Lactose, Inhalation

1 Nonproprietary Names

None adopted.

2 Synonyms

InhaLac; inhalation lactose; *Lactohale*; *Respitose*.
For grades, *see* Tables I and II.

3 Chemical Name and CAS Registry Number

Inhalation lactose is lactose monohydrate, O-β-D-galactopyranosyl-(1→4)-α-D-glucopyranose monohydrate (*see* Lactose Monohydrate), or anhydrous lactose, O-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose, or a mixture of O-β-D-galactopyranosyl-(1→4)-β-D-glucopyranose and O-β-D-galactopyranosyl-(1→4)-α-D-glucopyranose (*see* Lactose, Anhydrous).

CAS numbers for lactose monohydrate include [5989-81-1] (lactose monohydrate); [10039-26-6] (lactose monohydrate, cyclic), and [64044-51-5] (lactose monohydrate, open form). The CAS number for anhydrous lactose is [63-42-3].

4 Empirical Formula and Molecular Weight

$C_{12}H_{22}O_{11}$ 342.30 (for anhydrous)
$C_{12}H_{22}O_{11}\cdot H_2O$ 360.31 (for monohydrate)

5 Structural Formula

See Lactose, Anhydrous; Lactose Monohydrate.

6 Functional Category

Dry powder inhaler carrier.

7 Applications in Pharmaceutical Formulation or Technology

Inhalation lactose is widely used as a carrier, diluent, and flow aid in dry powder inhalation formulations. Inhalation lactose of suitable particle size can also be used to prepare soft pellets of dry powder inhaler formulations.

See also Lactose, Anhydrous; Lactose Monohydrate.

8 Description

Lactose occurs as white to nearly white crystalline particles or powder. It is odorless and slightly sweet-tasting.

9 Pharmacopeial Specifications

See Lactose, Anhydrous; Lactose Monohydrate.

10 Typical Properties

Density (bulk) *see* Table I.
Density (tapped) *see* Table I.
Loss on drying *see* Table I.
Particle size distribution *see* Table II.
Surface area *see* Table I.

11 Stability and Storage Conditions

Inhalation lactose should be stored in a well-closed container in a cool, dry, odor-free place.

Table I: Typical physical properties of selected commercially available inhalation lactose.

Supplier/grade	Surface area (m^2/g)	Density (bulk) (g/cm^3)	Density (tapped) (g/cm^3)	Loss on drying (%)
DFE Pharma				
Lactohale 100	–	–	–	≤0.2
Lactohale 200	–	–	–	≤0.2
Lactohale 300	–	–	–	≤0.5
Respitose ML001	0.9	0.57	0.88	–
Respitose ML006	1.6	0.43	0.75	–
Respitose SV003	0.4	0.63	0.78	–
Respitose SV010	0.2	0.69	0.83	–
Meggle GmbH				
InhaLac 70	0.1	0.59	0.69	–
InhaLac 120	0.2	0.69	0.80	–
InhaLac 230	0.2	0.69	0.83	–
InhaLac 250	0.3	0.65	0.85	–
InhaLac 400	1.9	0.33	0.53	–

Table II: Typical particle size distribution of selected commercially available inhalation lactose.

Supplier/grade	d_{10} (μm)	d_{50} (μm)	d_{90} (μm)
DFE Pharma			
Lactohale 100[a]	45–65	125–145	200–250
Lactohale 200[a]	5–15	50–100	120–160
Lactohale 201[a]	3–6	20–25	50–60
Lactohale 300[b]	–	<5	≤10
Respitose ML001[b]	4	55	170
Respitose ML006[a]	2	17	45
Respitose SV003[b]	30	60	100
Respitose SV010[a]	50	105	175
Meggle GmbH			
InhaLac 70	120	210	300
InhaLac 120	90	130	180
InhaLac 230	45	100	140
InhaLac 250	20	60	100
InhaLac 400	1.29	8.40	28.20

(a) Sympatec laser diffraction.
(b) Malvern (wet) laser diffraction.

12 Incompatibilities

Lactose is a reducing sugar. Typical reactions include the Maillard reaction with either primary[1] or secondary amines.[2]

See also Lactose, Anhydrous; Lactose Monohydrate.

13 Method of Manufacture

Inhalation lactose is manufactured by milling, sieving, air classifying, micronizing and/or blending pharmaceutical grade lactose, typically in dedicated facilities with suitable equipment in place to