



MATERIAL SAFETY DATA SHEET- GELATIN CAPSULES

The MSDS is compiled in accordance with accepted international standards and are intended to provide information to all who may use the products or may be affected by their use in a work environment. This MSDS Conforms to EC Directive 91/155/EEC also.

SECTION I- IDENTIFICATION			
Commercial Product Name	:	Empty (Porcine) Hard Gelatin Capsule	
Chemical name and synonym	:	Hard Gelatin Capsules.	
Trade name and synonyms	:	Torpac Capsules	
Manufacturer's name & address	:	Various manufacturers identified by Batch number. C/o Torpac Inc., 333B Route 46 West, Fairfield, NJ 07004	
Emergency Tel#	:	Tel: 1-973-244-1125 Fax: 1-973-244-1365	
SECTION II- COMPOSITION / INFORMATION ON INGREDIENTS			
Description/ Identity	:	Container to accommodate medicine	
CI No.	:	Not available	
CI Construction number	:	Not available	
Class	:	Not available	
Hazardous Ingredients	:	None	
Capsule composition	:	Ingredients	
		Weight %	
		Gelatin	81.6 – 82.6
		Water	13-14
		Methyl Paraben*	0.75
		Propyl Paraben*	0.08
		Sodium Lauryl Sulphate	0.25
	Propylene glycol*	3.33	
	* Sizes 000, 00, 0, 0el, 1, 2, 3, 4 and 5 capsules may or may not contain these ingredients		
SECTION III- HAZARD IDENTIFICATION			
Basic raw material used is gelatin, which is classified as a natural food and is essentially non-toxic.			
Hazardous ingredients	:	None	
Hazardous mixtures of other liquids, solids or gases	:	None	
Hazard warning	:	None	
SECTION IV- FIRST-AID MEASURES			
Eye contact	:	Flush with water or standard eye wash solution	
Skin contact	:	Not considered to have any adverse properties affecting skin	
Ingestion	:	Drink a glass of water. Product is non-hazardous	
SECTION V- FIRE FIGHTING MEASURES			
Hard gelatin capsules will burn if ignited.			
Extinguishing media	:	Water, powder, Foam, CO ₂	
Protective equipment for fire fighters	:	Standard fire fighting equipment	
Unusual fire and explosion Hazards	:	None	
Special fire fighting procedures	:	None.	

SECTION VI- ACCIDENTAL RELEASE MEASURES

No special treatment is necessary. Material can be scooped up and disposed off according to local regulations.

SECTION VII- HANDLING AND STORAGE

Handling	: Use metal/plastic bowl or scoops to remove capsules from bag. Do not stack more than 4 boxes one above the other.
Storage	: Prevent damage to empty capsules. Protect from moisture. Storage between 15 to 25°C (60 to 80°F), 40-60% Relative Humidity. Keep away from direct heat sources (e.g., radiators, sunlight, etc.)

SECTION VIII- EXPOSURE CONTROL AND PERSONAL PROTECTION

In accordance with good manufacturing practice. Handle with skin and eye protection.

SECTION IX- PHYSICAL AND CHEMICAL PROPERTIES.

Appearance	: As per customer order
Physical form	: Elliptical hollow form
Color	: As per customer order
Odor	: Odorless
pH of aqueous solution (1%)	: 5.0 to 6.0
Boiling point	: Not applicable
Melting point	: Not applicable
Flash Point	: Not applicable
Flammability	: Not applicable
Auto flammability	: Not applicable
Explosive properties	: Not applicable
Oxidizing properties	: Not applicable
Vapour pressure	: Not applicable
Solubility in water	: Does not dissolve in cold water. Swells in cold water. Completely soluble in hot water.
Microbial test	: Conforming to Indian Pharmacopoeia/ United States Pharmacopoeia / Ph. Eur.

SECTION X- STABILITY AND REACTIVITY

Thermal decomposition	: No thermal decomposition when stored and handled as mentioned in Section VII.
Hazardous polymerization	: Will not occur.

SECTION XI- TOXICOLOGICAL INFORMATION

Non-toxic. Status generally regarded as safe.

SECTION XII- ECOLOGICAL INFORMATION

Aquatic Toxicity	: Non toxic
Biodegradability	: Gelatin is a media for bacterial growth when it is in solution. It is fully biodegradable.
Effect on effluent	: The product is substantially removed in biological treatment.
Treatment	: No special treatment required as gelatin is biodegradable.

SECTION XIII-DISPOSAL CONSIDERATIONS

Takes several hours to dissolve in water below 30°C. When in solution acts as a bacterial growth media. Dispose in safe manner in accordance with Local / National regulations.

SECTION XIV-TRANSPORT INFORMATION

Do not expose to direct sunlight or temperature over 30°C. Use temperature controlled vehicles or in insulated vehicles when the temperature during transportation is above 30°C.

SECTION XV- REGULATORY INFORMATION

EEC Labeling	:	No specific regulatory information necessary
Pharmacopoeia Standards	:	Complies with United States, European and Japanese Pharmacopoeias.
Disintegration time	:	Within 30 minutes at 37 ± 2°C in specified apparatus (test method is as per latest British Pharmacopoeia and United States Pharmacopoeia)
Gelatin properties	:	Gelatin is a macromolecular protein and is physiologically inert. Gelatin is considered pharmacologically relatively inert with the exception of: aldehydes, strong acids or bases and materials with significant free moisture.

SECTION XVI- OTHER INFORMATION

No special precautions other than stated on shipping label.

The data given here is based on current knowledge and experience. The purpose of this SAFETY DATA is to describe the product in terms of their safety requirements. The data does not signify any warranty with regard to the product properties.

Quality Assurance