

Scientific Documentation

Naproxen, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Naproxen, USP (N1034)

Item Number	N1034
Item	Naproxen, USP
CAS Number	22204-53-1
Molecular Formula	C ₁₄ H ₁₄ O ₃
Molecular Weight	230.26
MDL Number	
Synonyms	(+)-2-(6-Methoxy-2-naphthyl)propionic Acid ; Aleve

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.5 %
SPECIFIC ROTATION	+83.0° to +89.5°	
CHROMATOGRAPHIC PURITY		
INDIVIDUAL IMPURITY		0.5 %
TOTAL IMPURITIES		2.0 %
LOSS ON DRYING		0.5 %
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B (UV)		3%
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	N1034	Lot Number	4II0006
Item	Naproxen, USP	Manufacturer Lot	176021613
CAS Number	22204-53-1	Manufacturer Code	14516
Molecular Formula	C ₁₄ H ₁₄ O ₃	Molecular Weight	230.26

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.5	101.5 %	99.9 %
SPECIFIC ROTATION	+83.0° to +89.5°		+84.9°
CHROMATOGRAPHIC PURITY			.
INDIVIDUAL IMPURITY		0.5 %	<0.5 %
TOTAL IMPURITIES		2.0 %	<2.0 %
LOSS ON DRYING		0.5 %	0.0 %
ELEMENTAL IMPURITIES:			.
NICKEL (Ni)	AS REPORTED		<10 µg/g
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B (UV)		3%	1.8 %
EXPIRATION DATE			26-JUL-2020
DATE OF MANUFACTURE			27-JUL-2017
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm

Certificate of Analysis Results Entered By:

MPEREZ
Melchor Perez
28-OCT-19 10:55:23

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MPEREZ
Melchor Perez
28-OCT-19 10:55:43

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repackaging or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Zhejiang Charioteer Pharmaceutical Co., Ltd. at Tongyuanxi, Dazhan, Xianju, Taizhou, Zhejiang 317321, China. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 05/14/2015

Revision Date: 9/28/2018

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: N1034
Product Name: NAPROXEN, USP

Other means of identification

Synonyms: (+)-6-Methoxy-alpha-methyl-2-naphthaleneacetic acid
 (S)-6-Methoxy-alpha-methyl-2-naphthaleneacetic acid
 (+)-2-(Methoxy-2-naphthyl)-propionic acid
 d-2-(6-Methoxy-2-naphthyl)propionic acid
 2-Naphthaleneacetic acid, 6-methoxy-alpha-methyl-, (+)- (8CI)
 2-Naphthaleneacetic acid, 6-methoxy-alpha-methyl-, (S)- (9CI)

CAS #: 22204-53-1
RTECS # UF5275000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication. reduce inflammation. Analgesic.
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 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 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 2

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes serious eye irritation
Causes skin irritation
May cause respiratory irritation
May cause damage to organs through prolonged or repeated exposure
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
Wear protective gloves/protective clothing/eye protection/face protection
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Wear eye/face protection
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

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 occurs: Get medical advice/attention
Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
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Product code: N1034

Product name: NAPROXEN, USP

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Naproxen	22204-53-1	100
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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.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. 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.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	Causes serious eye irritation Moderately irritating to the eyes Causes skin irritation Moderately irritating to the skin Irritating to respiratory system For Non-steroidal anti-inflammatory drugs (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, decreased urinary output, difficult or troubled breathing, blood disorders, cardiovascular thrombotic events, cardiovascular effects, myocardial infarction, stroke, prolonged bleeding/bruising May affect the liver
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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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 chemical. Carbon dioxide (CO ₂). Water spray. Foam.
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Unsuitable Extinguishing Media:	No information available.
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Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon Monoxide, Carbon Dioxide.
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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. 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. Use appropriate tools to put the spilled solid in a suitable 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. All equipment used when handling the product must be grounded. Avoid dust formation. Keep away from incompatible materials. Remove all sources of ignition.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe 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. Air sensitive. Sensitive to light. Store in light-resistant containers. 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	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Naproxen	22204-53-1	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Naproxen	22204-53-1	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Naproxen	22204-53-1	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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
Full Suit
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. 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: Powder. Crystalline.	Color: White. Off-white.
Odor: Odorless.	Taste No information available.	Formula: C14H14O3
Molecular/Formula weight (g/mole): 230.26	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	Melting point/range(°C/°F): 155°C/ 311°F	Decomposition temperature(°C/°F): No information available

Boiling point/range(°C/°F):

No information available

Bulk density:

No information available

Density (g/cm3):

No information available

Specific gravity:

No information available

pH:

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):**

3.18

Viscosity:

No information available

Miscibility:

No information available

Solubility:Slightly soluble in Ether
Soluble in Methanol
Soluble in Chloroform
Insoluble in water
Freely soluble in alcohol**10. STABILITY AND REACTIVITY****Reactivity**

Reactive with oxidizing agents

Chemical stability**Stability:**

Sensitive to light. Exposure to light accelerates decomposition. Sensitive to air. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur**Conditions to avoid:**

Heat. Avoid dust formation. Exposure to light. Exposure to air. Incompatible materials.

Incompatible Materials:

Oxidizing agents

**Hazardous decomposition
products:**

Carbon oxides.

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:**

Inhalation. Ingestion.

Acute Toxicity**Component Information**

Naproxen

CAS-No.

22204-53-1

Product code: N1034**Product name:** NAPROXEN, USP**6 / 12**

LD50/oral/rat = 248 mg/kg Oral LD50 Rat
LD50/oral/mouse = 360 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 = 248 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 360 mg/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: Causes skin irritation. Moderately irritating to the skin.

Eye Contact: Causes serious eye irritation. Moderately irritating to the eyes.

Inhalation Irritating to respiratory system.

Ingestion Harmful if swallowed. Can cause gastrointestinal tract irritation with nausea, thirst, abdominal discomfort, cramps, constipation, heartburn, anorexia, colitis, flatulence. It may affect behavior and cause central nervous system effects such as headache, muscle weakness, dizziness or vertigo, drowsiness, lightheadedness, malaise, insomnia, fatigue, sleep disorders, dream abnormalities, inability to concentrate mental depression, nervousness, seizures. May cause other adverse reactions such as sores, ulcers, or white spots on the lips or in the mouth, pruritus, skin eruptions, rash, ecchymoses, urticaria, sweating, photosensitive dermatitis, photosensitivity reactions resembling porphyria cutanea tarda and epidermolysis bullosa and purpura. tinnitus, edema, congestive heart failure, palpitations, dyspnea, visual and hearing disturbances, blood problems (thrombocytopenia, leukopenia, granulocytopenia, eosinophilia, agranulocytosis, aplastic anemia, hemolytic anemia). Health effects for nonsteroidal anti-inflammatory drugs (NSAIDs): nausea, vomiting, diarrhea, constipation, heartburn, stomach/abdominal pain, black or tarry stools, inhibition of platelet aggregation, prolonged bleeding time/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 in

the ears, tremors, difficulty breathing, increased heart rate or palpitations. Delayed effects may include gastrointestinal ulceration or bleeding, hypertension, kidney impairment, decreased urine output, interstitial nephritis, blood disorders, cardiovascular thrombotic events, stroke, congestive heart failure, fluid retention and edema, other central nervous system effects (coma, convulsions, seizures, somnolence, analgesia, depression, anxiety, fatigue). NSAIDs may also cause serious adverse skin reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome, and toxic epidermal necrosis, and may affect the liver (borderline elevations of one or more liver tests).

Aspiration hazard No information available.

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

Chronic Toxicity Ingestion: Prolonged or repeated ingestion may affect the kidneys (nephritis, impairment of renal function, dysuria, hematuria, renal papillary necrosis, renal failure, nephrotic syndrome), liver (hepatitis, jaundice), behavior/central nervous system (CNS effects similar to those for acute ingestion), blood (anemia and symptoms similar to acute ingestion). It may cause ulceration or bleeding from the stomach and duodenum and also reactivate latent peptic ulcers or may cause peptic ulcers in individuals with no previous history of ulcers. Rarely, hemorrhage and perforation of ulcers may occur. It may also affect metabolism and cause hyperkalemia. Anaphylactoid reactions may occur in both aspirin-sensitive individuals as in those without any known hypersensitivity. Medical Conditions Aggravated by Exposure: Hypersensitivity to material, allergies to aspirin or other nonsteroidal anti-inflammatory drugs, active alcoholism, blood disorders including hemophilia, liver or kidney impairment, stomatitis.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Naproxen	22204-53-1	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects based on animal data
Crosses the placenta in humans

Developmental Effects: Possible risk of harm to the unborn child
May cause adverse developmental effects based on animal data
There may be an increased risk of congenital anomalies or defects when Non-steroidal Anti-Inflammatory Drugs (NSAIDs) (e.g. naproxen, ibuprofen) when taken during early pregnancy
Naproxen use during pregnancy has been suggested to increase miscarriage risk. Some, but not all, epidemiology studies have associated pregnancy use of Non-steroidal Anti-inflammatory Drugs (NSAIDs), including naproxen, with an increase in heart defect risk. Use of this medication in late pregnancy is avoided

Teratogenic Effects: due to concerns about premature closure of the ductus arteriosus
No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure.
Target Organs: Liver. Gastrointestinal tract.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: Not readily biodegradable

Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is low.

Mobility: It is expected to have moderate mobility based upon estimated Koc.

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	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Naproxen	22204-53-1	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.(Naproxen)
Hazard Class: 6.1
Subsidiary Class No information available
Packing group: III
Emergency Response Guide Number 154
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, III

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
Description: No Information available
 UN2811, Toxic solid, organic, n.o.s., 6.1, III

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: III
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMO / IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.(Naproxen)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No information available
EMS: F-A
Special Provisions 223, 274
Description UN2811, Toxic solid, organic, n.o.s. (NAPROXEN), 6.1, III

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
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, 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
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III
Special Provisions A3, A5

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
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines	Japan ENCS	CHINA	Australia	EINECS-No.
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				(PICCS)			(AICS)	
Naproxen	22204-53-1	Not Listed	Present KE-23317	Not present	Not present	Not present	Present	Present 244-838-7

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	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Naproxen	22204-53-1	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	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 de minimis
Naproxen	22204-53-1	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Naproxen	22204-53-1	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Naproxen	22204-53-1	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Naproxen	22204-53-1	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Naproxen	22204-53-1	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Product code: N1034

Product name: NAPROXEN, USP

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Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Naproxen	22204-53-1	No information

EU - CLP (1272/2008)

R-phrases(s)

R22 - Harmful if swallowed.

S -phrase(s)

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

S36/37 - Wear suitable protective clothing and gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Naproxen	22204-53-1		No information	

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

Indication of danger:

Xn - Harmful.

Xn



16. OTHER INFORMATION

Preparation Date: 05/14/2015
Revision Date: 9/28/2018
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



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
N1034	Naproxen, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

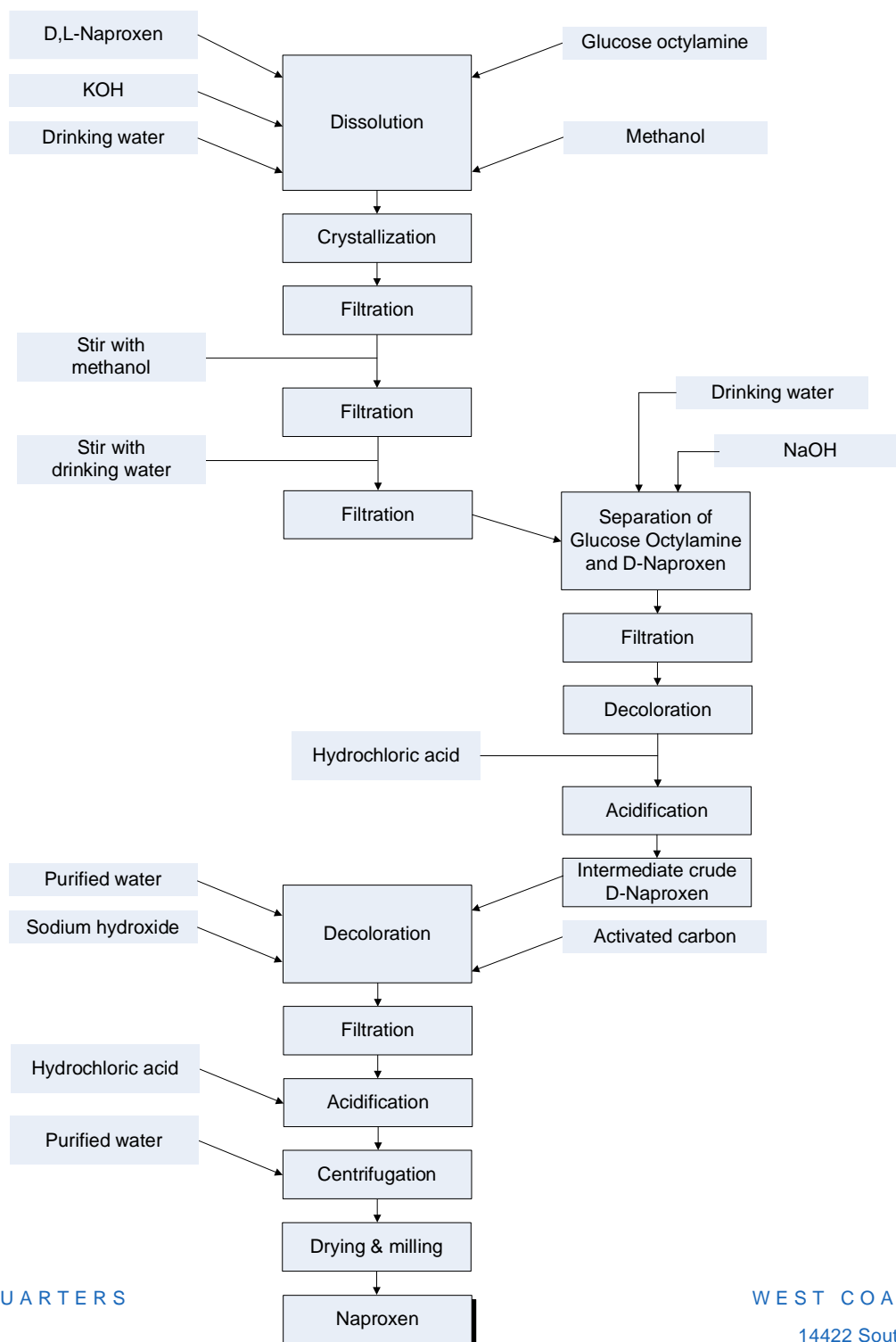
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez".

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Naproxen, USP - N1034



CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

N1034, Naproxen, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the above mentioned catalog item and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Naproxen, USP (Cat# N1034)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3 ppm
Cobalt	Co	2A	< 5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 5 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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RE: Residual Solvents - Naproxen, USP (Cat# N1034)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm

No Class 1, Class 3 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

DANGER

- Toxic if swallowed • Causes serious eye irritation
- Causes skin irritation • May cause respiratory irritation
- May cause damage to organs through prolonged or repeated exposure • Suspected of damaging fertility or the unborn child.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood

• Do not eat, drink or smoke when using this product

• Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Immediately call a POISON CENTER or physician. 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 attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

N1034

SIZ SY

Naproxen

USP

CAS 22204-53-1

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solid, organic, n.o.s. (naproxen), 6.1, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{14}H_{14}O_3$ F.W. 230.26

Manufacturer/Supplier Code ?
Manufacturer Lot Number ?

Assay (Dried Basis) 98.5-101.5%
Specific Rotation, $[\alpha]_D^{25}$ +83.0° to +89.5°
Chromatographic Purity To pass test

MAXIMUM LIMITS


Loss on Drying 0.5%
Elemental Impurities As reported
Residual Solvents To pass test

LIGHT SENSITIVE, AIR SENSITIVE: Keep tightly closed in light-resistant containers.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

Repackaged by Spectrum as:
Lot No. XQ####

Exp. Date: 00-00-0000



Spectrum Chemical Mfg Corp

Corporate Headquarters:

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