

Material Safety Data Sheet

12601 Twinbrook Parkway Rockville, MD 20852 USA Telephone calls: (301) 881-0666 8:00am - 5:00pm EST Mon. - Fri.

Responsible Party: Reference Standards Technical Services

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ACENOCOUMAROL

Catalog Number: 1001003 Package Size: 200 mg Revision Date: September 22, 2003

EMERGENCY OVERVIEW - Toxic. Reproductive Hazard.

SECTION 1 - IDENTIFICATION

Common Name: Acenocoumarol Formula: C19H15NO6

Synonym: Nicoumalone; Acenocoumarin

Chemical Name: 2H-1-Benzopyran-2-one, 4-hydroxy-3-[1-(4-nitrophenyl)-3-oxobutyl]-

CAS Number: 152-72-7 **RTECS Number:** GN4900000

Chemical Family: A Coumarin derivative

Therapeutic Category: Anticoagulant

SECTION 2 - INGREDIENT INFORMATION

<u>Principle Components</u> <u>Percent</u> <u>Exposure Limits</u>

Acenocoumarol Pure Material n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of acenocoumarol is 1 to 10 mg per day.

Adverse Effects: Adverse effects may include skin rash, hives, or itching; fever or chills; cough or hoarseness; lower back or

side pain; painful or difficult urination; bloated feeling or gas; cold intolerance; loss of appetite; and stomach cramps or pain. Anticoagulants may cause minor bleeding resulting in nose bleeds, blood in urine, bleeding from gums when brushing teeth, pinpoint red spots on skin, unusual bleeding or bruising, and unusually heavy or unexpected menstrual bleeding. Possible allergic reaction to material if inhaled, ingested

or in contact with skin.

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Overdose Effects: An overdose of an anticoagulant may cause severe bleeding. Symptoms may include abdominal or stomach

pain or swelling; diarrhea; dizziness; headache; nausea; vomiting; nervousness; weakness; joint pain, stiffness, or swelling; black, tarry stools; blood in stools; bloody vomit or vomit that looks like coffee grounds; constipation; confusion; paralysis; bleeding in eye; blurred vision; chest pain; coughing up blood;

shortness of breath; and back pain or backaches.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation and excessive bleeding.

Chronic: Possible hypersensitization, cumulative anticoagulant effect, and hair loss from scalp.

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is readily and rapidly absorbed from the

gastrointestinal tract. Duration of action is 48 hours.

Medical Conditions Aggravated by Exposure:

Hypersensitivity to material; recent or threatened miscarriage or abortion; bleeding disorders or history of uncontrolled bleeding; recent surgery; recent childbirth; high blood pressure; severe diabetes; liver function impairment; ulcers or lesions of the gastrointestinal, respiratory, or urinary tract; diverticulitis; vasculitis;

vitamin K deficiency; active alcoholism; and heart problems.

Cross Sensitivity: n/f

Pregnancy Comments: Adequate and well-controlled pregnancy studies in humans have not been done. Coumarin derivatives have

been reported to cause abnormal development in the fetus, birth defects, miscarriage, stillbirth, low birth weight, growth retardation, fetal or neonatal hemorrhage, fetal death from hemorrhage in utero, and

increased risk of maternal hemorrhage during second and third trimesters.

Pregnancy Category: n/f

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity

(anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial

respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment of anticoagulant overdose should be symptomatic and supportive and may include the following:

1. To reverse anticoagulant effects, administer oral or parenteral vitamin K1. Repeated doses may be

necessary.

2. For serious overdose or life-threatening bleeding, a transfusion of fresh plasma or prothrombin (factor IX) complex concentrate along with vitamin K1 may be necessary. Use of purified factor IX complex

preparation is NOT recommended.

3. Packed red blood cells may be administered for significant blood loss. Although whole blood may be given if blood loss has been extensive, transfusion of whole blood will not elevate procoagulant factor concentrations sufficiently to eliminate the need for administration of plasma or prothrombin complex

concentrate.

4. If acute adrenal hemorrhage or insufficiency is suspected, measure plasma cortisol concentrations and immediately institute a high-dose intravenous corticosteroid therapy (preferably with hydrocortisone, since other glucocorticoids may not provide sufficient sodium retention). Delay of treatment while awaiting laboratory confirmation may prove fatal. It has been proposed that abdominal CAT scans may be useful in diagnosing this condition may prove rapidly. [LISP DI 2003]

diagnosing this condition more rapidly. [USP DI 2003]

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 513 mg/kg
Oral Mouse: LD50: 1470 mg/kg

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Irritancy Data: n/f

Target Organ(s): Liver

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f Lower Flammable Limit: n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground

mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing

equipment and protective clothing.

SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: n/f

Incompatibilities: Strong oxidizers

Decomposition Products: When heated to decomposition material emits toxic fumes of NOx. Emits toxic fumes under fire

conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

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. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label

instructions to ensure product integrity.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up

spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site. Place contaminated clothing in closed

containers for storage until laundered or discarded.

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey

involving air monitoring. In the event that a respirator is not required, an approved dust mask should be

used.

Ventilation: Recommended.

Gloves: Rubber

Eve Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

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NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: Off-white to buff-colored crystalline powder; odorless or almost odorless.

Melting Point: 196 - 199° C

Solubility in Water: Practically insoluble Vapor Density: n/f

 $\begin{tabular}{lll} \textbf{Boiling Point:} & n/f \\ \end{tabular} & \textbf{Evaporation Rate:} & n/f \\ \end{tabular}$

Vapor Pressure: n/f % Volatile by Volume: n/f