

Dr Albert Bär
Bioresco Ltd

on behalf of Arla Food Ingredients (Denmark)

14 December 2005

Reference: NFU 535

D-Tagatose

Dear Dr Bär

I am writing to inform you of the outcome of your application made to the UK for the pre-market assessment of D-Tagatose in accordance with Articles 4 and 6 of (EC)258/97.

1. On 1 March 2005 Bioresco Ltd on behalf Arla Food Ingredients made a request to the Food Standards Agency, the designated competent food assessment body in the UK, to place D-Tagatose on the market as a novel food ingredient.
2. On 15 August 2005 the Food Standards Agency issued its initial assessment report, having obtained expert advice from the Advisory Committee on Novel Foods and Processes (ACNFP), the committee that advises the Agency on all novel food issues. This report concluded that D-Tagatose meets the criteria for acceptance of a novel food, as defined in Article 3(1) of the Regulation.
3. The Commission forwarded this initial assessment report to all Member States on 13 September 2005.
4. Within the 60 day period laid down in Article 6(4) of (EC) 258/97 no reasoned objections to the marketing of this product were presented by the Commission or the Member States.
5. Therefore on the basis of the initial assessment report it is established that D-Tagatose complies with the criteria laid down in Article 3(1) of Regulation (EC)



258/97 when placed on the market in accordance with the conclusions of the initial assessment report, namely:

- I. D-Tagatose shall comply with the purity criteria set out in the Annex to this letter.
 - II. The designation D-Tagatose shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.
 - III. In a prominently displayed footnote related to the designation D-Tagatose by means of an asterisk (*) the words “excessive consumption may produce laxative effects” shall be displayed on the label of any product where the level of D-Tagatose exceeds 15g per serving and all beverages containing greater than 1% D-Tagatose (as consumed). The words shall have a typeface of at least the same size as the list of ingredients itself.
6. Please note that as regards the provision of nutritional information and allergen labelling, the rules in Directives 90/496/EC and 2003/89/EC (which amends 2000/13/EC) will apply. Your product must also comply with other applicable legislation.
 7. I understand that you have received copies of comments from Member States and that you will be responding to these.
 8. Arla Food Ingredients may therefore place D-Tagatose on the market in accordance with the conditions in this letter. This letter will be published on the Food Standards Agency website and a copy will be forwarded to the Commission for transmission to all other Member States and general publication as appropriate.

Yours sincerely

Dr Chris Jones

For the UK Competent Authority

ANNEX

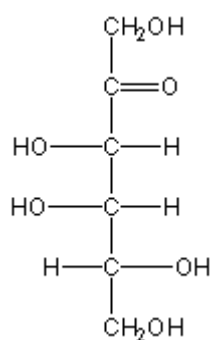
Definition D-Tagatose (synonym D-lyxo-Hexulose) is a ketohexose, an epimer of D-fructose inverted at C-4, with a sweet taste. It is obtained from D-galactose by isomerisation under alkaline conditions in the presence of calcium.

Chemical name D-tagatose

CAS number 87-81-0

Chemical formula C₆H₁₂O₆

Structural Formula



Formula weight 180.16

Assay Not less than 98% on a dry weight basis

Description Virtually odourless, white, or almost white crystals

Loss on drying Not more than 0.5% (102°C, 2 hours)

Lead 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 method described in FNP 5. 'Instrumental methods'¹.

Specific Rotation $[\alpha]_{\text{D}}^{20}$: -4 to -5.6° (1% aqueous solution)¹

Melting range 133 – 137°C¹

¹ Food and nutrition paper 5 Rev 2 – Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p. English – ISBN 92-5-102991-1