

SAFETY DATA SHEET

Section 1: Identification

Product identifier used on the label;

Product name: Salonpas®

Other means of identification;

No information

Recommended use of the chemical and restrictions on use;

Recommended use: Anti-inflammatory and analgesic drug for external use

Restrictions on use: No information

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party;

Name: Hisamitsu Pharmaceutical Co., Inc.
Department in Charge: Quality assurance department
Address: 408, Tashirodaikan-machi, Tosu, Saga, Japan
Telephone number: +81-942-81-1555
Fax number: +81-942-81-1528
e-mail address:

Emergency phone number

+81-942-81-1555

Section 2: Hazard(s) identification

Classification of the chemical in accordance with paragraph (d) of §1910.1200;

No applicable GHs classification data. This product is an over-the-counter drug packaged by the pharmaceutical manufacturer for sale, which is not subject to this regulation.

Physical Hazards

Not classified

Health Hazards

Serious eye damage/eye irritation: Category 2
Specific target organ toxicity single exposure: Category 1 (Central nervous system)
Specific target organ toxicity repeated or prolonged exposure: Category 1 (Nervous system, liver)

Environmental Hazards

Not classified

Other Hazards

No information

Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200;

Symbol(s)



Signal word

Danger

Hazard Statement(s)

Causes serious eye irritation
Causes damage to central nervous system
Causes damage to nervous system, liver through prolonged or repeated exposure

Precautionary Statement(s)

[Prevention]

Do not breathe dust/fume/gas/mist/ vapors/spray.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves/protective clothing/eye protection/face protection.

[Emergency response]

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If exposed or concerned: Call a poison center/doctor.
Get medical advice/attention if you feel unwell.
If eye irritation persists: Get medical advice/attention.

[Storage]

Store locked up.

[Disposal]

Dispose of contents/container in accordance with local/regional/national/international regulations.

Description of any hazards not otherwise classified;

No information

Ingredient with unknown acute toxicity in the mixture

Not applicable

Section 3: Composition/information on ingredients

Note) This product is an over-the-counter drug packaged by the pharmaceutical manufacturer for sale, which is not subject to § 1910.1200 "Hazard communication". For your information, please refer to § 1910.1200 (6) (vii) which says this section does NOT apply to drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs). The exact contents of the inactive ingredients of this product are trade secret, and the following information is described based on the results from the U.S. FDA's website, "Inactive Ingredient Search for Approved Drug Products" (<https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>).

Compositions (contents of the product)

Chemical name	CAS No.	Concentration/concentration ranges (wt %)
Camphor	76-22-2	3.1
Menthol	2216-51-5	6
Methyl salicylate	119-36-8	10
Titanium oxide	13463-67-7	a*

a: trade secret: listed on the U.S. Inactive Ingredient Database (IID) and NMT the Maximum Potency per Unit Dose (MPUD)

Section 4: First-aid measures

Necessary first-aid measures by relevant routes of exposure;

IF INHALED	If you feel unwell, get medical advice/ attention immediately and at rest. If symptoms continue, call a doctor/physician.
IF ON SKIN	Rinse with plenty of water. If symptoms continue, call a doctor/physician.
IF IN EYES	Immediately rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms continue, call a doctor/physician.
IF SWALLOWED	Rinse mouth. Immediately get medical advice/attention.

Most important symptoms/effects, acute and delayed;

- Causes serious eye irritation
- Causes damage to central nervous system
- Causes damage to nervous system, liver through prolonged or repeated exposure

Indication of immediate medical attention and special treatment needed, if necessary;

No information

Section 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media;

Suitable extinguishing media:

Use water mist, dry chemical powder, fire foam or carbon dioxide.

Unsuitable extinguishing media

Applying direct water may be dangerous because fire may expand to surroundings.

Specific hazards arising from the chemical;

In case of fire, toxic decomposition products may be generated.

Special protective equipment and precautions for fire-fighters;

- Cut off any ignition sources and extinguish with an appropriate agent.
- Cool the surrounding tank and the buildings with direct water jet to avoid risk of fire spreading.
- Take action from windward.
- Keep out except responsible personnel.
- Move container to a safe area if it can be done without risk.

Section 6: Accidental release measures

Personal precautions, protective equipment, and emergency procedures;

- Keep out except responsible personnel.
- Wear suitable protective equipment described in Section 8: Exposure controls/personal protection.
- Avoid release into the environment because product may cause local effects.

Methods and materials for containment and cleaning up;

- Stop leak if you can do it without risk.
 - In case of small amounts, wipe off spilled material with waste or wiping cloth and collect it in an adequate waste container.
 - If case of large amounts, prevent leakage and enclose by embankment.
 - Do not eat or drink near handling and storage locations.
 - ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area).
 - Prevent to flowing into drains, sewers, basements or closed areas.
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Section 7: Handling and storage

Precautions for safe handling

Protective measures:

- Install appropriate equipment and wear suitable protective apparatus described in Section 8: Exposure controls/personal protection.
- Wash hands thoroughly after handling.
- Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- Ground/bond container and receiving equipment.
- Use explosion-proof electrical/ventilating/lighting equipment.
- Use only non-sparking tools.
- Take precautionary measures against static discharge.
- Do not eat, drink or smoke when using this product.
- Wash contaminated clothing before reuse.

Advice on general occupational hygiene:

- Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures:

- In the storage area, install adequate light and ventilation systems to handle hazardous materials.
- Take precautionary measures against static discharge.

Incompatible materials:

- Oxidizing agents, reducing agents

Conditions for safe storage:

- Avoid sunlight. Store in a cool place.
- Avoid high-temperature materials.

Packing material:

Use a sealed container without damage or leakage.

Section 8: Exposure controls/personal protection

Occupational Exposure Limits;

OSHA PEL	15 mg/m ³ (Titanium dioxide) (Total dust)
ACGIH TLV-TWA (2014)	2 ppm (Camphor, synthetic)
	10 mg/m ³ (Titanium dioxide)
ACGIH TLV-STEL (2014)	3 ppm (Camphor, synthetic)

Appropriate engineering controls;

Shower and eye washer should be available in the work area.

Under high temperature or in case of mist generation, use ventilation.

Individual protection measures, such as personal protective equipment;

Respiratory protection	Wear appropriate protective mask or air aspirator as required.
Hand protection	If hand contact is possible, wear protective gloves.
Eye protection	Wear safety glasses or goggles if in eyes.
Skin and body protection	Wear protective clothing and apron if necessary.

Section 9: Physical and chemical properties

Appearance (physical state, color, etc.)	Gel-like white-brownish white sheet
Odor	Menthol odor
Odor threshold	No information
pH	No information
Melting point/freezing point	No information
Initial boiling point and boiling range	No information
Flash point	No information
Evaporation rate	No information
Flammability (solid, gas)	No information
Upper/lower flammability or explosive limits	No information
Vapor pressure	No information
Vapor density	No information
Relative density	No information
Solubility (ies)	No information
Partition coefficient: <i>n</i> -octanol/water	No information
Auto-ignition temperature	No information
Decomposition temperature	No information
Viscosity	No information

Other information

No information

Section 10: Stability and reactivity

Reactivity

Stable under normal handling condition.

Chemical stability

Stable under normal handling condition.

Possibility of hazardous reactions

No hazardous reaction expected under normal handling.

Conditions to avoid

Avoid sunlight. Store in a cool place.

Incompatible materials

Oxidizing agents, reducing agents

Hazardous decomposition products

In case of fire, toxic decomposition products may be generated.

Section 11: Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics;

Information on product:

No information

Information on ingredients:

Camphor

Acute toxicity (oral):

Mouse LD₅₀ = 1,310 mg/kg

Acute toxicity (inhalation: vapors):

Rat LC₅₀ = 0.5 mg/L

Serious eye damage/irritation:

There is a report that camphor may be somewhat irritating to the eyes, but no serious injuries have been reported, the substance is classified as "Eye irr" by ACGIH-TLV.

Specific target organ toxicity single exposure:

There are numerous reports of cases describing serious symptoms which resulted in death or hospitalization after camphor ingestion. Characteristic symptoms include nausea, convulsions, coma, seizures or grand-mal seizures, status epilepticus, and visual disturbances. In some cases, restlessness, confusion or delirium can occur. Since the substance is reported to induce CNS stimulation and excitation of the cerebrum, these symptoms are considered to be results from the CNS stimulation.

Specific target organ toxicity repeated exposure:

An illness resembling Reye's syndrome with coma and hepatomegaly was reported in a child who had been chronically administered the substance. In a woman who regularly ingested the substance, hepatomegaly was found,

with granulomas, necrosis and eosinophils apparent on biopsy. In addition, headache, dyspnea, coma were reported as symptoms caused by occupational exposure. Based on the report of resembling Reye's syndrome and coma, and the findings of hepatomegaly, granulomas, necrosis and eosinophils on biopsy.

Menthol

Acute toxicity (oral):	Rat LD ₅₀ = 2,426 mg/kg
Skin corrosion/irritation:	In the rabbit skin test (corresponding to OECD TG 404) using undiluted solution, the average score of erythema and edema was 3.0 and 2.9 respectively, with recovery observed by 14 days.
Serious eye damage/irritation:	The undiluted menthol liquid showed mild eye irritation (type of isomer unknown).
Specific target organ toxicity single exposure:	Narcotic effect was seen in the oral administration of rat (1,000-4,000 mg / kg).

Titanium oxide

Acute toxicity (oral):	Rat LD ₅₀ > 20,000 mg/kg
Acute toxicity (dermal):	Rabbit approxLD ₅₀ >10,000 mg/kg
Acute toxicity (inhalation: dust/mist):	Rat LC > 6.82 mg/L/4h
Serious eye damage/irritation:	Report on a result of "mild irritation" in a rabbit test.
Carcinogenicity:	Since IARC classified the substance into "Group 2B" based on the data for ultrafine grades of titanium dioxide (particle size of 10-50 nm). In 103-week feeding tests in rats and mice, it was concluded that the substance was not carcinogenic for both species. Chronic inhalation of ultrafine grades of titanium dioxide produced an increased incidence of lung tumors in rats but not in mice. In contrast, the available case reports and epidemiological tests do not show clear evidence for this relationship with the substance.

Delayed and immediate effects and also chronic effects from short- and long-term exposure;

- Causes serious eye irritation
- Causes damage to central nervous system
- Causes damage to nervous system, liver through prolonged or repeated exposure

Numerical measures of toxicity (such as acute toxicity estimates);

Not applicable

Whether the chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, or by OSHA;

IARC: Group 2B (Titanium dioxide based on the data for ultrafine grades)

NTP Report: Not listed

OSHA: Not listed

Section 12: Ecological information

Ecotoxicity:

Information on product: No information

Information on ingredients:

Camphor

Aquatic acute toxicity: Fish (Zebrafish) 96h-LC₅₀ = 35 mg/L

Aquatic chronic toxicity: No information

Menthol

Aquatic acute toxicity: Fish (Zebrafish) 96h-LC₅₀ = 15.6 mg/L

Algae (*Pseudokirchneriella subcapitata*) 96h-NOEC = 9.65 mg/L

Aquatic chronic toxicity: No information

Persistence and degradability:

Information on product: No information

Information on ingredients:

Camphor

Biodegradability by BOD = 94%

Menthol

Biodegradability by BOD = 79-92%

Bioaccumulative potential:

Information on product: No information

Information on ingredients: No information

Mobility in soil:

Information on product: No information

Information on ingredients: No information

Other adverse effects:

No information

Section 13: Disposal considerations

Waste treatment methods

Dispose of waste in accordance with applicable local, regional and international regulations and standards.

When disposing, consult to a certificated waste trader or local offices if they deal with the waste.

Used container should be recycled after cleaning or dispose of in compliance with related laws and local regulations.

Contents should be removed completely when dispose of empty containers.

Section 14: Transport information

UN number	Not applicable
UN proper shipping name	Not applicabl
Transport hazard class(es)	Not applicable
Packing group	Not applicable
Environmental hazards	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and IBC code	Not applicable

Special precautions for user

When transporting, avoid direct sunlight. Confirm no leakage to containers. When loading, prevent containers from falling, dropping off or damaging. Take preventive measures of collapse.

Section 15: Regulatory information

OSHA:	Hazardous chemical
TSCA inventory:	All ingredients in this product are listed on the TSCA Inventory.
TSCA SNUR:	Not listed
SARA Title III:	Section 302 (Extremely Hazardous Substances): Not listed Section 304 (Hazardous Substances): Not listed Section 313 (TRI Chemicals): Not listed
Clean Air Act:	This product does not contain any substances regulated as hazardous air pollutants under Section 112 of the Clean Air Act.
Clean Water Act:	This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act.

Section 16: Other information, including date of preparation or last revision

Update history:

Date of issue: Xth May, 2015

References:

Information of Hisamitsu Pharmaceutical Co., Inc.
NITE GHS classification results (2015).
ACGIH, American Conference of Governmental Industrial Hygienists (2014) TLVs and BEIs.

[Disclaimer]

This SDS has been prepared based on the best available information however, it may not be sufficient in some cases. It is user's responsibility to modify or update any contents in this SDS regarding information on hazardous properties and/or instruction for safe handling of the product when they become available. Precautionary measures in this SDS are only applicable for normal handling conditions and it is necessary to take appropriate additional measures to ensure safe handling which depend on your specific use conditions or situations.