SAFETY DATA SHEET

1. IDENTIFICATION

Product code: IN126
Product Name: INDOMETHACIN, USP

Other means of identification
1. IDENTIFICATION

Synonyms:
- (1-p-Chlorobenzoyl-5-methoxy-2-methylindol-3-yl)acetic acid
- 1-(p-Chlorobenzoyl)-2-methyl-5-methoxy-3-indole-acetic acid
- 1-(p-Chlorobenzoyl)-2-methyl-5-methoxyindole-3-acetic acid
- 1-(p-Chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid
- Amuno
- Artracin
- Artrinovo
- Artrivia
- Confortid
- Dolovin
- Idomethine
- Imbrilon
- Inacid
- Indacin
- Indo-recotolmin
- Indo-tablinen
- Indocid
- Indomecol
- Indomed
- Indomee
- Indometacin
- Indometacine
- Indomethacin
- Indomethacine
- Indoptic
- Inflazon
- Infrocin
- Inteban SP
- Lausit
- Liometacen
- Metacen
- Metartril
- Methazine
- Metindol
- Mezolin
- Mikametan
- Mobilan
- N-p-Chlorbenzoyl-5-methoxy-2-methylindole-3-acetic acid
- Reumacid
- Sadoreum
- Tannex
- alpha-(1-(p-Chlorobenzoyl)-2-methyl-5-methoxy-3-indolyl)acetic acid

CAS #: 53-86-1
RTECS #: NL3500000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
Uses advised against: No information available

Supplier: Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com
2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral Category 1

Label elements

Danger

Hazard statements
Fatal if swallowed

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage
Store locked up

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
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<td>Indomethacin</td>
<td>53-86-1</td>
<td>100</td>
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</table>

4. FIRST AID MEASURES
4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required. Get medical attention.

Ingestion: Fatal if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms Fatal if swallowed. May cause eye/skin/respiratory tract irritation. NSAIDs: Nausea, vomiting, diarrhea, headache, diarrhea, constipation, heartburn, abdominal pain, black/tarry stools, swelling, ringing in ears, tremors, somnolence, insomnia, anxiety, confusion, dizziness, drowsiness and other central nervous system effects, itching, gastrointestinal ulceration/bleeding, hypertension, kidney failure, blood disorders, cardiovascular effects, stroke. Seizures. Paresthesia (numbness and tingling of the extremities). May affect the liver. It may affect the kidneys. May affect respiration.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry powder. Carbon dioxide (CO2). Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical


Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

Product code: IN126 Product name: INDOMETHACIN, USP
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid breathing dust. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities


8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
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<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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Canada

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<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
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Australia and Mexico

<table>
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<th>Components</th>
<th>Australia</th>
<th>Mexico</th>
</tr>
</thead>
</table>

Product code: IN126 Product name: INDOMETHACIN, USP
Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent. 

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands and face before breaks and immediately after handling the product. When using, do not eat, drink or smoke.
9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state:** Solid

**Appearance:** Powder. Crystalline powder. Crystalline solid.

**Color:** Light yellow.

**Odor:** Odorless.

**Taste**
No information available

**Formula:** C19H16NO4Cl

**Molecular/Formula weight:** 357.79 g/mole

**Flammability:** No information available

**Flash Point Tested according to:** Not available

**Autoignition Temperature (°C/°F):** No information available

**Lower Explosion Limit (%):** No information available

**Upper Explosion Limit (%):** No information available

**Decomposition temperature(°C/°F):** No information available

**Boiling point/range(°C/°F):** No information available

**Density (g/cm3):** No information available

**Specific gravity:** No information available

**Evaporation rate:** No information available

**Vapor density:** No information available

**Odor threshold (ppm):** No information available

**Partition coefficient (n-octanol/water):** 4.3

**Miscibility:** No information available

**Solubility:**
- Soluble in diethyl ether
- Soluble in Acetone
- Insoluble in cold water
- Soluble in Ethanol
- Soluble in castor oil
- Solubility in Chloroform: 1 gram dissolves in 30 ml of chloroform
- Solubility in Water: 0.937 mg/l at 25°C

10. STABILITY AND REACTIVITY

**Reactivity**
- Reactive with oxidizing agents
- Reactive with bases

**Chemical stability**

**Stability:** Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:**
- Heat.
- Avoid dust formation.
- Exposure to light.
- Incompatible materials.

**Incompatible Materials:**
- Oxidizing agents.
- Bases.

**Hazardous decomposition products:**
- Carbon monoxide.
- Carbon dioxide.
- Nitrogen oxides (NOx).
- Hydrogen chloride gas.

**Other Information**

**Corrosivity:** No information available
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) = 2mg/kg

Component Information

Indomethacin - 53-86-1

LD50/oral/rat = 11.5-15 mg/kg Oral LD50 Rat
LD50/oral/mouse = 25.6 mg/kg Oral LD50 Mouse
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = 135 mg/kg Oral LD50 Rabbit
81 mg/kg Oral LD50 Hamster
100 mg/kg Oral LD50 Guinea pig
160 mg/kg Oral LD50 Dog
320 mg/kg Oral LD50 Cat

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 11.5-15mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 25.6mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation

Eye Contact: May cause eye irritation

Product code: IN126
Product name: INDOMETHACIN, USP
Inhalation

Irritating to respiratory system

Ingestion

Fatal if swallowed. Effects on the central nervous system (convulsions/seizures, drowsiness, lethargy, mental confusion, disorientation, aggressive behavior, headache, dizziness, ataxia, stiffness, general anesthetic, analgesia, coma). Health effects for nosteroidal anti-inflammatory drugs (NSAIDs): nausea, vomiting, diarrhea, constipation, heartburn, stomach/abdominal pain, black or tarry stools, bleeding/bruising, swelling, sores/ulcers/white spots on lips and mouth, sweating, bluish colored skin, insomnia, mood/mental/personality changes, confusion, dizziness/drowsiness, headache, analgesia, itching, rash, weight gain/loss, vision and speech problems, ringing, tremors, difficulty breathing, increased heart rate or palpitations.

Delayed effects may include gastrointestinal ulceration or bleeding, hypertension, kidney impairment, blood disorders, cardiovascular thrombotic events, stroke, congestive heart failure, fluid retention and edema, central nervous system effects (coma, convulsions, seizures, somnolence, analgesia, depression, anxiety, fatigue). May affect the liver (hepatitis) and urinary system. May cause renal failure. Hematuria (blood in the urine). May affect the peripheral nervous system (paresthesia - a tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles") generally of the hands and feet (extremities)).

Aspiration hazard

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity

Prolonged or repeated ingestion may cause weight loss, and affect the gastrointestinal system (see acute effects), central nervous system (see acute effects), blood (aplastic anemia, normocytic anemia, changes in serum composition, changes in platelet count), urinary system, musculoskeletal system (joints), spleen, and pituitary gland.

Sensitization:

No information available

Mutagenic Effects:

Mutations in microorganisms
Experiments with bacteria and/or yeast have shown mutagenic effects

Carcinogenic effects:

Not considered carcinogenic

<table>
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<tr>
<th>Components</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
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<td>Not listed</td>
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</tbody>
</table>

Reproductive toxicity

No data is available

Reproductive Effects:
May cause adverse reproductive effects based on animal data

Developmental Effects:
No information available

Teratogenic Effects:
May cause birth defects (teratogenic effects) based on animal test data

Specific Target Organ Toxicity

STOT - single exposure
No information available

STOT - repeated exposure
No information available

Target Organs:
No information available
12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

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<tbody>
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<td>Indomethacin</td>
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</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (indomethicin)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I
ERG No: 154
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): G

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I
Marine Pollutant: No Information available

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: I
Subsidiary Risk: No information available

Product code: IN126  Product name: INDOMETHACIN, USP
14. TRANSPORT INFORMATION

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I
Marine Pollutant: No information available
EMS: F-A

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I

ICAO

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: I
ERG Code: 6L
Special Provisions: No information available

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
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<td>Present KE-05544</td>
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<td>Present (9)-361</td>
<td>Not present</td>
<td>Present</td>
<td>Present 200-186-5</td>
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</table>

U.S. Regulations

Indomethacin

Massachusetts RTK: Present


Chemicals Known to the State of California to Cause Cancer:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
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CERCLA/SARA

<table>
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<tr>
<th>Components</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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<tbody>
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U.S. TSCA

<table>
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<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
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</thead>
<tbody>
<tr>
<td>Indomethacin</td>
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Canada

WHMIS hazard class:
D1A  Very toxic materials

Canada Controlled Products Regulation:
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

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<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
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<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
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<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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EU Classification

R-phrase(s)
R28 - Very toxic if swallowed.

S-phrase(s)
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S36/37 - Wear suitable protective clothing and gloves.

<table>
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<tr>
<th>Components</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
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The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
T+ - Very toxic.
16. OTHER INFORMATION

Preparation Date: 6/30/15
Revision Date: 6/30/15
Prepared by: Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet