MALTOL
(TENTATIVE)

Revised specifications prepared at the 65th JECFA (2005) and published in FNP 52 Add13 (2005), superseding specifications prepared at the 25th JECFA (1981) and published in FNP 52 (1992). An ADI of 0-1 mg/kg bw established at 25th JECFA (1981)

Information on functional uses and method of assay required

SYNONYMS INS No. 636

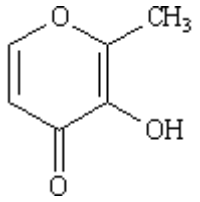
DEFINITION

Chemical names: 3-Hydroxy-2-methyl-4-pyrone

C.A.S. number: 118-71-8

Chemical formula: $C_6H_6O_3$

Structural formula:



Formula weight: 126.11

Assay: Not less than 99%

DESCRIPTION White to off-white crystalline powder having a characteristic caramel-butterscotch odour

FUNCTIONAL USES Flavour enhancer, stabilizer, flavouring agent (see Flavouring agents monograph No. 1480)

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol.4): Soluble in water and ethanol

Melting range (Vol. 4): 160 - 164°

Test for phenol: Dissolve 0.1 g of the sample in 10 ml of ethanol and add 3 drops of ferric chloride TS. A reddish violet colour is produced.

Precipitation test: Dissolve 0.5 g of the sample in 10 ml of sodium hydroxide TS and pass carbon dioxide through the solution. White crystals are formed; collect and recrystallize from dilute ethanol. The crystals melt between 160 - 164°.

Iodoform reaction: Dissolve 0.1 g of the sample in 5 ml dioxane, add 1 ml of sodium hydroxide TS, and add sufficiently iodine-potassium iodide TS (Iodine TS) with shaking until the colour remains. Heat on a water bath for 5 min. Yellow crystals are formed.

PURITY

Lead (Vol. 4)

Not more than 1 mg/kg
Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the methods described in Volume 4, “Instrumental Methods”.

METHOD OF ASSAY

Standard Solution
Transfer about 50 mg of Maltol Reference Standard (available from the United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, Md. 20852, USA), accurately weighed, into a 250-ml flask, dilute to volume with 0.1 N hydrochloric acid, and mix. Pipet 5 ml of this solution into a 100-ml volumetric flask, dilute to volume with 0.1 N hydrochloric acid, and mix.

Assay Solution
Transfer about 50 mg of the sample, accurately weighed, into a 250-ml flask, dilute to volume with 0.1 N hydrochloric acid. Pipet 5 ml of this solution into a 100-ml volumetric flask, dilute to volume with 0.1 N hydrochloric acid, and mix.

Procedure
Determine the absorbance of each solution in a 1-cm quartz cell at 274 nm using 0.1 N hydrochloric acid as the blank.

Calculate the percent of Maltol in the sample by the formula:

$$\% \text{ of Maltol} = 100 \times W_S \times A_A / A_S \times W_A$$

where
A_A = absorbance of the Assay Solution
A_S = absorbance of the Reference Standard Solution
W_A = weight in mg of the Assay solution (sample)
W_S = weight in mg of the Reference Standard