

PRODUCT: O0650

Trade Name: Oxeladin Citrate Ph.Eur.

Synonyms:

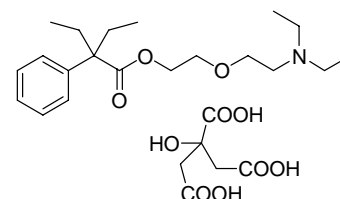
Molecular Formula: C₂₆H₄₁NO₁₀

Formula Weight: 527.62

CA-Registry-No.: 52432-72-1

EINECS-Number: 257-910-8

RTECS: ET1760000



O0650

PHYSICAL PROPERTIES (literature data):

melting point: 91 °C
 boiling point: -
 density: -
 flash point: -

SAFETY DATA/TRANSPORT:

Custom Tariff Code: 2922 50 00

Dangerous goods: **Yes** Primary Label: 6.1 Secondary Label: -
 UN-Number: 2811 Class: 6.1 Packing Group: **III**
 Kemler#: 60 GGVSee-EmS: F-A, S-A
 PSN (See+Luft): Toxic solid, organic, n.o.s.

R/S-Sentences: R: 23/24/25
 S: 22-24/25-36/37/39

Labelling: T

SPECIFICATION:

Product is in conformity with the requirements of the current European Pharmacopoeia (Oxeladin Hydrogen Citrate monograph).

Appearance:	white or almost white, crystalline powder
Identity:	IR-spectrum conforms
Assay:	99.0 - 101.0 % (T, based on dry material)
Solubility:	freely soluble in water, slightly to very slightly soluble in ethyl acetate
Appearance of Solution:	clear and colour not more intense than Y6 comparison
Loss on Drying:	max. 0.5 %
Sulphated Ash:	max. 0.1 %
Residual Solvents:	Isopropanol: max. 1000 ppm, Hexane: max. 100 ppm, Toluene: max. 20 ppm
Related substances (GC):	Ph.Eur. Impurity C: max. 0.2 %, Ph.Eur. Impurity D: max. 0.3 % any other impurity: max. 0.1 %, total: max. 1.0 % (disregard limit: max. 0.05%)

APPLICATION: Antitussive agent

STORAGE: Store in a dry place. Protect from light.

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Directive 92/32/EEC: Art 2 (2): 7

The information submitted in this publication is based on our current knowledge and experience