# ZINCI OXIDI SUSPENSIO CUM LEVOMENTHOLO

### CZ 143:2025

### Zinc oxide suspension with levomenthol

### DEFINITION

It is a suspension of zinc oxide (ZnO;  $M_r$  81.38) and talc in a mixture of 85% glycerol (C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>;  $M_r$  92.09) and mucilage of anhydrous colloidal silica, with added levomenthol (C<sub>10</sub>H<sub>20</sub>O;  $M_r$  156.27) and ethanol 96% (V/V).

#### Content:

- *zinc oxide*: 23.75 % to 26.25 %;

*– glycerol:* 20.4 % to 22.6 %;

- levomenthol: 0.25% to 0.35%.

#### COMPOSITION AND PROCEDURE

Zinci oxidum (0252)	25.0 g
Talcum (0438)	25.0 g
Glycerolum 85% ( <i>0</i> 497)	25.0 g
Ethanolum 96 % (V/V) (1317)	1.0 g
Silica colloidalis anhydrica (0434)	1.0 g
Levomentholum (0619)	1.0 g
Aqua purificata (0008)	to 100.0 g

Gradually mix anhydrous colloidal silica with part of the purified water in a mortar. Dissolve levomenthol in 96% ethanol and mix with zinc oxide and talc. Gradually add 85% glycerol and mucilage of anhydrous colloidal silica in purified water. Make up the suspension to the total weight with purified water and mix thoroughly.

#### PROPERTIES

Appearance. White suspension, odour of menthol.

#### **IDENTIFICATION TESTS**

- **A.** Colouring in the determination of levomenthol content is also an identity test *(levomenthol).*
- **B.** Evaporate 1 g in a crucible, burn, and ignite. Add 5 ml *hydrochloric acid 3 mol/l RS* to the residue and heat for about 5 minutes in a water bath, add 5 ml of *water R* and filter. The filtrate complies with the zinc test (2.3.1).

- **C.** Dissolve 0.5 g by boiling in a mixture of 10 ml *dilute sodium hydroxide RS* and 10 ml *water R*. To 1 ml of this solution, add 0.5 ml *ammonium molybdate RS* and 0.25 ml *sulphuric acid R*. A yellow colour will develop. After adding 1 ml of a solution, prepared by mixing 0.1 ml of a solution of *stannous chloride R* (400 g/l) in *hydrochloric acid R1*, 2.5 ml of *dilute sodium hydroxide RS* and 2.5 ml of *water R*, an intense blue colour appears (*silicates*).
- **D.** Mix about 5 g with 0.5 g of *potassium hydrogen sulphate R* in a porcelain crucible and heat slowly; it carbonizes and a pungent acrolein smell develops (*glycerol*).

#### DETERMINATION OF CONTENT

#### Levomenthol

*The tested solution*. Weigh 1.300 g into a volumetric flask and dilute with *ethanol* 96% *R* to 50.0 ml.

After shaking, filter through dense filter paper.

*Reference solution.* Weigh 0.200 g *levomenthol CRL* into a volumetric flask and dilute with *ethanol* 96% *R* to 50.0 ml. Dilute 1.0 ml of this solution with *ethanol* 96% *R* to 50.0 ml. *Dimethylaminobenzaldehyde solution.* Dissolve 0.25 g *dimethylaminobenzaldehyde R* in a chilled mixture of 32.0 ml *Sulphuric acid R* and 20.0 ml *water R*.

*Control solution.* 1.0 ml of *ethanol* 96% *R* and 5.0 ml of dimethylaminobenzaldehyde solution. *Prepare all solutions at the same time.* 

Add 5.0 ml of dimethylaminobenzaldehyde solution to each test tube containing 1.0 ml of the test solution or 1.0 ml of the comparator solution and mix. Seal the test tubes with a stopper fitted with a thin capillary, immerse them for 2 minutes in a boiling water bath, and then cool them rapidly in a stream of running water. Measure the absorbance (*2.2.25*) of both solutions immediately in a 1 cm cuvette at 530 nm against the reference solution.

Calculate the content of C10H20O as a percentage.

**Zinc oxide.** Dissolve 0.600 g in 10 ml *dilute acetic acid RS* and perform chelatometric titration of zinc (2.5.11).

1 ml 0.1 mol/l disodium edetate VS corresponds to 8.138 mg ZnO.

**Glycerol.** Dilute 2.000 g in a volumetric flask with *water R* to 50.0 ml. Filter 10.0 ml of this liquid through a moistened dense paper filter into a stoppered flask and wash the filter with *water R*. Dilute the combined filtrates to a total volume of about 40 ml, add 25.0 ml of *sodium periodate R* solution (21.4 g/l), close the flask, mix its contents, and leave to stand for 15 minutes protected from light. Then add 5.0 ml of *ethylene glycol R* solution (500 g/l), mix again and leave to stand for 20 minutes while protected from light. Add 0.2 ml *phenolphthalein* 

# RS

and titrate with 0.1 mol/l sodium hydroxide VS. Perform a blind test.

1 ml of 0.1 mol/l sodium hydroxide VS is equivalent to 9.209 mg C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>.

## STORAGE

See Article Liquida cutanea (0927).

# SHELF LIFE

Six months when stored in glass wide-necked containers at a temperature of 15 °C to 25 °C and protected from light.

# LABELLING

See Article Liquida cutanea (0927).

The labelling shall include a warning that the product must be shaken before use.