



TECHNICAL DATA SHEET

1285-TDS-ENG-2023

METILO SALICILATO Ph. Eur.		
DESCRIPTION DCI: METHYL SALICYLATE		DESCRIPTION DOE: SALICILATO METILO
CAS N°: 119-36-8	EC N°: 204-317-7	AEMPS CODE: 136MD
MOL. WEIGHT: 152.15	MOL. FORMULA: C8H8O3	ARTICLE CODE: 1285

ATTRIBUTES	SHOULD BE
Appearance	Colourless or slightly yellow liquid
Solubility	Very slightly soluble in water, miscible with ethanol (96 %) and with fatty and essential oils
Identification A	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y7
Acidity	= < 0.4 mL of 0.1 M NaOH
Relative density	1.182 - 1.188
Refractive index	1.535 - 1.538
Related substances	
Impurity B	= < 50 ppm
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep tightly closed. In a well-ventilated, cool, dry place and away from sources of ignition.

REMARKS

Methyl Salicylate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

It is obtained synthetically or by means of maceration and subsequent steam distillation of the leaves of the *Gaultheria procumbens* L. (Fam. Ericaceae) or the slow *Betula* bark L. (Fam. Betuláceas).

Presents analgesic, anti-inflammatory, antipyretic and revulsive activity, being used topically in creams, lotions, or liniments as skin irritant in rubefacient preparations for the treatment of musculoskeletal and joint and soft tissue alterations, such as rheumatic pains, contusions, sprains, contractures, tendonitis, etc ..., and in minor peripheral vascular disorders such as chilblains.

It is rapidly absorbed through intact skin.

It is usually associated with other rubefacientes such as menthol and camphor. It is also part of formulations intended for inhalation for the symptomatic relief of upper respiratory tract disorders. Finally it can be found in some mouthwashes.

Dosage



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Topical route, usually at 3 - 25%.

Via buccal, 0.05%.

Side effects

Exceptionally, erythema and itching may appear at the application site.

Its prolonged use or extensive air can cause systemic poisoning by salicylates.

The ingestion of relatively small amounts, of the order of 4 mL, can cause acute poisoning with nausea, vomiting, acidosis, etc ..., and even death in children, since it is easily absorbed by the gastrointestinal tract.

Precautions

Its use is not recommended in patients allergic to salicylic acid or other inhibitors of prostaglandin synthesis.

It should not be administered in areas near the eyes, on mucous membranes or wounds.

Interactions

After its topical application, an increase in the anticoagulant action of warfarin has been observed.

Incompatibilities

Alkalis, iron salts, and some plastic containers.

Boiling with water causes its decomposition.

Compounding examples

Analgesic ointment

Menthol - **10 g**

METHYL SALICYLATE- **15 g**

Yellow wax - **10 g**

Lanolin - **65 g**

Liniment of compound METHYL SALICYLATE

METHYL SALICYLATE - **25 mL**

Menthol - **4 g**

Eucalyptus essence - **10 mL**

Peanut oil c.s.p. - **100 mL**