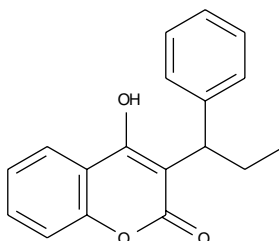


1. Product and Company Identification

Product name	Phenprocoumon	
Product code	04 2171 5	
Company information	Manufacturer: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland	Local representation:
	Phone	+41-61/688 54 80
	Fax	+41-61/681 72 76

2. Composition/Information on ingredients

Characterization	pharmaceutical active substance (coumarin derivative)
Chemical name	<ul style="list-style-type: none"> - 3-(α-Ethylbenzyl)-4-hydroxycoumarine - 3-(1-Phenylpropyl)-4-hydroxycoumarine - 4-Hydroxy-3-(1-phenylpropyl)-2H-1-benzopyrane-2-one
Synonyms	<ul style="list-style-type: none"> - MARCOUMAR substance - Liquamar - Marcumar
CAS number	435-97-2
EINECS number	207 108 9
UN number	2811
Roche number	Ro 01-4849/003
Empirical formula	C ₁₈ H ₁₆ O ₃
Molecular mass	280.32 g/mol



Phenprocoumon

3. Hazards identification

Most important hazards - Toxic by inhalation, in contact with skin and if swallowed.

4. First-aid measures

- Eye contact
- rinse immediately with tap water for 10 minutes - open eyelids forcibly
 - consult physician
- Skin contact
- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
 - consult physician
- Inhalation
- remove the casualty to fresh air and keep him/her calm
 - get medical treatment
- Note to physician
- in cases of acute poisoning, primarily irritations of mucous membranes and skin; symptomatic treatment
 - only after a delay of several hours, at low doses even only after 1 - 2 days, disturbance of coagulation through blocking of the production of vitamin-K-dependent coagulation factors: decrease of the quick-value (time of prothrombin)
 - in case of suspected intake use as prophylaxis 10 - 20 mg Konakion i.v., if necessary repeated once a day for the following days; surveillance of the coagulation by determination of the time of prothrombin (quick) immediate (starting value), then during 2 - 3 days 3 times per day, finally in longer intervals (up to 1 week, if a decrease has been observed)
 - if disturbances of coagulation did occur, there have to be transfused coagulation-factors

5. Fire-fighting measures

- Suitable extinguishing media - water spray jet, dry powder, foam, carbon dioxide
- Specific hazards
- consider dust explosion hazard
 - substance is hazardous for water: contain fire-fighting wastewater
- Protection of fire-fighters - precipitate gases/vapours/mists with water spray

6. Accidental release measures

- Environmental protection - do not allow to enter drains or waterways
- Methods for cleaning up - collect solids (avoid dust formation) and hand over to waste removal

Phenprocoumon

7. Handling and storage

Handling

Technical measures

- local exhaust ventilation necessary
- take precautionary measures against electrostatic charging
- avoid dust formation; very high dust explosion hazard
- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

Suitable materials

- aluminium, glass, plastic

Storage

Validity

- 48 months, at room temperature

Packaging materials

- tightly closing; material: aluminium, glass, plastic, metals

8. Exposure controls/Personal protection

Engineering Measures

- see 7.

Monitoring

Threshold value (Roche) air

- IOEL: 10 µg/m³

Analytcs

- sampling on glass fibre filter and gravimetric or chemical determination

Personal protective equipment

Respiratory protection

- in case of open handling or accidental release:
particle mask or respirator with independent air supply

Hand protection

- protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection

- safety glasses

Body protection

- protective clothing

General protective and hygiene measures

- instruction of employees mandatory
- employees on medical treatment with coumarin derivatives may not carry out any operations with a risk of exposure

Phenprocoumon

9. Physical and chemical properties

Colour	practically white
Form	solid substance
Odour	almost odourless
Solubility	~ 36'300 mg/l, ethanol 96 % (20 °C) < 100 mg/l, water (20 °C) < 100 mg/l, hexane (20 °C) ~ 4'300 mg/l, diethyl ether (20 °C) ~ 28'300 mg/l, methanol (20 °C)
Partition coefficient	log P _{ow} 3.62 (octanol/water)
Dissociation constant	pK ₁ = 4.1
Melting temperature	178 to 181 °C

10. Stability and reactivity

Note	- no instabilities and dangerous reactions known
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11. Toxicological information

Acute toxicity	- LD ₅₀ 190 mg/kg (oral, mouse) - LD ₅₀ 200 mg/kg (oral, rat) - LD ₅₀ 32 mg/kg (i.v., mouse)
Subchronic toxicity	- anticoagulant: decreased coagulation of blood, affection to bleeding - substance cumulates because of the long half-life of elimination
Reproduction toxicity	- in cases of absolute indication, Phenprocoumon is applied also during pregnancy. In cases of longer during therapies during early pregnancies there were seen rarely individual cases of disturbances of bone-growth in the fetus
Note	- dosage: day 1: 15 mg, day 2: 9 mg, day 3: 3 mg, afterwards depending of the time of prothrombin, in average 0.75 - 0.45 mg/day - the effect sets in after 1 - 2 days. After reaching an anticoagulation, few amounts of phenprocoumon will be sufficient for a large intensification of the affection of bleeding. - Phenprocoumon is mostly completely metabolized in the liver - side-effects: internal and external bleedings, gastro-intestinal disturbances, necrosis of the skin - elimination half-life: 160 hours

12. Ecological information

Ready biodegradability	- not readily biodegradable < 10 %, 28 days (CO ₂ Evolution Test, Modified Sturm Test, OECD No. 301B)
Air pollution	- observe local/national regulations

Phenprocoumon

13. Disposal considerations

Waste from residues

- incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal

14. Transport information

IATA	Class	UN/ID	PG		PI	Label	
	6.1	2811	III		619/619	6.1	
IMDG	Class	UN	PG	EmS	PI	Label	Mark
	6.1	2811	III	F-A S-A	P002/IBC08	6.1	
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Classif.code
	6.1	2811	III	60	P002/IBC08	6.1	T2

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.
(Phenprocoumon)

15. Regulatory information

Classification and labelling according to EU directives



T

R23/24/25

S45

S36/37/39

Toxic by inhalation, in contact with skin and if swallowed.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Wear suitable protective clothing, gloves and eye/face protection.

Emission limit (Switzerland)

20 mg/m³ at mass-flux ≥ 0.1 kg/h (organic, class 1)

Water hazard class (Germany)

3: strongly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

Phenprocoumon

16. Other information

- | | |
|-----------------------|--|
| Use | - pharmaceutical active substance (anticoagulant) |
| Safety-lab number | - BS-4192 |
| Edition documentation | - changes from previous version in sections 4, 8, 14 |

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.