

Safety Data Sheet

Product Name: **PerioPatch**

Version:2 Date:04Sep2017

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

- **Product Form:** Patch
- **Product Name:** PerioPatch
- **Synonyms:** None
- **Chemical Family:** Not determined

Intended use

PerioPatch® is intended for the management of all types of oral wounds, injuries and ulcerations of the gingival and oral mucosa, including stomatitis, minor chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery.

PerioPatch is a complement treatment subsequent to dental treatment, allowing more rapid healing of sore tissue.

Company Name, Address, and Telephone (Responsible Party)

Izun Pharmaceuticals Corp.
One Rockefeller Plaza – 11th floor
New York, NY 10020
USA
+1 (212) 618-6357

Emergency Telephone Number

Izun Pharmaceuticals Corp. (24 hours)
US +1 (877) 210-2621
International +972-(0)72-245-6191

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS-US Classification: Not classified

Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US): None

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Hazard Statements (GHS-US): H317 – May cause an allergic skin reaction
Precautionary Statements (GHS-US): P102 – Keep out of reach of children
 P103 – Read label before use
Other Hazards: None

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Specific needs may vary depending upon the potential for exposure in the workplace.

Unknown Acute Toxicity (GHS-US): No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance: Not applicable
Chemical characterization: Mixture
Description: Mixture of substances listed below with non-hazardous additions.

Ingredient	CAS Number	GHS-US classification	%
<i>Centella asiatica</i> herba extract	84696-21-9	Not Listed	*
<i>Echinacea purpurea</i> radix extract	90028-20-9	Not Listed	*
<i>Sambucus nigra</i> flos extract	84603-58-7	Not Listed	*
Hydroxymethyl propylcellulose	9004-65-3	Not Listed	*
Carbopol 971	9003-01-4	Not Listed	*
Glycerol	56-81-5	Not Listed	*
Strawberry flavor	Not available	GHS02, GHS07	*
Titanium dioxide	13463-67-7	H316, H351	*
Ethyl cellulose	9004-57-3	Not Listed	*
Acacia gum	9000-01-5	Not Listed	*
Castor oil	8001-79-4	Not Listed	*
Iron oxide red	1332-37-2	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	*
Maltodextrin, DE 4.0 – 7.0	9050-36-6	Not Listed	*
Colloidal anhydrous silica	7631-86-9	Not Listed	*

Additional Information: *In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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SECTION 4: FIRST AID MEASURES

First-aid measures by route of exposure:

- **After Eye Contact:** Not applicable.
- **After Skin Contact:** If skin irritation occurs, consult a doctor.
- **After Ingestion (Swallowing):** If swallowed and symptoms occur, consult a doctor.
- **After Inhalation:** Not applicable.

Most important symptoms and effects (acute or delayed)

Passing mild irritation.

Immediate medical attention and special treatment, if necessary

No further relevant information available.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:

Use fire-fighting measures that suit the environment.

Unsuitable extinguishing media

No further relevant information available.

Specific hazards arising from the hazardous product (e.g., hazardous combustion products)

No further relevant information available.

Special protective equipment and precautions for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

Not required.

Methods and Materials for Containment and Cleaning Up

Not required.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Not required.

Conditions for safe storage (including incompatible materials)

Store as directed by product packaging.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters, including occupational exposure guidelines or biological exposure limits and the source of those values (components with occupational exposure limits):

Glycerol CAS No. 56-81-5

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m ³	ppm	mg/m ³
Australia		10		
Belgium		10		
Canada - Ontario		10		
Canada - Québec		10		
Finland		20		
France		10		
Germany (AGS)		200	400	
Germany (DFG)		200	400	
Ireland		10		
New Zealand		10		
Poland		10		
Singapore		10		
South Korea		10		
Spain		10		
Switzerland		50 inhalable aerosol	100 inhalable aerosol	
USA - OSHA		15 inhalable dust		
		5 respirable dust		
United Kingdom		10		

Source of data: EU Occupational Exposure Limits (OELs) - GESTIS: International occupational exposure limit values for chemical agents.

Appropriate engineering controls: Not required.

Individual protection measures (e.g. , personal protective equipment)

Respiratory protection: In case of inadequate ventilation wear respiratory protection.
 Hand protection: Wear chemically resistant protective gloves. The breakthrough time of the selected gloves must be greater than the intended use period.
 Eye protection: Chemical goggles or safety glasses.

Titanium dioxide CAS No. 13463-67-7

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m ³	ppm	mg/m ³
Australia		10		
Belgium		10		
Canada - Ontario		10		
Canada - Québec		10		
Denmark		6 total dust		12 total dust
France		11 inhalable aerosol		
Ireland		10		
		4		
Japan - JSOH		0,3		
New Zealand		10		
China		8		
Poland		10		
Singapore		10		30
South Korea		10		
Spain		10 inhalable aerosol		
Sweden		10 inhalable aerosol		
Switzerland		3 respirable aerosol		
USA - OSHA		15 total dust		
United Kingdom		4 respirable aerosol		

Source of data: EU Occupational Exposure Limits (OELs) - GESTIS: International occupational exposure limit values for chemical agents

Appropriate engineering controls: Not required.

Individual protection measures (e.g., personal protective equipment)

Industrial hygiene measures	Maintain exposures below applicable exposure limits.
Respiratory protection	A respirator must be used if the dust concentration is likely to exceed the occupational exposure limit. At higher concentrations wear particle filter DIN EN 143 - P2.
Hand protection	Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.
Eye protection	The use of approved dustproof goggles is recommended if the dust concentration is likely to exceed the occupational exposure limit.
Skin protection	TiO ₂ pigments are not an irritant but, as with all fine powders, they can absorb moisture and natural oils from the surface of the skin during prolonged exposure. Prolonged exposure should be avoided by wearing suitable protective gloves and clothing.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Patch (dry hydrogel)
Aroma:	Mild strawberry
Odor Threshold	No data available
Molecular Formula	Mixture
pH	No data available
Melting/Freezing Point (°C)	No data available
Boiling Point (°C)	No data available
Evaporation rate	No data available
Flammability (solid; gas)	No data available
Lower flammable/explosive limit	No data available
Upper flammable/explosive limit	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Solubility	No data available
Partition coefficient -n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	No further relevant information available.
Chemical stability:	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reactions known.
Conditions to avoid	No further relevant information available.
Incompatible materials	No further relevant information available.
Hazardous decomposition products	No dangerous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact):

Skin contact, ingestion

Symptoms related to the physical, chemical and toxicological characteristics:

No further relevant information available.

Delayed and immediate effects and chronic effects from short-term and long-term exposure:

No further relevant information available.

Numerical measures of toxicity:

Cytotoxicity (ISO 10993-5)	Moderate cytotoxicity
Sensitization (ISO 10993-10)	No skin sensitization
Irritation (ISO 10993-10)	Mild irritation

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SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity	No further relevant information available.
Persistence and Degradability	No further relevant information available.
Bioaccumulative Potential	No further relevant information available.
Mobility in Soil	No further relevant information available.
Other Adverse Effects	No further relevant information available.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

No further relevant information available.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Data Sources: Izun Pharmaceuticals proprietary development information. Publicly available toxicity information.

Revision date: 04-Sep-2017

Prepared by: Izun Pharmaceuticals Corp.

Izun Pharmaceuticals believes that the information contained in this Safety Data Sheet is accurate and, while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet