## CONFIDENTIAL

#### ANNEX 1

Specifications of raw material, process chemicals, and ion exchange resins

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#### ANNEX 2

Safety data of immobilized lactase

### ANNEX 3

JECFA specifications of D-tagatose

# Compendium of food additive specifications

Addendum 9

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#### **D-TAGATOSE**

Specifications prepared at the 55th JECFA (2000), maintained at 57th JECFA and published in FNP 52 Add 9 (2001). An ADI of 0-80 mg/kg bw was established at the 57th JECFA (2001).

**SYNONYMS** 

D-lyxo-Hexulose

**DEFINITION** 

D-Tagatose is a ketohexose, an epimer of D-fructose inverted at C-4, with a sweet taste. It is obtained from D-galactose by isomerization under alkaline conditions in the presence of calcium.

Chemical names

**D-Tagatose** 

C.A.S. number

87-81-0

Chemical formula

 $C_6H_{12}O_6$ 

Structural formula

CH<sub>2</sub>OH

| C = O
| HO-C-H
| HO-C-H
| H-C-OH
| CH<sub>2</sub>OH

Formula weight

180.16

Assay

Not less than 98% on the dry basis

DESCRIPTION

Virturally odourless, white or almost white crystals

**FUNCTIONAL USES** 

Sweetener, texturizer, stabilizer, humectant, formulation aid

**CHARACTERISTICS** 

**IDENTIFICATION** 

Solubility (FNP 5)

Very soluble in water, very slightly soluble in ethanol

Specific rotation (FNP 5)

 $[\alpha]_{\rm p}^{20}$ : -4 to -5.6° (1% aqueous solution)

Melting rannge (FNP 5)

133 - 137°

Reaction with alkaline cupric tartrate

Proceed as directed for the measurement of reducing sublstances (Method II). A copious red precipitate of cuprous oxid is formed.

Chromatography

The retention time for the major peak in the chromatogram of the sample solution corresponds to that for D-tagatose in the chromatogram of reference standard D-tagatose (available from Arla Foods Ingredients amba, Skanderborgvej 277, 8260 Viby, Denmark) using the conditions described in the METHOD OF ASSAY.

**PURITY** 

Loss on drying (FNP 5)

Not more than 0.5% (102°, 2 h)

Lead (FNP 5)

Not more than 1mg/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 method described in FNP 5, "Instrumental methods".

Total ash (FNP 5)

Not more than 0.1%

METHOD OF ASSAY

Determined by liquid chromatography (FNP5) using the following procedure.

<u>Preparation of sample solution:</u> Weigh accurately about 50 mg of dry sample into a 10-ml volumetric flask and add about 8 ml of purified, deionized water. Bring sample to complete dissolution and dilute to mark with purified deionized water. Filter through a  $0.2~\mu m$  filter.

<u>Preparation of reference solution:</u> Use dry standard D-tagatose. Prepare a solution of the reference material as described for the sample solution.

Apparatus: Liquid chromatograph equipped with a refractive index detector and an integrator.

Conditions:

Column: Biorad Aminex HPX-87C (length 30 cm, diameter 7.8 mm, particle size 9

μm) or equivalent

Column temperature: 85°

Mobile phase: Deionized water with 50 ppm calcium acetate

Flow rate: 0.6 ml/min Injection volume: 20 µl

<u>Procedure:</u> Separately inject equal volumes of the sample solution and the reference solution into the chromatograph. Record the chromatograms and measure the response of D-tagatose peak. Calculate the content of D-tagatose in the sample solution by the following formula:

% D-Tagatose =  $100 (A_S/A_R) (W_R/W_S)$ 

Where

 $A_S$  = Peak area of sample solution

 $A_R$  = Peak area of reference solution

 $W_S$  = Weight of dry sample (mg)

W<sub>R</sub> = Weight of dry reference standard (mg)