1. Identification of the substance/mixture and of the company/undertaking

Designation: Persantin®, liquid (Bulk), <= 5%

Synonyms:
Active ingredient: Dipyridamole
Persantin® ampoules, Persantin® solution for injection

Identified uses:
Solution for production of finished medicinal products.

Company:
Boehringer Ing. Pharma GmbH & Co.KG
Binger Str. 173
55216 Ingelheim am Rhein

Telephone: +49800/7790900
Telefax number: +496132/729999
E-mail address: gefahr@boehringer-ingelheim.com

Information providing division:
Quality & Environmental Health & Safety

Emergency information:
(+49) (0)61 32 / 77 23 22 (24 h)

2. Hazards Identification

Classification according to Regulation (EC) No. 1272/2008:
This product is a non-hazardous solution of single components and need not be labelled according to EC-Directive 1999/45/EC, as amended.

3. Composition/Information on Ingredients

Hazardous ingredients

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Bis-(diethanolamino)-4,8-dipiperidino-pyrimido-(5,4-d)-pyrimidine</td>
<td></td>
<td>&lt;= 5%</td>
<td></td>
</tr>
<tr>
<td>Molecular formula: C24-H40-N8-O4</td>
<td>CAS-No.: 58-32-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight: 504.64</td>
<td>EC-No.: 200-374-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Classification</th>
<th>GHS classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-hazardous galenic excipients</td>
<td></td>
<td></td>
<td>&gt;= 95%</td>
</tr>
</tbody>
</table>
4. First-aid Measures

General advice : Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety.

Eye contact : Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.

Skin contact : Wash off immediately with plenty of water. Cover wound with sterile dressing. Call a physician immediately.

Inhalation : Move to fresh air. Call a physician immediately.

Ingestion : Rinse mouth. Drink plenty of water. Call a physician immediately.

Notes to physician
Treatment : Observe the summary of product characteristics of proprietary medicinal products

5. Fire-fighting Measures

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water, Dry chemical, Foam, Carbon dioxide (CO2)

Hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes. Can be released in case of fire. Carbon oxides, nitrogen oxides (NOx)

Protective equipment for fire-fighting : Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

6. Accidental Release Measures

Personal precautions : Ensure adequate ventilation. Wear personal protective equipment. Refer to protective measures listed in sections 7 and 8. Keep people away from and upwind of spill/leak.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods for cleaning-up or taking-up : For large amounts: Pump off product. For residues: Contain with absorbent material (e.g. sand, silica gel, acid binder, general purpose binder, sawdust). Pack in tightly closed containers for disposal.

Additional information : High risk of slipping due to leakage/spillage of product.

7. Handling and Storage

Handling
Advice on safe handling: Provide sufficient air exchange and/or exhaust in work rooms. Breathing must be protected when large quantities are decanted without local exhaust ventilation. Keep container closed when not in use.

Hints for protection against fire and explosion: No hazards which require special first aid measures.

Hygienic measures: General industrial hygiene practice. Wash hands and face before breaks and immediately after handling the product. Keep working clothes separately.

Storage

Requirements for storage rooms and vessels: Protect from heat and direct sunlight. Keep containers tightly closed in a cool, well-ventilated place. Jointless smooth floor.

Advice on storage compatibility: Keep away from food, drink and animal feedingstuffs. Advice on Segregation

Storage class according to VCI: 12 Non Combustible Liquids

8. Exposure controls/personal protections

Exposure controls: Local exhaust Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection: Not required; except in case of aerosol formation.
Hand protection: Chemical safety glove category III (EN 374). Glove material: Nitrile rubber, Layer thickness: 0.43 mm (f.e. Camatril® green, Article No.732, Company KCL). Resistance (permeability): Level 6 (480 min).
Eye protection: Safety glasses with side-shields conforming to EN166
Body protection: Laboratory: laboratory coat; factory: disposable Overall.
Additional information: Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

General protective measures: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not breathe vapour. Do not breathe spray.

9. Physical and Chemical Properties

Form: Aqueous solution
Colour: No data available.
Odour: No data available.
Odour threshold: No data available.
pH value: No data available.
Melting point/-range : No data available.
Boiling point/boiling range : No data available.
Flash point : not applicable
Ignition temperature : not applicable
Evaporation rate : No data available.
Flammability : does not ignite
Lower explosion limit : not applicable
Upper explosion limit : not applicable
Vapour pressure : No data available.
Relative vapour density : No data available.
Relative density : No data available.
Solubility in water : No data available.
Miscibility with water : miscible in all proportions
Partitioning coefficient n-octanol/water (log Pow) : No data available.
Thermal decomposition : No data available.
Viscosity, dynamic : No data available.
Explosiveness : No data available.
Peroxides : No data available.

Further information
Density : No data available.

10. Stability and Reactivity
Hazardous reactions : No data available.
Conditions to avoid : No data available.
Substances to avoid : No data available.
Hazardous decomposition products : No data available.

11. Toxicological Information
Acute oral toxicity : LD50 > 12,000 mg/kg rat
The values mentioned are those of the active ingredient.
Acute inhalation toxicity : No data available.
Acute dermal toxicity: No data available.
Skin irritation: No data available.
Eye irritation: No data available.
Sensitization: No data available.
Genetic toxicity in vitro: Ames-test
  Result: negative
  The values mentioned are those of the active ingredient.
Genetic toxicity in vivo: Micronucleus assay
  mouse
  Result: negative
  The values mentioned are those of the active ingredient.
  Cytogenetic assay
  Chinese hamster
  Result: negative
  The values mentioned are those of the active ingredient.
Carcinogenicity: Dose: 75 mg/kg/day (rat)
  Exposition time: 142 weeks
  The values mentioned are those of the active ingredient.
Reproductive toxicity: Study for Effects on Embryo-Fetal Development
  rabbit
  NOAEL Parents: 125 mg/kg
  The values mentioned are those of the active ingredient.
  rat
  NOAEL Parents: 1.250 mg/kg
  The values mentioned are those of the active ingredient.
  Pre- and Postnatal development study
  rat
  NOAEL Parents: 100 mg/kg
  The values mentioned are those of the active ingredient.
Teratogenicity: No data available.
Aspiration hazard: No data available.
Assessment of carcinogenicity: Did not show carcinogenic effects in animal experiments.

12. Ecological information

Ecotoxicity
Toxicity to fish: LC50 > 3,15 mg/l (Brachydanio rerio) Exposition time: 96 h
  Method: Fish, Acute Toxicity Test
  The statement of the toxic effect relates to the analytically
determined concentration, No toxicity up to solubility limit.
  The values mentioned are those of the active ingredient.
Toxicity to daphnia: EC50 > 10 mg/l (Daphnia magna) Exposition time: 48 h Method: OECD Test Guideline 202
The statement of the toxic effect relates to the analytically determined concentration. No toxicity up to solubility limit. The values mentioned are those of the active ingredient.

Toxicity to algae: EC50 > 2.36 mg/l (Desmodesmus subspicatus (green algae)) Exposition time: 72 h Method: Algae, Growth Inhibition Test
The statement of the toxic effect relates to the analytically determined concentration. No toxicity up to solubility limit. The values mentioned are those of the active ingredient.

Toxicity to bacteria: NOEC = 1.000 mg/l (activated sludge, industrial) Method: OECD 209
The values mentioned are those of the active ingredient.

Chronic toxicity to fish: No data available.
Chronic toxicity to aquatic invertebrates: No data available.

**Persistence and degradability**

Biological degradation: Not easily biodegradable (by OECD criteria). 2 - 3 % Exposition time: 28 d Method: OECD 301 F Guideline
The values mentioned are those of the active ingredient.

Transport between environmental compartments: log KOC: 3.91

Bioaccumulation: Accumulation in organisms is not to be expected. The values mentioned are those of the active ingredient.

PBT and vPvB assessment: No data available.

### 13. Disposal Considerations

Product: Dispose of in accordance with local regulations.
Contaminated packaging: Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.
Further information: Not classified as dangerous for conveyance in the meaning of the regulations for the transport of dangerous goods by road and rail. Not classified as dangerous in the meaning of sea and air transport regulations.

15. Regulatory information

National legislation/regulations

Water hazard class: VVWWS
  WGK 1 slightly water endangering
  Annex 4 VVWWS (Germany) dated Mai, 17th 1999

16. Other particulars

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.