



Safety Data Sheet

Material Name: Thrombi-Gel® (thrombin/gelatin hemostat)

MSDS ID: 00232496

Section 1 - PRODUCT AND COMPANY IDENTIFICATION

Material Name: Thrombi-Gel® (thrombin/gelatin hemostat)

Manufacturer Information

KING PHARMACEUTICALS, INC.

Phone: (800) 776-3637

501 Fifth Street

Bristol, TN 37620

Synonyms

Thrombi-Gel 10 - Product Number 60793-907-01 (reference number 0907); Thrombi-Gel 40 - Product Number 60793-908-04 (reference number 0908); Thrombi-Gel 100 - Product Number 60793-909-10 (reference number 0909)

Section 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Color: white

Physical Form: sponge

Major Health Hazards: respiratory tract irritation, skin irritation, eye irritation, blood damage, allergic reactions, antibody formation against bovine thrombin may cause adverse hemostatic effects

POTENTIAL HEALTH EFFECTS

Inhalation

Short Term: irritation, cough, allergic reactions, antibody response, nausea, vomiting, difficulty breathing, headache, blood disorders

Long Term: irritation, cough, antibody response, allergic reactions, nosebleed, stomach pain, chest pain, difficulty breathing, wheezing, asthma, headache, lung damage

Skin

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Short Term: irritation, allergic reactions, antibody response, absorption may occur, itching, nausea, vomiting, headache, blood disorders

Long Term: irritation, itching, antibody response, allergic reactions, blood disorders

Eye

Short Term: irritation, itching, tearing

Long Term: irritation

Ingestion

Short Term: gastrointestinal irritation, nausea, vomiting, stomach pain, irregular heartbeat, drowsiness, convulsions

Long Term: no information on significant adverse effects

* * *Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS* * *

CAS	Component	Percent
9000-70-8	GELATIN	76 - 82.5
9004-32-4	SODIUM CARBOXYMETHYL CELLULOSE	10 - 13
10035-04-8	CALCIUM CHLORIDE, DIHYDRATE	7 - 9
9002-04-4	BOVINE THROMBIN	0.5 - 2
50-00-0	FORMALDEHYDE	<0.1

Component Related Regulatory Information

This product may be regulated, have exposure limits or other information identified as the following: Calcium chloride (10043-52-4).

* * *Section 4 - FIRST AID MEASURES* * *

Inhalation

Not a likely route of exposure. It is unlikely that emergency treatment will be required if used as directed.

Skin

This product is intended for topical use. It is unlikely that emergency treatment will be required if used as directed.

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Eyes

It is unlikely that emergency treatment will be required if used as directed. If contact does occur, flush eyes with plenty of water for at least 15 minutes and then get medical attention.

Ingestion

Not a likely route of exposure. If swallowed, get medical attention.

*** * *Section 5 - FIRE FIGHTING MEASURES* * ***

See Section 9 for Flammability Properties

NFPA Ratings: Health: 2 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

Flammable Properties

Slight fire hazard.

Extinguishing Media

carbon dioxide, regular dry chemical, regular foam, water

Fire Fighting Measures

Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

Thermal Decomposition Products

Combustion: oxides of carbon, oxides of sodium, oxides of calcium, hydrogen chloride

*** * *Section 6 - ACCIDENTAL RELEASE MEASURES* * ***

Water Release

Subject to California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Keep out of water supplies and sewers.

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Occupational spill/release

Notify Local Emergency Planning Committee and State Emergency Response Commission for release greater than or equal to RQ (U.S. SARA Section 304). If release occurs in the U.S. and is reportable under CERCLA Section 103, notify the National Response Center at (800)424-8802 (USA) or (202)426-2675 (USA). Move undamaged containers from spill area. Small dry spills: Sweep and scoop spilled material into clean, dedicated equipment. Keep out of water supplies and sewers.

* * *Section 7 - HANDLING AND STORAGE* * *

Storage Procedures

Store and handle in accordance with all current regulations and standards. Store between 2 C and 25 C. See original container for storage recommendations. Keep separated from incompatible substances.

* * *Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION* * *

Component Exposure Limits

FORMALDEHYDE (50-00-0)

ACGIH: 0.3 ppm Ceiling

OSHA (final): 0.75 ppm TWA

2 ppm STEL (see 29 CFR 1910.1048)

Ventilation

Under normal conditions of use, no special ventilation equipment is needed.

PERSONAL PROTECTIVE EQUIPMENT

Eyes/Face

Eye protection not required under normal conditions.

Protective Clothing

Wear appropriate clothing to minimize skin contact.

Glove Recommendations

Wear appropriate chemical resistant gloves.

Respiratory Protection

No respirator is required under normal conditions of use.

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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid	Appearance:	foil wrapped
Color:	white	Physical Form:	sponge
Odor:	Not Available	Odor Threshold:	Not available
Melting Point:	Not available	Boiling Point:	Not applicable
Vapor Pressure:	Not applicable	Vapor Density (air = 1):	Not applicable
Density:	Not available	Specific Gravity (water = 1):	Not available
Water Solubility:	Not available	Coeff. Water/Oil Dist:	Not available

Section 10 - STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and pressure.

Conditions to Avoid

Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

Materials to Avoid

oxidizing materials

Combustion: oxides of carbon, oxides of sodium, oxides of calcium, hydrogen chloride

Possibility of Hazardous Reactions

Will not polymerize.

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* * *Section 11 - TOXICOLOGICAL INFORMATION* * *

Immediate Effects

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and the following selected endpoints are published:

SODIUM CARBOXYMETHYL CELLULOSE (9004-32-4)

Inhalation LC50 Rat >5800 mg/m³ 4 h; Oral LD50 Rat 27000 mg/kg; Dermal LD50 Rabbit >2 g/kg

CALCIUM CHLORIDE, DIHYDRATE (10035-04-8)

Oral LD50 Rat 1000 mg/kg; Dermal LD50 Rat 2630 mg/kg (related to Calcium chloride)

FORMALDEHYDE (50-00-0)

Inhalation LC50 Rat 0.578 mg/L 4 h; Oral LD50 Rat 500 mg/kg

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Acute Toxicity Level

SODIUM CARBOXYMETHYL CELLULOSE (9004-32-4)

Non Toxic: ingestion

CALCIUM CHLORIDE, DIHYDRATE (10035-04-8)

Moderately Toxic: ingestion (related to Calcium chloride)

FORMALDEHYDE (50-00-0)

Highly Toxic: inhalation

Toxic: dermal absorption, ingestion

Component Carcinogenicity

FORMALDEHYDE (50-00-0)

ACGIH: A2 - Suspected Human Carcinogen

IARC: Monograph 100F [in preparation]; Monograph 88 [2006]; Monograph 62 [1995]; Supplement 7 [1987] (Group 1 (carcinogenic to humans))

DFG: Category 4 (no significant contribution to human cancer)

Local Effects

GELATIN (9000-70-8)

Irritant: inhalation, eye

CALCIUM CHLORIDE, DIHYDRATE (10035-04-8)

Irritant: inhalation, skin, eye

BOVINE THROMBIN (9002-04-4)

Irritant: inhalation, skin, eye

FORMALDEHYDE (50-00-0)

Irritant: skin, eye

Corrosive: inhalation, skin, eye, ingestion

Target Organs

BOVINE THROMBIN (9002-04-4)

blood

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FORMALDEHYDE (50-00-0)

immune system (sensitizer)

Medical Conditions Aggravated by Exposure

blood system disorders, blood system disorders, known sensitivity to bovine-derived products, known sensitivity to bovine-derived products, known sensitivity to porcine-derived products, allergic reactions

Additional Data

Individuals who are known to be sensitive to bovine-derived substances should not be exposed to this material. For topical use only. Individuals who are known to be sensitive to porcine-derived substances should not be exposed to this material. Not for intravenous administration. Refer to the current package insert for additional information. This substance may be fatal if it enters the bloodstream. Individuals who are known to be sensitive to bovine-derived substances should not be exposed to this material.

* * *Section 12 - ECOLOGICAL INFORMATION* * *

Component Analysis - Aquatic Toxicity

CALCIUM CHLORIDE, DIHYDRATE (10035-04-8)

Test & Species

96 Hr LC50 Lepomis macrochirus

Results & Conditions

10650 mg/L [static] related to Calcium chloride

Test & Species

48 Hr EC50 Daphnia magna

Results & Conditions

52 mg/L related to Calcium chloride

FORMALDEHYDE (50-00-0)

Test & Species

96 Hr LC50 Pimephales promelas

96 Hr LC50 Lepomis macrochirus

96 Hr LC50 Brachydanio rerio

96 Hr LC50 Oncorhynchus mykiss

Results & Conditions

22.6 - 25.7 mg/L [flow-through]

1510 µg/L [static]

41 mg/L [static]

0.032 - 0.226 mL/L [flow-through]

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96 Hr LC50 Oncorhynchus mykiss

100 - 136 mg/L [static]

96 Hr LC50 Pimephales promelas

23.2 - 29.7 mg/L [static]

Test & Species

Results & Conditions

48 Hr LC50 Daphnia magna

2 mg/L

48 Hr EC50 Daphnia magna

11.3 - 18 mg/L [Static]

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Methods

Dispose in accordance with all applicable regulations. Dispose in a puncture-resistant biohazard container.

Component Waste Numbers

FORMALDEHYDE (50-00-0)

RCRA: waste number U122

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* * *Section 14 - TRANSPORT INFORMATION* * *

US DOT Information

No Classification assigned.

* * *Section 15 - REGULATORY INFORMATION* * *

U.S. Federal Regulations

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 311/312 (40 CFR 370.21), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b), and/or require an OSHA process safety plan.

FORMALDEHYDE (50-00-0)

SARA 302: 500 lb TPQ

SARA 313: 0.1 % de minimis concentration

CERCLA: 100 lb final RQ; 45.4 kg final RQ

OSHA (safety): 1000 lb TQ

SARA 311/312

Acute Health: No **Chronic Health:** No **Fire:** No **Pressure:** No **Reactive:** No

U.S. State Regulations

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
FORMALDEHYDE	50-00-0	Yes	Yes	Yes	Yes	Yes	Yes

The following statement(s) are provided under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

WARNING! This product contains a chemical known to the state of California to cause cancer.

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Component Analysis - Inventory

Component	CAS	US	CA	EU	AU	PH	JP	KR	CN	NZ
GELATIN	9000-70-8	Yes	DSL	EIN	Yes	Yes	Yes	Yes	Yes	Yes
SODIUM CARBOXYMETHYL CELLULOSE	9004-32-4	Yes	DSL	No	Yes	Yes	Yes	Yes	Yes	Yes
CALCIUM CHLORIDE, DIHYDRATE	10035-04-8	No	No	No	Yes	Yes	Yes	No	Yes	Yes
BOVINE THROMBIN	9002-04-4	Yes	NSL	EIN	Yes	No	No	Yes	Yes	Yes
FORMALDEHYDE	50-00-0	Yes	DSL	EIN	Yes	Yes	Yes	Yes	Yes	Yes

Section 16 - OTHER INFORMATION

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; RID - European Rail Transport; RTECS - Registry of Toxic Effects of Chemical Substances®; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US - United States

Other Information

This material safety data sheet is offered solely for your information, consideration, and investigation. King Pharmaceuticals provides no warranties, either expressed or implied, and assumes no responsibility for the accuracy of the data contained herein.

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