

**Trade Name:** Klear Gummy™ Anhydrous Gelatin Base

## 1 Identification

### 1.1 Product identifier

**Trade name:** Klear Gummy™ Anhydrous  
**Product Code:** B0253  
**Application of the substance / the mixture:** Pharma Excipient

### 1.2 Details of the supplier of the safety data sheet

**Manufacturer/Supplier:**  
SpecializedRx Products, LLC  
3787 95<sup>th</sup> Ave. NE., Suite 100  
Circle Pines, MN 55014  
www.specializedrx.com  
sales@specializedrx.com

### Information department:

Tel.: 1-888-512-1209  
Fax: 1-612-424-8481

### 1.3 Emergency telephone number:

**Emergency Telephone:**  
US: 1-888-512-1209  
International: 1-888-512-1209

## 2 Hazard(s) identification

### 2.1 Classification of the substance or mixture

**Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.

### 2.2 Label elements

**Labelling according to Regulation (EC) No 1272/2008** Void  
**Hazard pictograms** Void  
**Signal word** Void  
**Hazard statements** Void

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

PBT: Not applicable.  
vPvB: Not applicable.

## 3 Composition/information on ingredients

### 3.1 Chemical Characterization: Mixture

**Description:** Mixture of the substances listed below with nonhazardous additions.

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**Dangerous components:** Void

### 3.2 Chemical Information:

**Chemical Name:** Not applicable

**Botanical Name:** Not applicable

**Synonym:** Not applicable

**Chemical Formula:** Not applicable

**CAS Number:** Not applicable

**Alternate CAS Number:** Not applicable

**Molecular Weight:** Not applicable

### 3.3 Composition:

A proprietary blend of organic/inorganic GRAS compounds for use in oral type preparations.

Chemical Name	CAS Number	% By Weight
Gelatin	9000-70-8	*Proprietary
Glycerin	56-81-5	*Proprietary
Sorbic Acid	110-44-1	*Proprietary
Bitter-Bloc™ (Natural Flavor)	1883732-47-5	*Proprietary

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

Notes: \*Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

## 4 First-aid measures

### 4.1 Description of first aid measures

**General information:** No special measures required.

**After inhalation:** If respiratory irritation occurs upon inhalation, remove to fresh air. Seek medical attention if symptoms develop or persist.

**After skin contact:** Generally, the product does not irritate the skin.

**After eye contact:** Rinse opened eye for several minutes under running water.

**After swallowing:** Do not induce vomiting. If significant quantity swallowed, see medical advice.

### 4.2 Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : Dust from this product may cause respiratory irritation.

Symptoms/injuries after skin contact : Dust from this product may cause skin irritation. May cause skin irritation.

Symptoms/injuries after eye contact : Dust from this product may cause eyes irritation. May cause irritation to the eyes.

Symptoms/injuries after ingestion : Ingestion of small amounts would not be expected to produce toxicity. ingestion of large amounts may produce gastrointestinal disturbances.

### 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## 5 Fire-fighting measures

**Trade Name:** Klear Gummy™ Anhydrous Gelatin Base

## 5.1 Extinguishing media

Suitable extinguishing agents: carbon dioxide (CO<sub>2</sub>), dry chemical powder, foam. Water fog.

## 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

## 5.3 Advice for firefighters

Protective equipment: No special measures required.

## 6 Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures:** Not required.

### 6.2 Environmental precautions:

Dilute with plenty of water.

### 6.3 Methods and material for containment and cleaning up:

Clean up with water.

### 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### Protective Action Criteria for Chemicals

PAC-1: None of the ingredients is listed.

PAC-2: None of the ingredients is listed.

PAC-3: None of the ingredients is listed.

## 7 Handling and storage

**7.1 Precautions for safe handling:** Prevent formation of dust.

Information about protection against explosions and fires: No special measures required.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.

**7.3 Specific end use(s):** No further relevant information available.

## 8 Exposure controls/personal protection

**Additional information about design of technical systems:** No further data; see item 7.

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## 8.1 Control parameters

### Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:** The lists that were valid during the creation were used as basis.

## 8.2 Exposure controls

### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

**Breathing equipment:** Fresh air mask

#### Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

#### Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

#### Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye protection:** Goggles recommended during handling.

## 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### General Information

**Appearance:** Translucent Amber Gel

**Form:** Semi-solid

**Color:** Amber

**Odor:** Characteristic to odorless

**pH-value:** Not determined

**Melting point/Melting range:** approx. 70°C - 80°C

**Boiling point/Boiling range:** Not determined

**Flash point:** Not determined.

**Flammability (solid, gaseous):** Not determined.

**Ignition temperature:** Not determined.

**Decomposition temperature:** Not determined.

**Auto igniting:** Product is not self-igniting.

**Danger of explosion:** Product does not present an explosion hazard.

#### Explosion limits:

**Lower:** Not determined.

**Upper:** Not determined.

**Vapor pressure:** Not determined.

**Density:** Not determined.

**Relative density:** Not determined.

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**Vapor density:** Not determined.  
**Evaporation rate:** Not determined.  
**Solubility in / Miscibility with Water:** Partially miscible.  
**Partition coefficient (n-octanol/water):** Not determined.  
**Viscosity:** Not determined.  
**Dynamic:** Not determined.  
**Kinematic:** Not determined.  
**Solvent content:** Not determined.

**9.2 Other information:** No further relevant information available.

## 10 Stability and reactivity

**10.1 Reactivity:** No further relevant information available.

### 10.2 Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

**10.3 Possibility of hazardous reactions:** No dangerous reactions known.

**10.4 Conditions to avoid:** Keep away from heat and sources of ignition.

**10.5 Incompatible materials:** No further relevant information available.

**10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological information

### 11.1 Information on toxicological effects

**Acute toxicity:** Based on available data, the classification criteria are not met.

#### Primary irritant effect:

**on the skin:** Based on available data, the classification criteria are not met.

**on the eye:** Based on available data, the classification criteria are not met.

**Sensitization:** Based on available data, the classification criteria are not met.

#### Additional toxicological information:

#### Carcinogenic categories

**IARC (International Agency for Research on Cancer):** None of the ingredients is listed.

**NTP (National Toxicology Program):** None of the ingredients is listed.

**OSHA-Ca (Occupational Safety & Health Administration):** None of the ingredients is listed.

## 12 Ecological information

### 12.1 Toxicity

**Aquatic toxicity:** No further relevant information available.

**12.2 Persistence and degradability:** No further relevant information available.

**12.3 Bioaccumulative potential:** No further relevant information available.

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**12.4 Mobility in soil:** No further relevant information available.

**Additional ecological information:**

**General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.5 Results of PBT and vPvB assessment**

**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 Other adverse effects:** No further relevant information available.

## 13 Disposal considerations

**13.1 Waste treatment methods**

**Recommendation:** Smaller quantities can be disposed of with household waste.

**Uncleaned packaging:**

**Recommendation:** Disposal must be made according to official regulations.

**Recommended cleansing agent:** Water, if necessary with cleansing agents.

## 14 Transport information

**14.1 UN-Number**

DOT, ADR, ADN, IMDG, IATA

Void

**14.2 UN proper shipping name**

DOT, ADR, ADN, IMDG, IATA

Void

**14.3 Transport hazard class(es)**

DOT, ADR, ADN, IMDG, IATA

Class

Void

**14.4 Packing group**

DOT, ADR, IMDG, IATA

Void

**14.5 Environmental hazards:**

Not applicable.

**14.6 Special precautions for user**

Not applicable.

**14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

**UN "Model Regulation":**

Void

## 15 Regulatory information

**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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## 16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

### Department issuing SDS:

SpecializedRx Products, LLC  
Quality Assurance

**Contact:** sales@specializedrx.com

**Date of preparation / last revision:** 27 Oct 2022

### Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit