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SALICYLIC ACID Pharmaceutical Grade

STRUCTURAL FORMULA:

Ph.D. Eur., USP grade CRYSTALLINE POWDER Roussillon, FRANCE [1/4]

PRODUCT DATA SHEET RON-SA-PHA-EPUSP-1606- V4

IDENTIFICATION:

CAS: 69-72-7

EINECS: 200-712-3

SYNONYMS:

2-hydroxybenzoic acid orthohydroxybenzoic acid

EMPIRICAL FORMULA:

MOLECULAR WEIGHT:

C7H6O3 MR = 138.12

Emergency telephone number: +420224919293, +420224915402 (phone 24h/daily) Toxicological information center, Na Bojišti 1, 128 08 Prague 2)

PHYSICO-CHEMICAL PROPERTIES: A

white, crystalline powder or white or colorless, acicular crystals. Not hygroscopic.

Sublimation point from 76°C

Solubility at 20°C

Ethanol Freely soluble
Chloroform, methylene chloride Sparingly soluble
Benzene, water Slightly soluble

APPLICATIONS:

- Pharmaceutical applications: salicylic acid is a keratolytic agent (mostly used in creams, ointments and shampoos).
- Chemical synthesis: starting material for the synthesis of active pharmaceutical ingredients, antiseptic agents, fragrance chemicals, etc
- Food industry (preservative)
- Personal care applications: cosmetics



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SPECIFICATIONS:

| Tests: | Limit: | Methods: |
|--|---------------------|----------------------------------|
| Identification - infrared absorption | Complies | Ph.D. Eur. / USP |
| Identification - retention time of major peak Complies | | USP |
| Identification - melting point | 158 - 161 °C | Ph.D. Eur. |
| Appearance of the solution S | Clear and colorless | Ph.D. Eur. |
| Assay HPLC (dry basis) | 98.0-102.0% | USP |
| Assay titration (dry basis) | 99.0-100.5% | Ph.D. Eur. |
| Loss on drying | 0.5% maximum | Karl Fischer(1) |
| Chloride | 0.0100% maximum | Ph.D. Eur.(1) |
| Sulphates | 0.0200% maximum | USP34(1) |
| Heavy Metals | 0.0020% maximum | Ph.D. Eur. |
| Sulfated ash / Residue on Ignition | 0.05% maximum | Ph.D. Eur. / USP (harmonized) |
| Related Substances | | |
| 4-Hydroxybenzoic acid (Compound A) | 0.1 % maximum | Ph.D. Eur. (HPLC) (1) |
| 4-Hydroxyisophthalic acid (Compound B) | 0.05% maximum | |
| Phenol | 0.01% maximum | |
| Other Impurities > 0.05% | none | |
| Total impurities | 0.2 % maximum | |

Notes: (1) validated against USP method



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Regulators:

EU: Certificate of Suitability ref. CEP 1993-008, current version Salicylic

GMO status: acid is GMO free BSE/TSE

status: Salicylic acid is free of BSE / TSE Residual solvents:

Only water is used in the final purification stages Residual catalysts: No catalysts

are utilized in the manufacturing process of salicylic acid

FEMA N°: 3985

INCI Name: Salicylic acid

REACH: Registration # 01-2119486984-17-0000

Regulatory support is provided to assist our customers in their registration process.

Packaging:

- White paper bags (polyethylene inner liner) of 25 kg net weight, printing in green on a 1140 x 1140 mm pallet (CP-9) or 800 x 1200 mm pallet (Euro) shrink-wrapped
- Flexible containers, from 500 to 1000 kg on a 1140 x 1140 mm pallet (CP-9)

Transport:

INLAND

International Legislation (RID-ADR)

- SEA FREIGHT (OMI)
- AIR FREIGHT (IATA)

Not regulated

Storage Conditions:

The product is stable under ICH accelerated conditions. Therefore, controlled conditions are not required for storage of salicylic acid.

Re-test date: 5 years



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PRODUCT DATA SHEET RON-SA-PHA-EPUSP-1606- V4

Safety Instructions:

Please consult our material safety data sheet

DISCLAIMER:

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