

# **Scientific Documentation**

# Gelatin, 250 Bloom, Powder, NF

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





# **Table of Contents**

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label



# Specification for Gelatin, 250 Bloom, Powder, NF (GE105)

Item Number	GE105
Item	Gelatin, 250 Bloom, Powder, NF
CAS Number	9000-70-8
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification	n
	Min	Max
SOURCE	AS REPORTED	
GEL STRENGTH (BLOOM VALUE)	200	300
pH	3.8	7.6
WATER CONDUCTIVITY		1 mS/cm
SULFUR DIOXIDE		50 ppm
PEROXIDES		10 ppm
IRON		30 ppm
CHROMIUM		10 ppm
ZINC		30 ppm
LOSS ON DRYING		15 %
MICROBIAL LIMITS:		
TOTAL BACTERIA COUNT		10 <sup>3</sup> cfu/g
TOTAL YEASTS AND MOLDS COUNT		10 <sup>2</sup> cfu/g
SALMONELLA	NEGATIVE	
ESCHERICHIA COLI	NEGATIVE	
ELEMENTAL IMPURITIES:		
CADMIUM (Cd)	AS REPORTED	
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	

Test	Specification			
	Min	Max		
MERCURY (Hg)	AS REPORTED			
COPPER (Cu)	AS REPORTED			
IDENTIFICATION A	SPECTRUM MATCHES REFERENCE			
IDENTIFICATION B	VIOLET COLOR PRODUCED			
IDENTIFICATION (C)	DOES NOT IMMEDIATELY FLOW			
RETEST DATE				
DATE OF MANUFACTURE				
APPEARANCE				
RESIDUAL SOLVENTS	AS REPORTED			

# Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248

732.214.1300 310.516.8000



# **Certificate Of Analysis**

Item Number	GE105	Lot Number	4NB0045
Item	Gelatin, 250 Bloom, Powder, NF	CAS Number	9000-70-8

TEST	SPECIFICATION		DECLUIT.	
TEST	MIN	MAX	RESULT	
SOURCE	AS REPORTED		PORCINE	
GEL STRENGTH (BLOOM VALUE)	200	300	258.05	
рН	3.8	7.6	5.56	
WATER CONDUCTIVITY		1 mS/cm	< 1 mS/cm	
SULFUR DIOXIDE		50 ppm	6.33 ppm	
PEROXIDES		10 ppm	0 ppm	
IRON		30 ppm	< 5.06 ppm	
CHROMIUM		10 ppm	< 10 ppm	
ZINC		30 ppm	0.107 ppm	
LOSS ON DRYING		15 %	8.24 %	
MICROBIAL LIMITS:				
TOTAL BACTERIA COUNT		10³ cfu/g	< 10 CFU/g	
TOTAL YEASTS AND MOLDS COUNT		10² cfu/g	10 CFU/g	
SALMONELLA	NEGATIVE		NEGATIVE	
ESCHERICHIA COLI	NEGATIVE		NEGATIVE	
ELEMENTAL IMPURITIES:				
CADMIUM (Cd)	AS REPORTED		< 0.05 ppm	
LEAD (Pb)	AS REPORTED		< 1.5 ppm	
ARSENIC (As)	AS REPORTED		< 1.5 ppm	
MERCURY (Hg)	AS REPORTED		< 1.0 ppm	
COPPER (Cu)	AS REPORTED		< 30 ppm	
IDENTIFICATION A	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B	VIOLET COLOR PRODUCED		VIOLET COLOR PRODUCED	

TECT	SPECIFI	CATION	RESULT	
TEST	MIN	MAX		
IDENTIFICATION (C)	DOES NOT IMMEDIATELY FLOW		DOES NOT IMMEDIATELY FLOW	
RETEST DATE			19-DEC-2028	
DATE OF MANUFACTURE			19-DEC-2023	
APPEARANCE			OFF-WHITE CRYSTALLINE POWDER	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED	
MONOGRAPH EDITION			NF 2023	

Certificate of Analysis Results Entered By:

CMARIN Catherine Marin 08-MAR-24 12:28:52

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 08-MAR-24 12:29:37

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.





Revision date 18-November-2020 Revision Number 2

#### 1. Identification

**Product identifier** 

Product Name GELATIN, POWDER, NF

Other means of identification

Product Code(s) GE105

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

#### 2. Hazard(s) identification

#### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### Hazards not otherwise classified (HNOC)

Not applicable

#### **Label elements**

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Powder Physical state Solid Odor Odorless

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### **Substance**

Chemical name	CAS No	Weight-%	Trade secret
Gelatin, powder	9000-70-8	100	*

<sup>\*</sup>The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. First-aid measures

#### **Description of first aid measures**

**Inhalation** Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash skin with soap and water.

**Ingestion** Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

**Symptoms** No information available.

Indication of any immediate medical attention and special treatment needed

#### 5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

#### 7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Moisture sensitive. Heat sensitive. Keep containers tightly closed in a dry, cool and

well-ventilated place.

#### 8. Exposure controls/personal protection

Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

**Appropriate engineering controls** 

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection**No special protective equipment required.

exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

**Appearance** Powder

Color White to yellowish; amber

Odor Odorless

**Odor threshold** No information available

Remarks • Method Property Values

no data available рΗ None known Melting point / freezing point no data available None known Boiling point / boiling range no data available None known Flash point no data available None known no data available **Evaporation rate** None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure None known No data available Vapor density no data available None known None known Relative density 1.2 None known

Water solubility Easily soluble in hot water

Insoluble in cold water

no data available Solubility(ies) None known Partition coefficient No data available None known **Autoignition temperature** no data available None known > 100 - °C 212 °F **Decomposition temperature** None known Kinematic viscosity no data available None known **Dynamic viscosity** No data available None known

Other information

No information available **Explosive properties Oxidizing properties** No information available Softening point No information available Molecular weight No information available No information available **VOC Content (%) Liquid Density** No information available **Bulk density** No information available

#### 10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

#### 11. Toxicological information

#### Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

Eve contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available. **Ingestion** Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

**Acute toxicity** 

Numerical measures of toxicity

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity No information available. No information available. No information available. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure Aspiration hazard No information available. No information available. No information available.

Other adverse effects No information available.

Interactive effects No information available.

#### 12. Ecological information

**Ecotoxicity**The environmental impact of this product has not been fully investigated.

Persistence and degradability

Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects No information available.

#### 13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

#### 14. Transport information

<u>DOT</u> not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

**IATA** not regulated

**IMDG** not regulated

RID not regulated

ADR not regulated

ADN not regulated

#### 15. Regulatory information

#### **International Inventories**

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

**ENCS** This product complies with ENCS: **IECSC** This product complies with China:

KECL Complies PICCS Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

#### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances **IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

#### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### <u>CERCLA</u>

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

#### 16. Other information

NFPA

Health hazards 0 Flammability 0 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

#### Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 18-November-2020 Revision Note 18-November-2020 No information available.

**Disclaimer** 

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet** 



#### Certification of Compliance with current Good Manufacturing Practices

#### Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name	
GE105	Gelatin, 250 Bloom, Powder, NF	

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632 Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

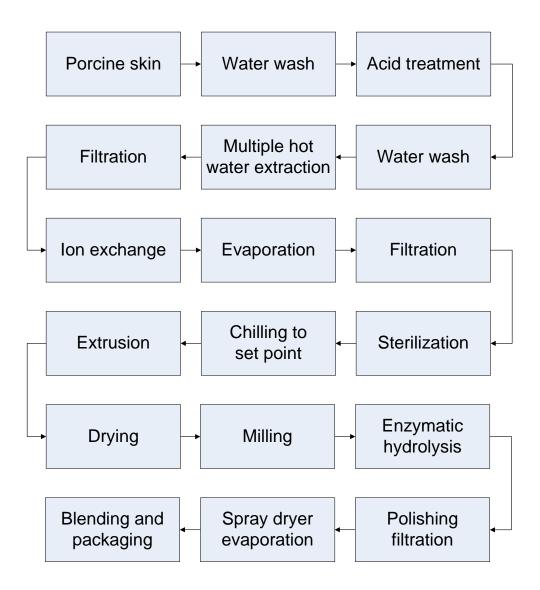
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

# Gelatin, 250 Bloom, Powder, NF - GE105



#### Spectrum Chemical Mfg Corp

West Coast Facility:



# GE105, Gelatin, 250 Bloom, Powder, NF

#### **Source Statement**

The above mentioned catalog item is manufactured by porcine skin. No plant derived products are used in the manufacturing process.

#### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

# **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the above mentioned catalog item and therefore are not expected to be present.

#### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

#### **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



#### **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

# **Animal Testing Statement**

The above mentioned catalog item has not been tested on animals.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

#### **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives



#### RE: Elemental Impurities - Gelatin, 250 Bloom, Powder, NF (Cat# GE105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.05 ppm
Lead	Pb	1	< 1.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 1.5 ppm
Copper	Cu	3	< 30 ppm

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



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CORPORATE HEADQUARTERS

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14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



#### RE: Residual Solvents - Gelatin, 250 Bloom, Powder, NF (Cat# GE105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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### **Label Information**

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

use care: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN** 

**GE105** 

SIZ SY

# Gelatin

250 Bloom

Powder, NF

CAS 9000-70-8

CAUTION: For manufacturing, processing or repacking. Not for use in intravenous drug products. Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Identification	To pass test
Source	As reported
Gel Strength (Bloom Value)	
pH	3.8-7.6
MAXIMUM LIMITS	
Water Conductivity	1 mS/cm
Sulfur Dioxide	50 ppm
Peroxides	
Iron	
Chromium	
Zinc	30 ppm
Loss on Drying	15%
Microbial Limits:	
Total Bacterial Count	103 cfu/g
Total Yeasts and Molds Count	102 cfu/g
Salmonella	Negative
Escherichia coli	Negative
Elemental Impurities	As reported
Residual Solvents	

MOISTURE-SENSITIVE; HEAT-SENSITIVE: Keep tightly closed. Store in a cool, dry place.

**WARNING:** Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 11/I5GHS ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

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