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.

H319 Causes serious eye irritation.

[Prevention]:
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
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.

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

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.

*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.
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.
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

<table>
<thead>
<tr>
<th>Exposure</th>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0015687-27-1</td>
<td>2-(4-isobutylphenyl) propionic acid</td>
<td>OSHA</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ACGIH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NIOSH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
</tbody>
</table>

Carcinogen Data

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0015687-27-1</td>
<td>2-(4-isobutylphenyl) propionic acid</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
</tbody>
</table>

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.
9. Physical and chemical properties

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

## 11. Toxicological information

### Acute toxicity

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

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

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

## 12. Ecological information

### 12.1. Toxicity

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

**Aquatic Ecotoxicity**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>96 hr LC50 fish, mg/l</th>
<th>48 hr EC50 crustacea, mg/l</th>
<th>ErC50 algae, mg/l</th>
</tr>
</thead>
</table>
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

14.1. UN number
DOT (Domestic Surface Transportation) Not Applicable

14.2. UN proper shipping name
Not Regulated

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable
IMDG: Not Applicable
Sub Class: Not Applicable

14.4. Packing group
Not Applicable
Not Applicable

14.5. Environmental hazards
IMDG Marine Pollutant: No

14.6. Special precautions for user
No further information
15. Regulatory information

Regulatory Overview  The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA)  All components of this material are either listed or exempt from listing on the TSCA Inventory.

WHMIS Classification  Not Regulated

US EPA Tier II Hazards

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure</td>
<td>No</td>
</tr>
<tr>
<td>Reactive</td>
<td>No</td>
</tr>
<tr>
<td>Immediate (Acute)</td>
<td>No</td>
</tr>
<tr>
<td>Delayed (Chronic)</td>
<td>No</td>
</tr>
</tbody>
</table>

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.
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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