COEI-1-THIAMIN Thiamine hydrochloride

3-[(4-amino-2-methyl-5-pyrimidinyl)methyl-5-(2-hydroxyethyl-4-methylthiazolium hydrochloride

Thiamini hydrochloridum

$C_{12}H_{18}Cl_2N_4OS$**= 337.**

1. Objective, origin and scope of application

This product is used to promote alcohol fermentation. Its use is subject to statutory restrictions placed on limiting thiamine content.

2. Labelling

The label should indicate the purity percentage of the product, the use-by date, and the safety and storage requirements.

3. Properties

White or substantially white crystalline powder or colorless crystals with a slight characteristic odor. Easily soluble in water, soluble in glycerol, minimally soluble in alcohol, virtually insoluble in chloroform and ethyl ether.

4. Solubility

Water at 20 °C	1000 g/l
Alcohol, 95% by vol.	12.5 g/l
Glycerol	63.3 g/l
Ethyl ether	insoluble

5. Proof

Proof test 5.1 may be omitted when tests 5.2 and 5.3 are performed. Proof test 5.2 may be omitted when tests 5.1 and 5.3 are performed (methods described in the Annex).

5.1. Examine the thiamine hydrochloride by absorption spectrophotometry in infrared light.

The maximum absorption values of the spectrum obtained from the substance tested correspond, in position and relative intensity, to those obtained from thiamine hydrochloride SCR. If the spectra exhibit differences, dissolve the substance to be tested and the chemical reference substance, respectively, in water. Evaporate the solutions until dry and produce new spectra from the resulting residues.

5.2. Dissolve about 20 mg thiamine hydrochloride in 10 ml of water. Add 1 ml dilute

acetic acid (R) and 1.6 ml of 1M sodium hydroxide (R). Heat in a 100 °C water bath for 30 minutes and let cool. Add 5 ml of dilute sodium hydroxide solution (R), 10 ml potassium hexacyanoferrate (III) solution (R) and 10 ml of butanol. Shake vigorously for 2 minutes. An intense light blue fluorescence will spread in the alcoholic layer, especially ultraviolet light at 365 nm. Repeat the test using 0.9 ml 1M sodium hydroxide and 0.2 g sodium sulfite replacing the 1.6 ml 1M sodium hydroxide. Virtually no fluorescence will be observed.

5.3. Thiamine hydrochloride produces chloride reactions (method described in the Annex).

5.4. Thiamine hydrochloride contains at least 98.5 pp 100, and at most the equivalent of 101.5 pp 100, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methylthiazo-lium hydrochloride, as calculated with respect to the anhydrous substance.

6. Tests

6.1. Desiccation Loss

Place 2 g of thiamine in an oven at 105 °C for 3 hours. Weight loss should not be greater than 5 pp 100.

6.2. Sulfur Ash

Using the method described in the annex, analye 2 g thiamine hydrochloride. The sulfur ash content should not be greater than 0.1 pp 100.

6.3. Preparing the Solution for Tests

Dissolve 5 g thiamine hydrochloride in water and fill to 100 ml.

6.4. Determining pH

The pH of the solution prepared for tests under Paragraph 5.3 and diluted by one-half should have a pH of between 2.7 and 3.3.

6.5. Nitrates

Add 1 ml water and 1 ml concentrated sulfuric acid (R) to 1 ml of the solution prepared for tests under Paragraph 5.3. Cool. Deposit 2 ml of the extemporaneously prepared 5 pp 100 iron (II) sulfate solution on the surface of the liquid. No brown ring should form at the interface of the 2 layers.

6.6. Heavy Metals

Test for heavy metals in 10 ml of the solution prepared for tests under Paragraph 5.3 using the method described in the Annex. (Heavy metal content expressed in terms of lead should be less than 10 mg/kg).

6.7. Lead

Using the method indicated in the annex, determine lead content in the test solution (5.3). (Lead content should be less than 5 mg/kg).

6.8. Mercury

Using the method indicated in the Annex, determine the mercury content in the test solution (5.3). (Mercury content should be less than 1 mg/kg).

6.9. Arsenic

Using the method indicated in the Annex, determine the arsenic content in the test splution (5.3). (Arsenic content should be less than 3 mg/kg).

7. Quantitative Analysis

Dissolve 0.150 g of thiamine hydrochloride in 5 ml anhydrous formic acid. Add 65 ml anhydrous acetic acid, then, while stirring, 10 ml mercuric acetate solution. Quantitatively analyze organic base halogenated salts in a non-aqueous medium by titrating with 0.1M perchloric acid. Determine the point of equivalence by potentiometric analysis. 1 ml of 0.1M perchloric acid corresponds to 16.86 mg of $C_{12}H_{18}Cl_2N_4OS$.

8. Storage

Thiamine hydrochloride should be stored in properly sealed, non-metal containers kept away from light.