Sarabhai Campus, Dr. Vikram Sarabhai Marg, Wadi Wadi, Vadodara 390 023, India.

MATERIAL SAFETY DATA SHEET [GHS(2)]

PRODUCT: ACENOCOUMAROL

Effective Date: 28.04.2011 Revision No: 00

1. Identification of the substance or mixture and of the supplier

Product identifier: Acenocoumarol

• Other Name : (RS)-4-hydroxy-3-(1-p –nitrophenyl-3-oxobutyl) coumarin.

• CAS Number : 152-72-7

• EINECS Number: 205-807-3

• Relevant identified uses of the substance or mixture and uses advised against

Application of the substance / the preparation. : Anticoagulant.

- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Asence Pharma Pvt.Ltd.

Sarabhai Campus, Dr. Vikram Sarabhai Marg,

Wadiwadi , Vadodara , Gujarat (INDIA)

Phone: +91-265-2323179

- Further information obtainable from: Sunil Pandya
- Emergency telephone number: +91-265-2323179

2. Hazards Identification

Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008: Flammable Liquid .
- Classification according to Directive 67/548/EEC or Directive 1999/45/EC:
 Not applicable as Acenocoumarol (API) doesnot fall under DANGEROUS SUBSTANCE
 Or DANGEROUS PREPARATIONS DIRECTIVE Category.
- Information concerning particular hazards for human and environment:
- Classification system:
- Label elements : As per GHS
- Labelling according to Regulation (EC) No 1272/2008

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• Hazard pictograms : Pictogram not required due to flammable liquid category 4 & Acute toxicity category 5 .

• Signal word "WARNING"

•Hazard statements:

Acute Toxicity: Oral – May be harmful if swallowed. (Category 5)

Skin – May be harmful in contact with skin . (Category 5)

Inhalation – May be harmful if inhaled . (Category 5)

• Precautionary statements : Store in a tightly closed light resistant container .

• Other hazards : Not Applicable

• Results of PBT and vPvB assessment

• PBT : Not Applicable

• vPvB :.Not applicable

3. Composition / Information on Ingredients

Substance

• Chemical Identity: Active Pharmaceutical Ingredient (API)

• Common Name : Acenocoumarol

• Other Name : (RS)-4-hydroxy-3-(1-p –nitrophenyl-3-oxobutyl) coumarin.

• CAS Number : 152-72-7

• EINECS Number: 205-807-3

Mixture

• Supplied as API only without mixture of any ingredients .

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4. First Aid Measures

Oral : Refer for Medical Attention.

Skin : Remove all contaminated clothing & flush skin , hairs etc. with running water.

Inhaled : Remove fresh air area & get medical attention if necessary.

Eye Contact: Immediately flush eyes with plenty of water & get medical attention

5. Fire Fighting Measures

Vapour Pressure : Not Available

Fire Extinguishing Media: Alcohol resistant Foam, Dry chemical powder, CO2, Water.

Special Information:

In the event of a fire, wear full protective clothing, Chemical protective goggles, gloves & appropriate respirator containing type A filter of sufficient capacity.

Fire Incompatibility : Avoid contamination.

6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8, and Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Do not flush to sewer.

7. Handling and Storage

Procedure for Handling:

- 1. Avoide personal contact including inhalation.
- 2. Wear protective equipments.
- 3. Use in a well ventilated area.
- 4. When handling do not eat, drink or smoke.

Recommended Storage: Store in a tightly closed light resistant container.

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8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

None established.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area.

Personal Respirators (NIOSH Approved):

Where open handling of powders occurs, use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR), unless air-monitoring data has shown that a lower level of respiratory protection is adequate.

Skin Protection:

Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact.

Eye Protection:

Use chemical safety goggles and/or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

An almost white to buff powder.

Odor:

It is odourless or almost odourless.

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Solubility:

Practically insoluble in water and in ether; slightly soluble in ethanol (96%) and in Chloroform. It dissolves in aqueous solutions of alkali hydroxides.

Relative Density:

Not Applicable

pH:

No information found.

Melting Point:

About 198°C.

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions in tightly closed containers protected from light.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Avoid reaction with oxidizing agents.

Conditions to Avoid:

Incompatibles.

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11. Toxicological Information

Acute Effects

May Be Harmful By Inhalation, Ingestion, or Skin Absorption.

May Cause Eye Irritation.

May Cause Skin Irritation.

Toxicity Data

Orl-Rat Ld 50:513 mg/Kg

Orl-mouse Ld 50:1470 mg/Kg

12. Ecological Information

Persistence : Water, Air -- High

Bioaccumulation: Low

Mobility : Medium

Do not discharge into sewer or waterways.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated as Acenocoumarol is not fall under DANGEROUS GOODS.

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15. Regulatory Information

This MSDS has been prepared according to the hazard criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the MSDS contains all of the information required by the GHS.

16. Other Information

Product Use: Active Pharmaceutical Ingredient (API)

Disclaimer:

Asence Pharma Pvt.Ltd provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose.

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Prepared by:

Quality Department

Asence Pharma Pvt.Ltd