

SAFETY DATA SHEET

Preparation Date: 3/29/2016

Revision Date: 3/29/2016

Revision Number: Not Applicable

1. IDENTIFICATION

Product identifier

Product code: S1743
Product Name: SULINDAC, USP

Other means of identification

Synonyms: Arthrocline
 Clinoril
 cis-5-Fluoro-2-methyl-1-((4-(methylsulfinyl)phenyl)methylene)-1H-indene-3-acetic acid
 (Z)-5-Fluoro-2-methyl-1-((p-(methylsulfinyl)phenyl)methylene)-1H-indene-3-acetic acid
 cis-Sulindac
 Sulindac sulfoxide

CAS #: 38104-50-2
RTECS # NK8226000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: 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>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by 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 3
Serious eye damage/eye irritation	Category 2B
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 2

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Avoid breathing dust/fume/gas/mist/vapors/spray
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Wear respiratory protection
Wear eye/face protection
Wear protective gloves

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

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

Components	CAS-No.	Weight %
Sulindac 38194-50-2	38194-50-2	100

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. First aider needs to protect himself. 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 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. Get medical attention.

Ingestion:

Toxic 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

Causes eye irritation. Mild eye irritation. May cause skin irritation. May cause sensitization by inhalation and skin contact. May cause an allergic skin reaction. May cause allergic respiratory reaction. May affect the cardiovascular system. It may affect the heart. May cause heartburn. May cause abdominal pain, nausea, vomiting, diarrhea. Eructation (Belching). May cause anorexia. May cause constipation. May affect the liver. It may affect the kidneys.

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:

Carbon dioxide (CO₂). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products:

Carbon monoxide, carbon dioxide, sulfur oxides, hydrogen fluoride

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

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Prevent product from entering drains.

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. Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. 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. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in well-ventilated areas. Do not breathe vapors/dust. Do not ingest. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Store in a segregated and approved area.

Incompatible Materials:

Oxidizing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Sulindac 38194-50-2	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Sulindac 38194-50-2	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
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Sulindac 38194-50-2	None	None
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Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas. 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

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

Respiratory protection: Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent..

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: Yellow.
Odor: No information available	Taste No information available	Formula: C20H17FO3S
Molecular/Formula weight: 356.41	Flammability: No information available	Flashpoint (°C/°F): 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	pH: No information available	Melting point/range(°C/°F): 182 - 185 °C (360 - 365 °F)
Decomposition temperature(°C/°F): 182 - 185 °C (360 - 365 °F)	Boiling point/range(°C/°F): No information available	Bulk density: No information available
Density (g/cm3): 1.39	Specific gravity: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): 3.42	Viscosity: No information available
Miscibility: No information available	Solubility: Insoluble in water	

10. STABILITY AND REACTIVITY

Reactivity
No information available

Chemical stability

Stability: Stable under recommended storage conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Oxidizing agents.

Hazardous decomposition products: Sulfur oxides. Carbon oxides. Hydrogen fluoride gas.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Sulindac - 38194-50-2

LD50/oral/rat = 264 mg/kg Oral LD50 Rat

LD50/oral/mouse = 507 mg/kg

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 = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 264mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 507mg/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:** Causes eye irritation. Mild eye irritation.
- Inhalation** May cause irritation of respiratory tract.
- Ingestion** Toxic if swallowed. 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 cause decreased appetite or anorexia. May also cause belching, excess air or gas in the stomach or intestines, passing gas, bloating, bleeding gums.
- 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 exposure may cause allergic respiratory and skin reactions
Prolonged or repeated ingestion may affect the liver, and kidneys
Chronic exposure may affect the kidneys and cause kidney damage
- Sensitization:** May cause sensitization by inhalation and skin contact
- Mutagenic Effects:** No information available
- Carcinogenic effects:** Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Sulindac	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity Suspected of damaging fertility or the unborn child

- Reproductive Effects:** No information available
- Developmental Effects:** May cause adverse developmental effects based on animal data
Animal studies have revealed evidence of developmental abnormalities
There are no adequate and well-controlled studies in humans
- Teratogenic Effects:** No information available

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

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Sulindac	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (sulindac)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
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: III
Marine Pollutant: No Information available

ADR

14. TRANSPORT INFORMATION

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

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: III
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: III

ICAO

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

IATA

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

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Sulindac</i>	Not Listed	Present KE-17029	Not present	Not present	Not present	Present	Present 253-819-2

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

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)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Sulindac	Not Listed	developmental toxicity	Not Listed	female reproductive toxicity

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
Sulindac	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Sulindac	Not Applicable	Not Applicable

Canada

WHMIS hazard class:
D1B 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

Components	Canada (DSL)	Canada (NDSL)
Sulindac	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances
Sulindac	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Sulindac	Not listed

EU Classification

R-phrase(s)

R22 - Harmful if swallowed.

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	Classification	Concentration Limits:	Safety Phrases
Sulindac		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful.

**16. OTHER INFORMATION**

Preparation Date: 3/29/2016
Revision Date: 3/29/2016
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