

SAFETY DATA SHEET

1. Identification

Product identifier Nabumetone

Other means of identification

Catalog number 1449518

Chemical name 2-Butanone, 4-(6-methoxy-2-naphthalenyl)-Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

Rockville

MD

20852-1790

US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US &

+1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Serious eye damage/eye irritation Category 2B

OSHA hazard(s) Not classified.

Label elements

No symbol. Hazard symbol Signal word Warning

Hazard statement Causes eye irritation.

Precautionary statement

Prevention Wash thoroughly after handling.

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.

Storage Not available. Disposal Not available. Not classified.

Hazard(s) not otherwise

classified (HNOC)

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name Common name and synonyms **CAS** number % Nabumetone 42924-53-8 100

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Material name: Nabumetone USP SDS US Most important symptoms/effects, acute and delayed

Irritation of eyes and mucous membranes.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Treatment of overdose may include the following: Induce vomiting or perform gastric lavage. DO NOT use syrup of ipecac. Administer activated charcoal. Antacids may relieve adverse gastrointestinal effects and enhance elimination. Nephritis or nephrotic syndrome, thrombocytopenia, hemolytic anemia, and severe cutaneous or other hypersensitivity reactions may respond to glucocorticoid administration. Administer as required: plasma volume expanders for severe hypotension; diazepam or other benzodiazepine for convulsions; vitamin K1 for hypoprothrombinemia; and/or dopamine plus dobutamine intravenously to prevent or reverse early indications of renal failure. [USP DI 2006]

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media

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

materials.

None known.

Unsuitable extinguishing

media

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

and precautions for firefighters

Wear suitable protective equipment.

Fire-fighting equipment/instructions As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained

breathing equipment and protective clothing.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Туре	Value	
Nabumetone (CAS	TWA	1000	
42924-53-8)		micrograms/m3	

Biological limit values

Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Material name: Nabumetone USP SDS US

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with sideshields are recommended. Face shields or goggles may be required if

splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Other

Hand protection Chemically compatible gloves. For handling solutions, ensure that the glove material is protective

against the solvent being used. Use handling practices that minimize direct hand contact.

Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex

gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection Where respirators are deemed necessary to reduce or control occupational exposures, use

NIOSH-approved respiratory protection and have an effective respirator program in place

(applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance White to off-white crystalline powder.

Solid. Physical state **Form** Powder Odor Not available. **Odor threshold** Not available.

7.1 - 7.4 (1% suspension) 172.4 - 181.4 °F (78 - 83 °C) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

(%)

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available.

0.0000027 kPa at 25 °C Vapor pressure

Vapor density Not available. Relative density Not available.

Solubility in water Practically insoluble.

Partition coefficient

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity**

Other information

Naphthylalkanone derivative. Chemical family

C15H16O2 Molecular formula Molecular weight 228 29

Solubility (other) Freely soluble in acetone; sparingly soluble in alcohol and in methanol.

10. Stability and reactivity

Reactivity No reactivity hazards known. Chemical stability Stable at normal conditions.

Possibility of hazardous No dangerous reaction known under conditions of normal use.

reactions

Material name: Nabumetone USP SDS US Conditions to avoid None known.

Incompatible materials None known.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

InhalationDue to lack of data the classification is not possible.Skin contactDue to lack of data the classification is not possible.

Eye contact Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Nonsteroidal anti-inflammatory drugs: Stomach upset. Nausea. Vomiting. Diarrhea. Headache. Dizziness. Ringing in ears. Blurred vision. Nervousness. Depression. Drowsiness. Difficulty

sleeping. Ulcers. Tiredness. Irritability. Constipation. Indigestion.

Delayed and immediate effects

of exposure

Nonsteroidal anti-inflammatory drugs: Hypotension. Coma. Respiratory depression. Gastrointestinal bleeding. Central nervous system effects. Kidney problems.

Cross sensitivity Persons sensitive to aspirin or other nonsteroidal anti-inflammatory agents may be sensitive to

this material also.

Medical conditions aggravated

by exposure

Nonsteroidal anti-inflammatory drugs: Asthma. Aspirin allergy. Active alcoholism. Anemia. Impaired kidney or liver function. Cardiovascular disorders. Bleeding disorders. Peptic ulcer or

gastrointestinal bleeding. Hypertension. Stomatitis.

Acute toxicity Based on available data, the classification criteria are not met.

Product Species Test Results

Nabumetone (CAS 42924-53-8)

Oral

LD50 Mouse 4290 mg/kg
Rat 3880 mg/kg

Skin corrosion/irritationBased on available data, the classification criteria are not met.

Serious eye damage/eye

irritation

Causes eye irritation.

Local effects

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eye.
Severity: Mild.
Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitization

Sensitization test Result: Non-sensitizing. Species: Guinea pig

Germ cell mutagenicity Due to lack of data the classification is not possible.

Mutagenicity

Chromosomal aberrations in lymphocytes (in vitro)

Result: Positive.

Mouse micronucleus test (in vivo)

Result: Negative.

S. typhimurium Ames assay

Result: Negative (with and without activation).

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to

be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Carcinogenicity study (mice and rats)

Result: No statistically significant tumorigenic effects.

Test Duration: 2 years

Material name: Nabumetone USP SDS US

Reproductive toxicity

Based on available data, the classification criteria are not met. Therapeutic use of NSAIDs during the second half of pregnancy may cause adverse effects on the fetus, such as premature closure of the ductus arteriosus which may lead to persistent pulmonary hypertension in the newborn. Animal studies have shown that administration of NSAIDs in late pregnancy may prolong gestation and cause difficult labor.

Reproductivity

100 mg/kg/day Reproductivity test Result: Fetotoxicity was observed. 320 mg/kg/day Reproductivity test

Result: Did not impair fertility in males or females.

Species: Rat

> 400 mg/kg/day Reproductivity test Result: Did not cause any birth defects.

Species: Rat

Specific target organ toxicity -

single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity -

repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potentialNot available.Mobility in soilNot available.Other adverse effectsNot available.

13. Disposal considerations

Disposal instructionsThis product, in its present state, when discarded or disposed of, is not a hazardous waste

according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA

criteria for hazardous waste. Dispose in accordance with all applicable regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

Contaminated packaging

be disposed of in a safe manner (see: Disposal instructions).

Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous

chemical

No

Material name: Nabumetone USP SDS US

Other federal regulations

Safe Drinking Water Act

(SDWA)

Not regulated.

Food and Drug

Administration (FDA)

Not regulated.

Inventory name

US state regulationsThis product does not contain a chemical known to the State of California to cause cancer, birth

defects or other reproductive harm.

International Inventories

Country(s) or region

Country(3) or region	inventory name	On inventory (yearno)
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

 Issue date
 03-13-2006

 Revision date
 07-16-2013

Version # 03

United States & Puerto Rico

Further information Not available.

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contained herein.

Revision Information

Physical & Chemical Properties: Multiple Properties

Material name: Nabumetone USP SDS US

On inventory (yes/no)*

No