SAFETY DATA SHEET

In accordance with Regulation (EC) 1907/2006 as amended

SECTION 1.
IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1. Substance identifier

Substance name:	**PYRANTEL PAMOATE**
Other names (if available): Sinonyms:	Pyrimidine, 1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]-(E)- 2-Naphtoic acid, 4,4'-methylenebis(3-hydroxy-,) salt 1:1
CAS number	22204-24-6
IUPAC name (if CAS is not available)	4-[(3-carboxy-2-hydroxynaphthalen-1-yl)methyl]-3 hydroxynaphthalene-2-carboxylic acid ; 1-methyl-2-[(E)-2-thiophen-2-ylethenyl]-5,6-dihydro-4H-pyrimidine
REACH Pre/Registration number	Not applicable, the substance is exempted from registration

1.2. Relevant identified uses of the substance and uses advised against

Relevant use(s)	Active pharmaceutical ingredient for the preparation of drugs. Professional use only
Uses advised against	Different from above mentioned uses

1.3. Details of the supplier of the safety data sheet

Manufacturer/Distributor/Importer: COSMA SPA
VIA COLLEONI 15/17
24040 CISERANO BG (ITALIA)
TEL 0039-035- 883055
FAX 0039 -035-4820501.
Safety data sheet e-mail: info@cosma.it

1.4. Emergency telephone number

Poison control centre – Niguarda Hospital, Milan: 0039 02 66101029 (24 hours)
National centre for toxicological information, Poison control centre, Pavia: 0039 03 8224444 (24 hours)

SECTION 2
HAZARDS IDENTIFICATION

2.1 Classification of the substance

- **Classification of the substance in accordance with Regulation (CE) n. 1272/2008:** not classified

Main adverse effects

Physico-chemical effects	No known physical / chemical effects due to this substance
Health effects	Ingestion: infrequent occurrence of abdominal pain, diarrhea, dizziness, insomnia, rash and headache. Exposure through inhalation: may cause irritation. Skin Contact: may cause mild irritation. Eye contact: may cause mild irritation. Sensitization: No data found in the literature search carried out
Environmental effects	No negative environmental impacts expected

See also sections from 9 to 12

2.2 Label elements

- **Labelling in accordance with regulation n. 1272/2008/EC:** not classified

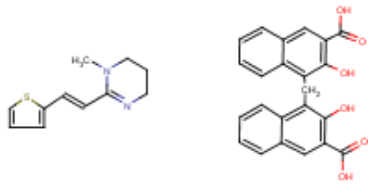
2.3 Other hazards (which do not results in the classification)

The substance satisfies the PBT criteria	YES	NO
- PBT		X
- vPvB		X

- Health hazards: Ingestion: infrequent occurrence of abdominal pain, diarrhea, dizziness, insomnia, rash and headache
  Exposure through inhalation: may cause irritation.
  Skin Contact: may cause mild irritation.
  Eye contact: may cause mild irritation.
- Environmental hazards: There are no known environmental hazards
- Specific effects: Not known

SECTION 3
COMPOSITION/INFORMATION ON INGREDIENTS

Description

Name of the component	Pyrantel pamoate
Concentration	>=99%
Structural formula	
Chemical formula	$C_{11}H_{14}N_2S.C_{23}H_{16}O_6$
Molecular weight	594.7 g/mol
Substance with Community OEL	---
CAS name	---
CAS number	22204-24-6
IUPAC name	4-[(3-carboxy-2-hydroxynaphthalen-1-yl)methyl]-3 hydroxynaphthalene-2-carboxylic acid ; 1-methyl-2-[(E)-2-thiophen-2-ylethenyl]-5,6-dihydro-4H-pyrimidine
EC number	244-837-1
Index number	---
Additive/ies (if classified)	No additives.

SECTION 4
FIRST AID MEASURES

4.1 Description of the first aid measures

- *Eye contact*: Wash thoroughly with water or saline. Keep the eyelids open during flushing. Consult your doctor and show the label.

- *Skin contact*	Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical advice and show the label to the doctor.
- *Ingestion*	If swallowed, rinse mouth thoroughly with water if the person is conscious.
- *Inhalation*	Avoid breathing aerosols and dusts that may be generated from handling the product. Move the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms will appear or if the exposure was significantly long or intense.

4.2 Most important symptoms and effects (acute and delayed)

- *Acute effects*	Ingestion: infrequent occurrence of abdominal pain, diarrhea, dizziness, insomnia, rash and headache Exposure through inhalation: may cause irritation. Skin Contact: may cause mild irritation. Eye contact: may cause mild irritation
- *Delayed effects:*	Not known

4.3 Indication of any immediate medical attention and special treatment needed

- *Medical monitoring:*	Please refer to chemical risk assessment
- *Antidotes, if known*	There are no known antidotes.
- *Contraindications*	There are no known contraindications.
- *Immediate treatment at workplace*	Not known

SECTION 5
FIREFIGHTING MEASURES

5.1 Extinguishing media

- *Suitable estinguishing media*	Water spray or regular foam, CO_2, dry powder
- *Unsuitable estinguishing media*	None

5.2 Special hazards arising from the substance

- *Hazardous combustion products*	May produce toxic fumes of COx, NOx, SOx.
- *Other special hazards*	None

5.3 Advice fo firefighters

- *Technical actions for protection*	Do not attempt to extinguish the fire without the use of a self-contained breathing apparatus (SCBA) and appropriate protective clothing.
- *Special protective equipment for firefighters*	Wear boots, gloves, eye and face protection, respirators. comply with relevant standards UNI for Italy and EN for Europe. Use the recommended devices in the best conditions of care based on information reported in the previous subsection.

SECTION 6
ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel

- *Eye*	Wear appropriate protective equipment (see Section 8)
- *Skin*	Wear full body protection clothing.

- *Inhalation* In case of fire and explosion avoid breathing fumes and vapors. Use a self-contained breathing apparatus (SCBA) and appropriate protective clothing. The fumes can be eliminated by spraying with water.

See also section 8

In case of accidental spilling (non in normal condition of use) the use of Personal Protection Equipment is always recommended. This PPE must be in accordance with EN criteria.

- **For emergency responders: see section 8**
- *Eye* Use special protective equipment
- *Skin* Use special protective equipment
- *Inhalation* Use special protective equipment

6.2 Environmental precautions

In case of accidental release in the environment avoid that the substance can reach drains, surface water and ground water.

6.3 Methods and material for containment and clearing up

- *Containment procedures:* Limit leakages with earth or sand
- *Cleaning up procedures:* Collect the product and send it to the incinerator.
  If necessary absorb it with inert material.
  After collection, rinse area and materials involved with water.

6.4 Reference to other sections

See also section 8 and 13

SECTION 7
HANDLING AND STORAGE

7.1. Precautions for safe handling

- *Recommandation for handling:* Handle away from sparkles and flames - sources of ignition
  As with all dry powders it is advisable to perform the grounding of the equipment in contact with them in order to dissipate the static electricity potential. No smoking. The substance may emit toxic fumes in case of fire.
  Handle in a well ventilated place
  Avoid contact with incompatible materials
  Wear suitable Personal Protection Equipment (see section 8)
  Keep the substance away from drains, surface or ground waters
- *Recommandation for personal hygiene:* Do note eat, drink and smoke in the working areas
  Wash hands after handling the substance
  Remove contaminated clothing and protective equipment before entering eating areas

7.2. Condition for safe storage including any incompatibilities

The risk management procedures described in this section are consistent with the physical and chemical properties reported in section 9.
The substance is not classified for any physical and chemical properties and no risk management is foreseen.

Risk Management measures related to :
- *Explosive atmosphere:* Organic powder, can cause explosive mixtures when finely dispersed in air in presence of an ignition source. Avoid the formation of clouds and deposits (layer accumulations) with any suitable device.

Procedure to control other effects
- *Weather conditions:* Do not expose to direct sunlight.
- *Ambient pressure:* Not applicable
- *Humidity* Protect from moisture.
- *Vibration:* Not applicable.

The adoption of the Risk Management procedure related to the physical and chemical properties is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

Material to keep the integrity of the substance
- *Stabilisers/antioxidants:* Not used

Other advice
- *Ventilation requirements* Provide adequate ventilation
- *Specific design of storage rooms* Not requested on the basis of the classification
- *Packaging compatibilities* See also 10.5

7.3. Specific end use(s)

- Recommendation for specific final use(s)

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X
- Industry or sector specific guidance available and attached		X

SECTION 8
EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

- National/European Occupational Exposure Limits: Not present in the data bases consulted.
- Other National/European Occupational Exposure Limits: Not present in the data bases consulted.
- National/European Biological Limits (BEI): Not present in the data bases consulted.
- Other National/European Biological Limits (BEI): Not present in the data bases consulted.
- Recommended monitoring procedures: The measurements of the substance/s) in the workplace must be carried out in accordance with standardized methods described by EN guidances.

- DNEL values (components): Not present in the data bases consulted.
- PNEC values (components): Not present in the data bases consulted.

8.2. Exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

8.2.1. Appropriate engineering controls

The adoption of the most appropriate engineering controls is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

The adoption of the most appropriate Personal Protective Equipment is also based on the local Risk Assessment done by the employer in its workplace conditions (use of the substance), particularly when a standardized exposure scenario is not available.
If the results of such risk evaluation done in accordance with Directive 98/24/EEC showed that the collective and general risk management measures are not sufficient to reduce the risks and, if the exposure to the substance cannot be reduce by other containment means, appropriate PPE must be adopted in compliance with technical EN guidance indication.

a) Eye and Face protection	Safety goggles as for EN 166; facial shield
b) Skin protection	
- *hands protection*	Wear protective gloves for non classified substances. Gloves resistant to chemical agents as for the EN 374, parts 1, 2 e 3 and the European Directive 89/89/CEE for classified substances. The gloves material must be waterproof and stable against the substance content. Select the glove material on the basis of the type of the material, typical or minimal breakdown times, permeability ranges, thickness. Penetration time of glove material: the exact break through time has to be found out by the manufacturer of the protective gloves and must be observed.
- *other, body protection*	Select the suitable protective equipment based on the activity of use and possible exposure. Wear gauntlets, boots, bodysuit and other devices in accordance with EN 14605 in case of sketches or EN 13982 in case of powders
c) Respiratory protection	When the risk evaluation foresees the need to use respirator devices with assisted ventilation, use a powder filter like P1, P2 and P3. Use only devices approved by the Competent Authorities such as NIOSH (USA) and CEN (EU) For your information powders are divide in three categories : **2a (inert powder with TLV= 10 mg/m3),** **2b (hazards powders with TLV = 0,1-10 mg/m3 (excluding asbestos),** **2c (toxic powders with TLV < 0,1 mg/m3 (asbestos, carcinogens, bacteria, viruses, enzymes, spores, etc).** **Cat. 2a: P1 filter, Cat. 2b: P2 filter, Cat.2c: P3 filter**
d) Thermal hazards	Not foreseen in the standard use. Assess possible Personal Protection Equipment on the basis of specific uses of the substance.

8.2.3 Environmental exposure controls

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 9
PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance:	Yellow powder.
Odor:	Odorless.
Melting point/freezing point:	247°C-265°C (decompose)
Lower flammability or explosive limits	25 mg/L
Water solubility:	Insoluble
Organic solvent solubility:	Soluble in dimethylsulfoxide; slighty soluble in dimethylformamide; insoluble in methanol.
Partition coefficient Octonol/water (Log Kow):	LowPow: 2,60 (pred. consensus ACD/PharmaAlgorythm/EPISuite)
Auto-ignition temperature:	550°C
Decomposition temperature:	247°C-265°C

Odour threshold/pH/Initial boiling point and boiling range/Flash point/Evaporation rate/Flammability (solids, gas)/Vapour pressure/ Vapour density/Apparent density/Viscosity/Explosive properties/Oxidising properties: Not present in the data bases consulted

9.2. Other information

Resistivity	$3.70 \cdot 10^{16}$ ohm·cm
Min. ignition energy	5 mJ (L=0 mH) 1,9 mJ (L=1 mH)

SECTION 10
STABILITY AND REACTIVITY

10.1. Reactivity

Under normal operating conditions the substance is not considered reactive

10.2. Chemical stability

The substance is stable at the normal condition of temperature and pressure and if stored in closed containers in well ventilated and cool place.

	NO	YES	Used stabiliser
- Stabilisers:	X		
- Change in physical appearance	X		

10.3. Possibility of hazardous reactions

	NO	YES
- Possibility of an exothermic reaction:	X	
- Possibility of a reaction re leasing excessive pressure	X	
- Possible degradation with instable product formation	X	

10.4. Condition to avoid

Do not expose to heat sources. Please also refer to section 7.2

10.5. Incompatible materials

Avoid contact with strong oxidizing substances and alkali.

10.6. hazardous decomposition products

If heated at high temperatures, decomposes re leasing fumes and toxic gases of COx, NOx, SOx.

SECTION 11
INFORMATION ON TOXICOLOGICAL EFFECTS

- Exposure routes:	YES	NO
- Inhalation:	X	
- Ingestion:	X	
- Skin contact:	X	
- Eye contact:	X	

- Effects (acute, delayed, chronic) following the exposure (short and/or prolonged):

- *Inhalation:* May cause irritation.
- *Ingestion:* Acute oral studies have not shown adverse effects if swallowed
- *Skin contact:* May cause irritation of the skin
- *Eye contact:* May cause burning sensation and irritation of the conjunctiva

- Toxico-kinetics information (ADME = Adsorption, Distribution, Metabolism, Excretion):
Not present in the data bases consulted

- Acute toxicity effects:

- *Oral::* LD50 rat: > 2000 mg/kg [(2)]
  LD50 rat: >24 g/kg
- *Dermal:* Not present in the data bases consulted.

- *Inhalation:* Not present in the data bases consulted.
- *Other effects:* LD50 intraperitoneal rat:535mg/kg [1]

- **Corrosion/Irritation effects:** Not present in the data bases consulted.
- **Severe ocular lesion *:*** Not present in the data bases consulted
- **Sensitisation:**
- *Dermal:* Not present in the data bases consulted.
- *Respisratory:* Not present in the data bases consulted.

- **Repeated dose toxicity (experimental.):** clinical effects from repeated administration studies are not reported. NOAEL not available.

- **CMR effects:**

- Mutagenicity	AMES test: negative [2]
- Germinal cell mutagenicity	It induces increases in sperm-head abnormalities in the murine sperm-head abnormality test
- Carcinogenicity:	Not available studies. Not present in the NTP, IARC and OSHA lists.
- Reproductive toxicity:	Studies in rats and rabbits showed no adverse reproductive effects at dose up to 250 mg/kg/day. A study in mice receiving Pyrantel pamoate indicated an increase in resorptions and stillbirths; dosage information was not available [2] RTECS number: QL2287000

- **Specific Target Organ Toxicity (STOT)-single exposure:**
Not present in the data bases consulted.
- **Specific Target Organ Toxicity (STOT)- repeated exposure :**
Not present in the data bases consulted.
- **Aspiration hazards:**
Not present in the data bases consulted.
- **Epidemiological information:**
Not present in the data bases consulted.
- **Other information**
Not present in the data bases consulted.

- **Reasons for the lack of classification:**
Where the substance resulted non classified, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data, or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in Directives mentioned in this data sheet.

SECTION 12
ECOLOGICAL INFORMATION

12.1. Toxicity

Acute toxicity: EC50 Daphnia Magna: 4,82 (pred. ECOSAR)

12.2. Persistence and degradability

Not present in the data bases consulted.

12.3. Bioaccumulative potential

LowPow: 2,60 (pred. consensus ACD/PharmaAlgorythm/EPISuite)

12.4. Mobility in soil

Not present in the data bases consulted.

12.5. Results of PBT e vPvB assessment

Based on the available information the substance does not satisfy the criteria to be considered a PBT or vPvB.

12.6. Other adverse effects

Not present in the data bases consulted

SECTION 13
DISPOSAL CONSIDERATION

13.1. Waste treatment methods

	Incineration	Recycling	Landfilling
- Substance wastes:	X		
- Contaminated packaging:	X		

Recover if possible. Send to authorized disposal plants or for incineration under controlled conditions. Operate in compliance with local and national regulations.

SECTION 14
TRANSPORT INFORMATION

The product is not subject to transport classification

SECTION 15
REGULATORY INFORMATION

In this section, all other information on regulation are reported if not provided in other sections/subsection of the Safety Data Sheet.

15.1 Safety, Health and Environmental regulation/legislation specific for the substance or its ingredients

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183 , 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements..

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the personal protective equipment

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131 , 05/05/1998 P. 0011 - 0023

15.2. Chemical Safety Assessment

	YES	NO
- Exposure scenario attached		X
- Chemical Safety Assessment (CSA) attached		X

SECTION 16
OTHER INFORMATION

Revisions:

- **Edition n. 01 – November 2010**
- **Revision n. 01 – October 2011**
- **Revision n. 02 – June 2015**
- **Revision n. 03 – March 2019**

Bibliography

-RTECS, (10/99)
-CHEMID PLUS [(1)]

- reference standard USP MSDS [2]

Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- ADR: Agreement concerning the carriage of dangerous goods by Road
- BCF: Bioaccumulative factor
- BEI : Biological Esposure Indices (Indici di esposizione biologica)
- CAS: Chemical Abstract Service (division of the American Chemical Society
- CHETAH : Computer programme for chemical termodynamics and energy release evaluation
- CLP: Classification, Labelling and Packaging
- CMR: Carcinogens, Mutagens, Toxic for re production substances
- EINECS: European Inventory of existing Commercial Substances
- EPA: US Environmental Protection Agency
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association Code
- IMDG: International Maritime Dangerous Goods Code
- IUPAC: International Union of Pure and Applied Chemistry
- LOEL: Lowest Observed Effect Level
- N.A.: Not Applicable
- N.A.: Not Available
- NOAEL: No Observed Adverse Effect Level)
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- PPE : Personal protective Equipment
- PBT: Persistent, Bioaccumulative and Toxic substances
- RID: Regulation concerning the International carriage of Dangerous goods by rail
- TLV/TWA: Threshold Limit Value/Threshold Weighted Average
- vPvB: very Persistent, very Bioaccumulative
- DNEL: Derived No-Effect Level (REACH)
- PNEC: Predicted No-Effect Concentration (REACH)
- LD_{50}: Lethal Dose, 50 percent
- EC_{50}: Half maximal Effective Concentration

Information on workers training

Follow criteria of Directive 98/24/CE, its amendments and National reinforcements

Restriction of use : none

Substance under authorisation : no

DISCLAIMER

This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material. The provider of this document can not provide any warnings about the dangers of ' use or interaction with other chemicals or materials. And 'the user's safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Regulation (EC) 1907/2006 as amended.