

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

### 1. Identification

#### 1.1. Product identifier

**Product Identity** CALDOLOR (ibuprofen) Injection  
**Alternate Names** Ibuprofen Injection; NDC: 66220-247-04 & 66220-287-08  
Strength( 100mg/mL)

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Intended use** See Technical Data Sheet.  
**Application Method** See Technical Data Sheet.

#### 1.3. Details of the supplier of the safety data sheet

**Company Name** Cumberland Pharmaceuticals  
2525 West End Avenue, Suite 950  
Nashville, TN 37203

#### Emergency

**CHEMTREC (USA)** (800) 424-9300  
**24 hour Emergency Telephone No.** +1 615-255-0068  
**Customer Service: Cumberland Pharmaceuticals** +1 615-255-0068 (phone)  
+1 615-255-0094 (fax)

### 2. Hazard(s) identification

#### 2.1. Classification of the substance or mixture

Eye Irrit. 2;H319 Causes serious eye irritation.

#### 2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



#### Warning

H319 Causes serious eye irritation.

#### [Prevention]:

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

### [Response]:

P305+351+338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.

P337+313 If eye irritation persists: Get medical advice / attention.

### [Storage]:

No GHS storage statements

### [Disposal]:

No GHS disposal statements

## 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
2-(4-isobutylphenyl) propionic acid CAS Number: 0015687-27-1	10 - 25	Acute Tox. 4;H302 Eye Irrit. 2;H319 STOT SE 3;H335	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

\*The full texts of the phrases are shown in Section 16.

Product also contains excipient L-2-amino-5-guanidyl-valeric acid (CAS# 74-79-3).

## 4. First aid measures

### 4.1. Description of first aid measures

#### General

In all cases of doubt, or when symptoms persist, seek medical attention.  
Never give anything by mouth to an unconscious person.

#### Inhalation

Immediately remove victim to fresh air. If breathing has stopped, give artificial respiration. If breathing is difficult, give oxygen

#### Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

#### Skin

Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

#### Ingestion

If large amount is swallowed, get medical attention.

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

#### Overview

**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.

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

**Skin Contact:** May cause irritation.

**Eye Contact:** May cause irritation.

**Chronic Exposure:** May cause allergic skin reactions.

**Aggravation of Pre-existing Conditions:** Persons with peptic ulcer disease, GI perforation or bleeding or impaired renal or cardiac function may be more susceptible to the effects of this substance.

**Accidental Injection:** Seek medical attention.  
See section 2 for further details.

### 5. Fire-fighting measures

#### 5.1. Extinguishing media

Water spray, dry powder chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Burning may produce carbon monoxide and carbon dioxide.

#### 5.3. Advice for fire-fighters

As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing apparatus. Avoid breathing smoke and vapor.

**ERG Guide No.** ----

### 6. Accidental release measures

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

Put on appropriate personal protective equipment (see section 8).

#### 6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

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

Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

Dispose of waste in accordance with all applicable Federal, State and local laws.

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

### 7. Handling and storage

#### 7.1. Precautions for safe 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.

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

Handle containers carefully to prevent damage and spillage.

Incompatible materials: Alkaline substances

This material should be handled and stored per label instructions.

#### 7.3. Specific end use(s)

No data available.

### 8. Exposure controls and personal protection

#### 8.1. Control parameters

##### Exposure

CAS No.	Ingredient	Source	Value
0015687-27-1	2-(4-isobutylphenyl) propionic acid	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

##### Carcinogen Data

CAS No.	Ingredient	Source	Value
0015687-27-1	2-(4-isobutylphenyl) propionic acid	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

#### 8.2. Exposure controls

##### Respiratory

When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

##### Eyes

Safety glasses or goggles.

##### Skin

Wear working clothing and rubber gloves.

##### Engineering Controls

No special ventilation is required.

##### Other Work Practices

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

### 9. Physical and chemical properties

<b>Appearance</b>	Clear Liquid
<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not Measured
<b>pH</b>	Not available
<b>Melting point / freezing point</b>	Not available
<b>Initial boiling point and boiling range</b>	Not available
<b>Flash Point</b>	Not applicable
<b>Evaporation rate (Ether = 1)</b>	Not available
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Upper/lower flammability or explosive limits</b>	<b>Lower Explosive Limit:</b> No data <b>Upper Explosive Limit:</b> No data
<b>Vapor pressure (Pa)</b>	Not applicable
<b>Vapor Density</b>	Not available
<b>Specific Gravity</b>	Not available
<b>Solubility in Water</b>	Soluble
<b>Partition coefficient n-octanol/water (Log Kow)</b>	Not Measured
<b>Auto-ignition temperature</b>	No data
<b>Decomposition temperature</b>	Not available
<b>Viscosity (cSt)</b>	Not available
<b>VOC Content</b>	Not available

#### 9.2. Other information

No other relevant information.

### 10. Stability and reactivity

#### 10.1. Reactivity

Hazardous Polymerization will not occur.

#### 10.2. Chemical stability

Stable under normal circumstances.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

High Temperatures

#### 10.5. Incompatible materials

Alkaline substances

#### 10.6. Hazardous decomposition products

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

Burning may produce carbon monoxide and carbon dioxide.

### 11. Toxicological information

#### Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
2-(4-isobutylphenyl) propionic acid - (15687-27-1)	1,800.00, Rat - Category: 4	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

### 12. Ecological information

#### 12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

#### Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

2-(4-isobutylphenyl) propionic acid - (15687-27-1)	Not Available	Not Available	Not Available
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### 12.2. Persistence and degradability

There is no data available on the preparation itself.

### 12.3. Bioaccumulative potential

Not Measured

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

### 12.6. Other adverse effects

No data available.

## 13. Disposal considerations

### 13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

## 14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
<b>14.1. UN number</b>	Not Applicable	Not Regulated	Not Regulated
<b>14.2. UN proper shipping name</b>	Not Regulated	Not Regulated	Not Regulated
<b>14.3. Transport hazard class(es)</b>	<b>DOT Hazard Class:</b> Not Applicable	<b>IMDG:</b> Not Applicable <b>Sub Class:</b> Not Applicable	<b>Air Class:</b> Not Applicable
<b>14.4. Packing group</b>	Not Applicable	Not Applicable	Not Applicable
<b>14.5. Environmental hazards</b>			
<b>IMDG</b>	Marine Pollutant: No		
<b>14.6. Special precautions for user</b>	No further information		

# Safety Data Sheet

## CALDOLOR (ibuprofen) Injection



SDS Revision Date:

04/22/2015

### 15. Regulatory information

<b>Regulatory Overview</b>	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
<b>Toxic Substance Control Act ( TSCA)</b>	All components of this material are either listed or exempt from listing on the TSCA Inventory.
<b>WHMIS Classification</b>	Not Regulated
<b>US EPA Tier II Hazards</b>	<b>Fire:</b> No <b>Sudden Release of Pressure:</b> No <b>Reactive:</b> No <b>Immediate (Acute):</b> No <b>Delayed (Chronic):</b> No

**EPCRA 311/312 Chemicals and RQs:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**New Jersey RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Pennsylvania RTK Substances (>1%) :**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.



**Safety Data Sheet**  
**CALDOLOR (ibuprofen) Injection**



SDS Revision Date:

04/22/2015

**16. Other information**

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

Cumberland Pharmaceuticals believes the information provided herein is accurate but makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries, which may result from use or reliance upon this information.

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