

Safety Data Sheet

acc. To OSHA HCS

Reviewed on 10/11/2022

Printing date 10/11/2022

Trade Name: Empty Gelatin Capsules

1 Identification

1.1 Product identifier

Trade name: Hard Empty Gelatin Capsules

Product Code: G4020, G4021, G4030, G4031, G4032, G4040, G4041, G4060, G4080, G4081, G4110

Application of the substance / the mixture: Vacant gelatin shells, for use as encapsulated dose administration.

1.2 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

SpecializedRx Products, LLC

3787 95th Ave NE Ste 100

Circle Pines, MN 55014 USA

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

Classification of the substance or mixture:

Not classified as dangerous according to the GHS (Globally Harmonized System of Classification & Labelling of Chemicals).

GHS Signal Word: N/A

GHS Hazard Phrases:

Not applicable.

GHS Precaution Phrases:

Not applicable.

GHS Response Phrases:

Not applicable

GHS Storage and Disposal Phrases: Not applicable

Eye Contact: Not applicable

Skin Contact: Not applicable

Ingestion: Not applicable

Inhalation: Not applicable

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3 Composition/information on ingredients

3 – Composition/Information on Ingredients

Chemical Name	CAS Number	% By Weight
Gelatin	9000-70-8	≥78%
pigment	-	< 1.0%
Sodium dodecyl sulfate	151-21-3	< 1.0%
Polyacrylic acid	9003-01-4	< 20%
Purified Water	7732-18-5	< 15%

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.

4 First-aid measures

4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Not applicable.

After skin contact: Wash with water if necessary; materials are not considered to have any adverse properties affecting skin.

After eye contact: Flush eyes with water as a precaution.

After swallowing: Not applicable. Product is non-hazardous. Drink a glass of water.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Flash Pt: Not applicable

Fire Fighting Instructions:

AS IN ANY FIRE, WEAR A SELF-CONTAINED BREATHING APPARATUS IN PRESSURE-DEMAND, MSHA/NIOSH (APPROVED OR EQUIVALENT), AND FULL PROTECTIVE GEAR.

Flammable Properties and Hazards: Carbon monoxide and carbon dioxide toxic gases are expected when product contacts fire.

Auto-ignition Pt: Not applicable.

Explosive Limits: LEL: Not determined UEL: Not determined

Suitable Extinguishing Media:

Use water spray, dry chemical, carbon dioxide, or alcohol-resistant foam. Use extinguishing media as appropriate for the surrounding fire.

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6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Non-emergency personnel: No special requirements

Emergency procedures: No special requirements.

Emergency responders: No special requirements.

6.2 Environmental precautions:

No special environmental precautions required.

6.3 Methods and material for containment and cleaning up:

Take up mechanically (sweeping/shoveling) and collect in suitable containers for disposal. No special measures required.

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:

No special measures required; product is non-hazardous. Avoid hard impacts, wetness and heat sources as these may alter the integrity of the capsules.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

No specific handling or storage procedure has been identified; however, it is recommended that the capsules are stored between 59-86°F & RH 40-65%. Avoid direct sunlight and direct transfer from high temperatures to low temperatures.

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.

Respiratory Equipment (Specify Type):

No personal respiratory protective equipment is normally required.

Eye Protection:

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No personal eye protection equipment is normally required.

Protective Gloves: No special protective equipment is required. Wear-resistant gloves may be worn if desired or deemed necessary.

Other Protective Clothing: No special protective equipment normally required.

Engineering Controls (Ventilation etc.): No special protection measures are normally required.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance: Elliptical hollow form solid, with or without color

Form: Solid

Color: Varies

Odor: Slight odor to odorless

pH-value: Not determined

Melting point/Melting range: Not applicable

Boiling point/Boiling range: Not applicable

Flash point: Not applicable

Flammability (solid, gaseous): Not applicable

Ignition temperature: Not determined

Decomposition temperature: Not determined

Auto igniting: Not determined

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

Explosion limits:

Lower: Not determined.

Upper: Not determined.

Vapor pressure: Not determined.

Specific gravity: Not determined

Density: Not determined

Relative density: Not determined.

Vapor density: Not determined.

Evaporation rate: Not determined.

Solubility in / Miscibility with Water: Water soluble

Partition coefficient (n-octanol/water): Not determined.

Viscosity: Not determined.

Dynamic: Not determined.

Kinematic: Not determined.

9.2 Other information: No further relevant information available.

10 Stability and reactivity

10.1 Reactivity: Stable under normal use conditions.

10.2 Chemical stability: Stable under normal use conditions.

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10.3 Possibility of hazardous reactions: No dangerous reactions known.

10.4 Conditions to avoid: Keep away from heat/open flame.

10.5 Incompatible materials: No specific data available.

10.6 Hazardous decomposition products: No data available.

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity:

Non-toxic, generally regarded as safe.

Primary irritant effect:

on the skin: Not classified

on the eye: Not classified

Sensitization: Not classified

Germ Cell Mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: None of the components of this product is listed as a carcinogen by IARC, NTP, US OSHA or the European Directive (67/548/EEC).

Reproductive Toxicity: Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity - Single Exposure (Globally Harmonized System): No human health effects upon single exposure.

Specific Target Organ Toxicity - Repeated Exposure (Globally Harmonized System): No human health effects upon repeated exposure.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Additional toxicological information:

No further relevant information available.

12 Ecological information

12.1 Toxicity

Aquatic toxicity: Not applicable.

12.2 Persistence and degradability: Fully biodegradable.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes:

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

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13 Disposal considerations

13.1 Waste treatment methods

THIS MATERIAL, AS SUPPLIED, IS NOT A HAZARDOUS WASTE ACCORDING TO FEDERAL REGULATIONS (40 CFR 261). THIS MATERIAL COULD BECOME A HAZARDOUS WASTE IF IT IS MIXED WITH OR OTHERWISE COMES IN CONTACT WITH A HAZARDOUS WASTE, IF CHEMICAL ADDITIONS ARE MADE TO THIS MATERIAL, OR IF THE MATERIAL IS PROCESSED OR OTHERWISE ALTERED. CONSULT 40 CFR 261 TO DETERMINE WHETHER THE ALTERED MATERIAL IS A HAZARDOUS WASTE. CONSULT THE APPROPRIATE STATE, REGIONAL, OR LOCAL REGULATIONS FOR ADDITIONAL REQUIREMENTS.

14 Transport information

14.1 UN-Number

DOT, ADR, ADN, IMDG, IATA Not Regulated

14.2 UN proper shipping name

DOT, ADR, ADN, IMDG, IATA Not Regulated

14.3 Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA
Class Not Regulated

14.4 Packing group

DOT, ADR, IMDG, IATA Not applicable.

14.5 Environmental hazards:

Not applicable.

14.6 Special precautions for user

Not applicable.

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Sara **Section 355 (extremely hazardous substances)**: Substance is not listed.
- Sara **Section 313 (Specific toxic chemical listings)**: Substance is listed.
- **TSCA (Toxic Substances Control Act)**: All components are listed or exempt from the TSCA inventory.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer**: Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females**: Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males**: Substance is not listed

15.1.1 EU-Regulations

Classification according to 67/548/EEC or 1999/45/EC: Not classified

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]: Not classified

15.2 Chemical safety assessment

CSA is not required; substance is not hazardous.

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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: 10/11/2022

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)

LD50: Median lethal dose

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