning rate : Did not ignite. at 20 °C (UN TDG test & criteria - Test N1)

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

Do not eat, drink or smoke when using this product.

Environmental precautions

No data available

Methods and materials for containment and cleaning up

Keep in suitable, closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Do not eat, drink or smoke when using this product.

Conditions for safe storage

Keep container tightly closed.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Components with workplace control parameter

KOSHA : No data available

US ACGIH : No data available

Appropriate engineering controls : No data available

Personal protective equipment

Respiratory protection : General vapor mask

Hand protection : Protective gloves

Eye protection : Protective goggles

Skin and body protection : No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

State : Solid at 20 °C

Appearance form : Gel

pH : 6.5 ~ 7.5 at 20 °C ※ Sample : H₂O = 1 : 5 (V/V)

Flash point : No flash occurred under 93 °C (Rapid equilibrium method)

Autoignition temperature : No spontaneous combustion under 200 °C

Water solubility : Water soluble at 20 °C

Density : 1.0 at 20 °C

Boiling point (Initial) : > 97 °C

Flammability

Burning rate : Did not ignite. at 20 °C ※ UN TDG test & criteria - Test N1

Explosive properties : No self-reaction hazard ※ UN TDG test & criteria - Test E3

Melting range : No data available

Vapour pressure : No data available

Decomposition temperature : No data available

Partition coefficient (*n-octanol/water*) : No data available

Viscosity : No data available

Lower explosion limit / Upper explosion limit : No data available

10. STABILITY AND REACTIVITY

Chemical stability

Stable under general condition.

Conditions to avoid

Avoid inhalation of vapor, mist or gas.

Materials to avoid

Substances which, in contact with water, emit flammable gases

Hazardous decomposition products

Carbon oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral	rat	LD50 : > 2,000 mg/kg	※ from US NLM / ECHA
Inhalation	rat	LC50 : No data available	
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 : No data available

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 : No data available	※ from US NLM / ECHA
Crustacean	EC50 : No data available	
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

Korea Hazardous Materials Safety Control Act : Not hazardous material

Korea Chemicals Control Act : Not toxic chemical

Korea Persistent Organic Pollutants Control Act : Not applicable

US OSHA Hazards (GHS) : Not applicable

16. OTHER INFORMATION

Issued Date : 2016. 05. 23.

Revision No. : 0

Revision Date : -

References

- GHS Classification :
Korea MSDS Testing Lab Certificate (Report No. 2016-03-002325), 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

- ECHA : European chemical agency, <http://echa.europa.eu/>
- US NLM : U.S. National Library of Medicine, <http://chem.sis.nlm.nih.gov/chemidplus/>
- 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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The product composition is provided by the mentioned company of this SDS' section 1.
This SDS is composed in line with The Korea Occupational Safety and Health Act Article 41 to protect the health of the employees, and for documentation.
This SDS is composed with reference to documents and criteria provided by KOSHA.

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