

## SECTION 1: Identification of the substance /mixture and of the company undertaking

### 1.1 Product Information

Product name	Plastibase
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, and Korea.
Synonyms	Plastibase 5W; Plastibase 50W; Plastibase 55W; Plasticized hydrocarbon gel
Intended Uses	This material is used as a component in topical products.

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

Manufacturer, Supplier:	Contract Pharmaceuticals Limited Canada 7600 Danbro Crescent, Mississauga Ontario Canada L5N 6L6 T: 905-821-7600 <a href="http://www.cplltd.com">www.cplltd.com</a>
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### 1.3 Emergency Telephone Number

Emergency Telephone Number: **1-833-821-7600**

## SECTION 2: Hazard Identification

### 2.1 Classification of the substance or mixture

Classification and Labelling Common - to All Jurisdictions

Classification	Not classified
Precautionary Statements	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure. Handle as a potentially hazardous material.
Other information	5.5% of the mixture consists of ingredients(s) of unknown hazards to the aquatic environment.

## SECTION 3 : Composition /Information on ingredients

### 3.1 Substances

Components	Concentration	CAS No.	EU only		Other Registration No.
			EC No./REACH Registration No.	H- code(s)	
<i>Hazardous components</i>					
Mineral Oil	>= 90 %	8042-47-5	232-455-8	--	--
<i>Other ingredients</i>					
Non-Hazardous Ingredients	< 10 %	Not available	--	--	--
See section 16 for H-code text.					

## SECTION 4: First Aid Measures

### 4.1. Description of First Aid Measures

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
Notes to Physician	Refer to Section 11.
Medical Surveillance	Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

## SECTION 5: Fire-Fighting Measures

### 5.1 Advice For Fire-Fighters

Flammable Properties	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Not available Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides (CO <sub>x</sub> )
Other information	Decontaminate protective clothing and equipment before reuse.

## SECTION 6: Accidental Release Measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

## SECTION 7. Handling and Storage

### 7.1 Precautions For Safe Handling

Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in sturdy containers appropriate to maintain the integrity of this material for its intended use. Store in spill containment pallet or other device to confine spills.

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

Storage Conditions	Store above 4°C (39°F) and below 30°C (86°F). Protect against light. Keep away from heat, sparks and flames. Do not store near incompatible substances.
Specific use(s)	Refer to Section 1

## SECTION 8: Exposure Controls / Personal Protection

### 8.1 Control Parameters

Exposure limit(s)	Company Guideline	ACGIH	Germany OEL	UK MEL
Mineral Oil		10 mg/m3 STEL	--	--
		5 mg/m3 TWA		
		10 mg/m3 STEL		
		sampled by method that does not collect vapor		
		5 mg/m3 TWA		
		sampled by method that does not collect vapor		

Mineral Oil Occupational Exposure Limits have been established by:  
 - Belgium - Czech Republic - Denmark - Spain - Finland - Greece - Hungary - Ireland - The Netherlands - Norway - Poland - Portugal - Sweden

Monitoring Methods General - The health hazard risk of handling this material is dependent on many factors, including physical form, % API in material being handled, duration and frequency of process task, and effectiveness of controls. If it is necessary to handle this compound outside of engineering controls, an exposure risk assessment should be conducted and procedures documented by a qualified EHS professional.

## 8.2 Exposure Controls / Personal Protection For Material As Supplied

This formulation contains an active pharmaceutical ingredient (API) with the guideline limit noted above. To keep the API below the recommended guideline, the material as supplied should be controlled during handling to limit total airborne aerosol exposure to: 5,263.16  $\mu\text{g}/\text{m}^3$  (Material is assigned to Exposure Control Band 1 (range 1,000 - 10,000  $\mu\text{g}/\text{m}^3$ ), < 1  $\mu\text{g}/\text{m}^3$ ).

Engineering Controls and Ventilation	If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. When handling quantities up to 1.5 grams, a standard laboratory with general laboratory dilution ventilation (e.g. 6-12 air changes per hour) is appropriate. When handling quantities from 1.5 grams to 1 kilogram, work in a standard laboratory using a fume hood; biological safety cabinet(Class II, all types), approved vented enclosure; specific local exhaust. Quantities exceeding 1 kilogram should be handled in a designated laboratory. A laminar flow/powder containment booth is recommended for handling >1 kilograms of active substance. When handling solutions with low energy operations (pipette transfers, pouring, low velocity stirring, fraction collection, etc.) use protective shielding to limit the spread of splash or splatter.
Respiratory protection	Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient control exposure, wear an approved respirator with NIOSH Class 100 or high efficiency particulate (HEPA) filters or cartridges (EN 140/EN 136) when exposures are up to 10 times the exposure control guideline. Wear a loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator (PAPR) (EN 12941) when exposures are 10-25 times the exposure control guideline. Wear a full facepiece negative pressure respirator with Class 100 or HEPA filters (EN 136) when exposures are 25-50 times the exposure control guideline. Wear a tight-fitting, full facepiece HEPA PAPR (EN 12942) when exposures are 50-100 times the exposure control guideline. Wear a hood-shroud HEPA PAPR (EN 12941) or full facepiece supplied air respirator (EN 139) operated in a pressure demand or other positive pressure mode when exposures are 100-1000 times the exposure control guideline.
Eye protection	Safety glasses with side-shields are recommended (EN 166). Face shields or chemical safety goggles (EN 166) may be required if splash potential exists or if corrosive materials are present. Note: Choice of eye protection may be influenced by the type of respirator which is selected.
Hand protection	Impervious nitrile, rubber and latex gloves are recommended. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.
Skin and body protection	Wear a laboratory coat (EN340) when handling quantities up to 1 kilogram. For quantities over 1 kilogram, wear laboratory coat (EN 340) or coverall of low permeability.
Hygiene	Wash hands and face before breaks and immediately after handling the product.
Environmental exposure controls	Prevent release to drains and waterways.

## SECTION 9: Physical And Chemical Properties

### 9. 1 Information On Basic Physical And Chemical Properties

#### Appearance

Physical State	liquid
Color	white translucent
Form	paste

#### Odour

Odour	Not available
Odor Threshold	Not available
pH	Not available

#### Other information

Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coefficient [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
Specific Gravity/ Relative density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available

#### Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	230 °C
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Non-explosive based on chemical structure.
Flammability	Not available
Flash point	115 - 268 °C, (Mineral oil component)
Melting Point	Not available
Oxidizing Potential	Non-oxidizer based on chemical structure.

#### Vapor Properties

Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

## SECTION 10. Stability and Reactivity

### 10. 1 Information on Stability and Reactivity

#### Stability

Chemical Stability	Stable under recommended storage conditions.
Conditions to avoid	Not available
Materials to avoid	strong oxidizing agents
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.: carbon oxides (COx)
Hazardous reactions	None known.

## SECTION 11: Toxicological Information

### 11. 1 Information on Toxicological Effects

Routes of Entry	Ingestion, inhalation, Eye contact, Skin contact
Eye Irritation	<u>Mineral Oil</u> Mildly and/or transiently irritating to eyes
Skin Irritation	<u>Mineral Oil</u> Not irritating to skin.
Respiratory Irritation	Not available
Sensitization	<u>Mineral Oil</u> Not a dermal sensitizer
Acute Toxicity Study	<b>Acute Oral</b> <u>Mineral Oil</u> LD50 (rat, males and females): > 5,000 mg/kg  <b>Acute Dermal</b> <u>Mineral Oil</u> LD50 (rabbit, males and females): > 2,000 mg/kg  <b>Acute inhalation toxicity</b> <u>Mineral Oil</u> LC50 (rat): > 5 mg/l/4 H
Repeated Dose Toxicity	<u>Mineral Oil</u> 90 days oral (daily) rat study with recovery period (28 days) (males and females): LOEL = 1.7 mg/kg; Low dose microscopic effects include: liver, lymph nodes.
Genetic Toxicity	<u>Mineral Oil</u>

## 11. 1 Information on Toxicological Effects

### Mutagenicity Assessment

Not classified as mutagen according to GHS criteria.

Carcinogenicity

Mineral Oil

### Carcinogenicity Assessment

This material did not show carcinogenic potential in animal studies.

**Carcinogenicity**

**ACGIH**

**IARC**

**NTP**

Mineral Oil

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Reproductive Toxicity

Mineral Oil

### Assessment Reproductive Toxicity

Data indicate that this compound is not a reproductive hazard. This compound and/or its metabolites may be excreted into the milk.

Developmental Toxicity

Mineral Oil

### Developmental Toxicity Assessment

Available data do not indicate a potential for selective developmental toxicity.

Human experience

### Experiences with Human Exposure

Mineral Oil

Acute exposure General effects low exposure - acute effects include: vomiting, diarrhoea, weakness, inhalation of oil mist or aerosol may cause lipid pneumonia. low exposure - long term exposure effects include: skin effects.

Target Organs

Not available

Symptoms

Not available

Pharmacokinetics/  
Toxicokinetics

Not available

Other Toxicity Information

Not available

## SECTION 12: Ecological Information

### 12.1 Eco Toxicity Effects

Acute Toxicity To Fish - Mineral Oil - Lc50 (Lepomis Macrochirus, 96 H): > 10 G/L.

### 12.2 Mobility - Not Available

### 12.3 Persistence And Degradability

**Biodegradation - Mineral Oil** - Inherent biodegradation (28 days): 20 %; Inherently biodegradable - biodegrades in the environment.

### 12.4 PBT AND VPVB ASSESSMENT Not available

## SECTION 13 : Disposal Considerations

### 13.1 Waste Treatment Methods

Advice On Disposal And Packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.

Other information

Disposal by incineration is recommended.

## SECTION 14: Transport Information

### 14.1 Transport Information

This material is not a dangerous good for the purpose of transportation in all modes.

## SECTION 15: Regulatory Information

### 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### United States of America

313 Toxic Release Inventory      No components listed on the SARA 313 inventory.

TSCA Inventory      Mineral Oil (White)

#### EU Regulation (EC) No 1272/2008)

Regulatory Authorizations and Restrictions:      Not available

# SAFETY DATA SHEET

**SECTION 16: Other Information**

*Text of H-code(s) mentioned in Section 3.*

Not available

*Recommended Restrictions for Use:*

Not available

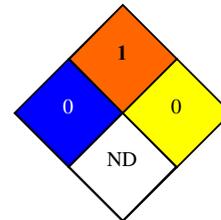
*Other information*

**HMIS**

Health	1
Flammability	1
Reactivity	0
Personal protective equipment	See Section 8.

**NFPA**

Health	0
Fire	1
Reactivity	0
Special	ND



The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information. and we assume no liability from its use.