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MATERIAL SAFETY DATA SHEET CALDOLOR™ (ibuprofen) Injection

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SECTION I - PRODUCT IDENTIFICATION

Product Name: Caldolor™	Formula: Mixture
Synonyms: Ibuprofen Injection,	Strength: (100mg/mL)
NDC: 66220-247-04 & 66220-287-08	Packaging: 400 mg in 5mL vials or 800 mg in 10mL glass vials

SECTION II – COMPOSITION / INFORMATION ON INGREDIENTS

The drug product, Ibuprofen Injection, 100mg/mL, consists of ibuprofen, arginine, and water.

Ibuprofen:

Chemical Name:	2-(4-isobutylphenyl) propionic acid
CAS:	(15687-27-1)
Principle Component:	Ibuprofen
Chemical Formula:	C ₁₃ H ₁₈ O ₂

Arginine:

Chemical Name:	L-2-amino-5-guanidyl-valeric acid
CAS:	(74-79-3)
Principle Component:	L-arginine
Chemical Formula:	C ₆ H ₁₅ N ₄ O ₂

SECTION III – HEALTH HAZARD INFORMATION

Health Hazards:

Inhalation:

May irritate the respiratory tract. Symptoms may include coughing, sore throat and shortness of breath.

Ingestion:

Symptoms may include gastrointestinal irritation or ulceration, constipation, nausea, heartburn, skin rashes, dizziness, fluid retention, and anemia.

Skin Contact:

May cause irritation.

Eye Contact:

May cause irritation.

Chronic Exposure:

May cause allergic skin reactions.

Aggravation of Pre-existing Conditions:

Person with peptic ulcer disease, GI perforation or bleeding or impaired renal or cardiac function may be more susceptible to the effects of this substance.

SECTION IV – FIRST AID MEASURES

Inhalation:

Remove from exposure to fresh air immediately and seek medical attention. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

Skin:	Wash thoroughly with water and soap. If irritation occurs, consult a physician.
Eyes:	Wash thoroughly with water. If irritation occurs, consult a physician.
Ingestion:	If large amount is swallowed get medical attention
Accidental Injection:	Seek medical attention.

SECTION V - FIRE HAZARD DATA AND FIRE FIGHTING MEASURES

Flash Points:	Not Applicable
Auto-Ignition Temperature:	No Data
Flammable Limit:	No Data
Extinguishing Measures:	Water spray, dry powder chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Protective Equipment:	Firefighters should use self-contained breathing apparatus. Avoid breathing smoke and vapor. Decomposition products include oxides of carbon.
Fire and Explosion Hazards:	NA
Fire Fighting Procedures:	As with all fires, evacuate personnel to a safe area.

SECTION VI- PHYSICAL HAZARDS

Conditions to Avoid:	No Data
Incompatibilities:	Alkaline substances.
Decomposition Products:	Burning may produce carbon monoxide and carbon dioxide.
Stability:	Yes at normal temperatures and pressures.
Hazardous Polymerization:	No

SECTION VII – ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear suitable protective clothing. When using material do not eat, drink or smoke.
Environmental Precautions:	Prevent flow to sewers/public waters without previous treatment.
Cleaning Procedures:	Collect spilled material by absorption with vacuum cleaner and dispose of in accordance with all applicable regulations.

SECTION VIII – HANDLING / STORAGE / SPILL / DISPOSAL MEASURES

Handling:	As a general rule, avoid all contact and inhalation of mist and/or vapors associated with the material. Use good personal hygiene practices. Wash hands thoroughly after handling and before eating, drinking, smoking or using toilet facilities. Avoid contact with skin and eyes.
Storage:	This material should be handled and stored per label instructions.
Spill Response:	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Place spillage in appropriately labeled container for disposal. Wash spill site.
Disposal:	Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION IX – EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection:	When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an
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Ventilation:
Hand Protection:
Eye Protection:
Skin Protection:

approved respirator may be warranted for conditions of heavy exposure.
No special ventilation required.
Rubber gloves
Safety glasses/goggles
Working clothing

SECTION X – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear solution	Vapour Pressure:	Not applicable
Odor:	None		
Solubility in Water:	Freely soluble		

SECTION XI – STABILITY AND REACTIVITY

Thermal Decomposition:	Stable under normal conditions of use.
Conditions To Avoid:	High temperatures
Hazardous Decomposition Products:	Carbon monoxide and carbon dioxide.

SECTION XII – TOXICOLOGICAL INFORMATION

Acute Toxicity:	
Oral Rat LD 50:	1.8 g/Kg
Target Organ(s):	No Data
Listed as a Carcinogen:	
NIP:	No
LARC:	No
OSHA:	No
Others:	No

SECTION XIII – ENVIRONMENTAL INFORMATION

General Information:	Prevent flow to sewers/public waters without previous treatment. When disposed of at a suitable concentration no modifications are produced in the active sludge of biologically adapted purifying plants.
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SECTION XIV – DISPOSAL CONSIDERATIONS

Methods of Disposal:	Combustion in an incinerator for chemical waste.
Danger(s):	Not available

SECTION XV – TRANSPORT INFORMATION

General Information:	Not classified as dangerous in the meaning of transport regulations.
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