

Submucosal Injectable Solution



Version: V2.0.0.1

Report No.: HGNM20Y4FH

Creation Date: 2020/08/11

Revision Date: 2020/08/11

*Prepared according to American OSHA HazCom Standard (2012)

1 Identification

Product identifier

Product Name	Submucosal Injectable Solution
Product Model	SML10
CAS No.	Not applicable
EC No.	Not applicable
Molecular Formula	Not applicable

Recommended use of the product and restrictions on use

Relevant identified uses	Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.
Uses advised against	No special note.

Details of the supplier of the Safety Data Sheet

Name of the company	Micro-Tech (Nanjing) Co., Ltd
Address of the company	No. 10, Gaoke 3rd Road, National Hi-Tech Zone, Nanjing, China, 210032
Post code	210032
Telephone number	+86 25 58743561
Fax number	+86 25 58744269
E-mail address	info@micro-tech.com.cn

Emergency phone number

Emergency phone number	+86 25-58646399
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2 Hazard(s) identification

Hazard classification according to GHS

Hazard classification according to GHS	Not applicable
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GHS Label elements

Hazard pictograms	Not applicable
Signal word	Not applicable

Hazard statements

Hazard statements	Not applicable
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Precautionary statements

- ◆ Prevention

Prevention	Not applicable
◆ Response	
Response	Not applicable
◆ Storage	
Storage	Not applicable
◆ Disposal	
Disposal	Not applicable

Other hazards

	Not applicable.
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Hazard description

◆ Physical and chemical hazards

	Liquid, soluble in water, no harm in general situation.
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◆ Health hazards

Inhaled	Inhalation of the product may produce adverse health effects or irritation of the respiratory tract following discomfort.
Ingestion	Accidental ingestion of the product may be harmful to the health of the individual.
Skin Contact	No harm in general situation.
Eye	This product may cause temporary discomfort following direct contact with the eye.

◆ Environmental hazards

	Please refer to 12th chapter of SDS.
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3 Composition/information on ingredients

Substance/mixture

	Mixture
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Component	CAS No.	EC No.	Concentration (wt, %)
Water for Injection	7732-18-5	231-791-2	Commercial secrets
Sodium chloride	7647-14-5	231-598-3	Commercial secrets
Sodium Hyaluronate	9067-32-7	618-620-0	Commercial secrets
Sodium phosphate dibasic	7558-79-4	231-448-7	Commercial secrets
Sodium dihydngen phoshate anhydrous	7558-80-7	231-449-2	Commercial secrets
Methylene blue	7220-79-3	615-731-6	Commercial secrets

4 First-aid measures

Description of first aid measures

General advice	Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if feel uncomfortable.
Skin contact	No harm in general situation. First aid is not needed.
Ingestion	Never give anything by mouth to an unconscious person. Call a physician

	immediately.
Inhalation	Move victim into fresh air. If breathing is difficult, give oxygen and consult a physician immediately.
Protecting of first-aiders	Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination.

| Most important symptoms/effects, acute and delayed

1	Please see section 11.
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| Indication of any immediate medical attention and special treatment needed

1	Treat symptomatically.
2	Symptoms may be delayed.

5 Fire-fighting measures

| Extinguishing media

Suitable extinguishing media	Use extinguishing media suitable for surrounding area.
Unsuitable extinguishing media	There is no restriction on the type of extinguisher which may be used.

| Specific hazards arising from the substance or mixture

1	Development of hazardous combustion gases or vapor possible in the event of fire.
2	Not combustible, not considered a significant fire risk, however containers may burn.

| Special protective equipment and precautions for fire-fighters

1	As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
2	Fight fire from a safe distance, with adequate cover.
3	Prevent fire extinguishing water from contaminating surface water or the ground water system.

6 Accidental release measures

| Personal precautions, protective equipment and emergency procedures

1	Ensure adequate ventilation. Remove all sources of ignition.
2	Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
3	Use personal protective equipment. Avoid breathing vapours, mist or gas.

| Environmental precautions

1	Prevent further leakage or spillage if safe to do so.
2	Discharge into the environment must be avoided.

| Methods and materials for containment and cleaning up

1	Absorb spilled material in dry sand or inert absorbent. In case of large amount of spillage, contain a spill by bunding.
2	Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.
3	Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

7 Handling and storage

Precautions for safe handling

1	Handling is performed in a well ventilated place.
2	Avoid contact with eyes.
3	Keep away from heat/sparks/open flames/ hot surfaces.

Conditions for safe storage, including any incompatibilities

1	Keep containers tightly closed.
2	Keep containers in a dry, cool and well-ventilated place.
3	Keep away from heat/sparks/open flames/hot surfaces.
4	Store away from incompatible materials and foodstuff containers.

8 Exposure controls/personal protection**Control parameters**

Component	Country/Region	Limit value - Eight hours		Limit value - Short term	
		ppm	mg/m ³	ppm	mg/m ³
Sodium chloride	Latvia	-	5	-	-

◆ Biological limit values

Biological limit values	No relevant regulations
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◆ Monitoring methods

1	EN 14042 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.
2	GBZ/T 300.1~GBZ/T 300.160-2017; GBZ/T 300.161~GBZ/T 300.164-2018 Determination of toxic substances in workplace air (Series standard).

Engineering controls

1	Ensure adequate ventilation, especially in confined areas.
2	Ensure that eyewash stations and safety showers are close to the workstation location.
3	Set up emergency exit and necessary risk-elimination area.
4	Handle in accordance with good industrial hygiene and safety practice.

Personal protection equipment

General requirement	No special requirements, please see the description below.
Eye protection	In general situation, eye protection is not needed. In the production process, when contacting with vapour, tightly fitting safety goggles (approved by EN 166(EU) or NIOSH (US).
Hand protection	In general situation, hand protection is not needed.
Respiratory protection	In general situation, respiratory protection is not needed. If exposure limits are exceeded or if irritation or other symptoms are experienced, use a full-face respirator with multi-purpose combination (US) or type AXBEK (EN 14387) respirator cartridges.
Skin and body protection	In general situation, skin and body protection are not needed.

9 Physical and chemical properties and safety characteristics**Physical and chemical properties**

Appearance	Blue transparent Liquid
Odor	Weak odor
Odor threshold	No information available
pH	6-8
Melting point/freezing point(°C)	No information available
Initial boiling point and boiling range(°C)	>35
Flash point(Closed cup, °C)	> 70
Evaporation rate	No information available
Flammability	Not combustible
Upper/lower explosive limits[%(v/v)]	Upper limit: Not combustible; Lower limit: Not combustible
Vapor pressure	No information available
Vapor density(Air = 1)	No information available
Relative density(Water=1)	No information available
Solubility	Soluble in water
n-octanol/water partition coefficient	No information available
Auto-ignition temperature(°C)	Not combustible
Decomposition temperature(°C)	No information available
Viscosity	3-15 mpa·s

10 Stability and reactivity

| Stability and reactivity

Reactivity	Contact with incompatible substances can cause decomposition or other chemical reactions.
Chemical stability	Stable under proper operation and storage conditions.
Possibility of hazardous reactions	In contact with active metals (alkali metals, Na, Ca etc.) causes a reaction and release hydrogen. In contact with organic peroxides cause a fire immediately.
Conditions to avoid	Incompatible materials, heat, flame and spark.
Incompatible materials	Alkali, sodium, calcium, and other active metal, halogen, metal oxide, nonmetal oxide, acyl halide and metal phosphide. Organic peroxides.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11 Toxicological information

| Acute toxicity

Component	LD ₅₀ (oral)	LD ₅₀ (dermal)	LC ₅₀ (inhalation,4h)
Sodium phosphate dibasic	17000mg/kg(Rat)	No information available	No information available
Sodium chloride	3000mg/kg(Rat)	> 10000mg/kg(Rabbit)	No information available
Sodium Hyaluronate	> 800mg/kg(Rat)	No information available	No information available
Sodium dihydngen phoshate anhydrous	8290mg/kg(Rat)	No information available	No information available

Carcinogenicity

Component	List of carcinogens by the IARC Monographs	Report on Carcinogens by NTP
Water for Injection	Not Listed	Not Listed
Sodium chloride	Not Listed	Not Listed
Sodium Hyaluronate	Not Listed	Not Listed
Sodium phosphate dibasic	Not Listed	Not Listed
Sodium dihydngen phoshate anhydrous	Not Listed	Not Listed
Methylene blue	Category 3	Not Listed

Others

Submucosal Injectable Solution	
Skin corrosion/irritation	Based on available data, the classification criteria are not met
Serious eye damage/irritation	Based on available data, the classification criteria are not met
Skin sensitization	Based on available data, the classification criteria are not met
Respiratory sensitization	Based on available data, the classification criteria are not met
Reproductive toxicity	Based on available data, the classification criteria are not met
STOT-single exposure	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
Aspiration hazard	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Based on available data, the classification criteria are not met
Reproductive toxicity(additional)	Based on available data, the classification criteria are not met

12 Ecological information**Acute aquatic toxicity**

Component	Fish	Crustaceans	Algae
Sodium chloride	LC ₅₀ : 7400mg/L (96h)(Fish)	EC ₅₀ : 2120mg/L (48h)(Crustaceans)	No information available

Chronic aquatic toxicity

Chronic aquatic toxicity	No information available
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Persistence and degradability

Component	Persistence (water/soil)	Persistence (air)
Water for Injection	Low	Low
Sodium chloride	Low	Low

Bioaccumulative potential

Component	Bioaccumulative potential	Comments
Water for Injection	Low	Log Kow=-1.38

Sodium chloride	Low	Log Kow=0.5392
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| Mobility in soil

Component	Mobility in soil	Soil Organic Carbon-Water Partitioning Coefficient (Koc)
Water for Injection	Low	14.3
Sodium chloride	Low	14.3

| Results of PBT and vPvB assessment

Component	Results of PBT and vPvB assessment [according to (EC) No 1907/2006]
Water for Injection	not PBT/vPvB
Sodium chloride	not PBT/vPvB
Sodium Hyaluronate	not PBT/vPvB
Sodium phosphate dibasic	not PBT/vPvB
Sodium dihydngen phoshate anhydrous	not PBT/vPvB
Methylene blue	not PBT/vPvB

13 Disposal considerations

| Disposal considerations

Waste chemicals	Before disposal should refer to the relevant national and local laws and regulation. Recommend the use of incineration disposal.
Contaminated packaging	Containers may still present chemical hazard when empty. Keep away from hot and ignition source of fire. Return to supplier for recycling if possible.
Disposal recommendations	Refer to section waste chemicals and contaminated packaging.

14 Transport information

| Label and Mark

Transporting Label	Not applicable
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| IMDG-CODE

IMDG-CODE	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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| IATA-DGR

IATA-DGR	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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| UN-ADR

UN-ADR	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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15 Regulatory information

| International chemical inventory

Component	EINECS	TSCA	DSL	IECSC	NZIoC	PICCS	KECI	AICS	ENCS
Water for Injection	✓	✓	✓	✓	✓	✓	✓	✓	✓

Sodium chloride	√	√	√	√	√	√	√	√	√
Sodium Hyaluronate	×	×	√	√	√	×	×	√	×
Sodium phosphate dibasic	√	√	√	√	√	√	√	√	√
Sodium dihydngen phoshate anhydrous	√	√	√	√	√	√	√	√	√
Methylene blue	×	×	×	×	√	×	×	×	×

[EINECS]	European Inventory of Existing Commercial Chemical Substances
[TSCA]	United States Toxic Substances Control Act Inventory
[DSL]	Canadian Domestic Substances List
[IECSC]	China Inventory of Existing Chemical Substances
[NZIoC]	New Zealand Inventory of Chemicals
[PICCS]	Philippines Inventory of Chemicals and Chemical Substances
[KECI]	Existing and Evaluated Chemical Substances
[AICS]	Australia Inventory of Chemical Substances
[ENCS]	Existing And New Chemical Substances

Note:

- “√” Indicates that the substance included in the regulations.
 “×” No data or not included in the regulations.

16 Other information

Information on revision

Creation Date	2020/08/11
Revision Date	2020/08/11
Reason for revision	-

Reference

- [1] IPCS: The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>.
- [2] IARC, website: <http://www.iarc.fr/>.
- [3] OECD: The Global Portal to Information on Chemical Substances, website: <https://www.echemportal.org/echemportal/substancesearch/index.action>.
- [4] CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>.
- [5] NLM: ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>.
- [6] EPA: Integrated Risk Information System, website: <http://cfpub.epa.gov/iris/>.
- [7] U.S. Department of Transportation: ERG, website: <http://www.phmsa.dot.gov/hazmat/library/erg>.
- [8] Germany GESTIS-database on hazard substance, website: <http://gestis-en.itrust.de/>.

Abbreviations and acronyms

CAS	Chemical Abstracts Service	UN	The United Nations
PC-STEL	Short term exposure limit	OECD	Organization for Economic Co-operation and Development
PC-TWA	Time Weighted Average	IMDG	International Maritime Dangerous Goods
MAC	Maximum Allowable Concentration	IARC	International Agency for Research on Cancer
DNEL	Derived No Effect Level	ICAO	International Civil Aviation Organization
PNEC	Predicted No Effect Concentration	IATA	International Air Transportation Association
NOEC	No Observed Effect Concentration	ACGIH	American Conference of Governmental Industrial Hygienists
LC ₅₀	Lethal Concentration 50%	NFPA	National Fire Protection Association
LD ₅₀	Lethal Dose 50%	NTP	National Toxicology Program
EC ₅₀	Effective Concentration 50%	PBT	Persistent, Bioaccumulative, Toxic
EC _x	Effective Concentration X%	vPvB	very Persistent, very Bioaccumulative
P _{ow}	Partition coefficient Octanol: Water	CMR	Carcinogens, mutagens or substances toxic to reproduction
BCF	Bioconcentration factor	RPE	Respiratory Protective Equipment

Disclaimer

This Safety Data Sheet (SDS) was prepared according to OSHA HazCom Standard (2012). The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.