



## Specification

Concerning Product:	
Article number	21510
Trade name / designation / denomination	Butamirat-dihydrogencitrat
CAS number	18109-81-4
Other names / synonyms	2-hydroxypropane-1,2,3-tricarboxylic acid; 2-phenylbutanoic acid 2-[2-(diethylamino)ethoxy]ethyl ester; Butamirate Dihydrogencitrate; diethyl[2-[2-(2-phenylbutyroyloxy)ethoxy]ethyl]ammonium dihydrogen citrate;
EC number	242-006-8
Molecular weight [g / mol]	499.55128
Formula	C <sub>24</sub> H <sub>37</sub> NO <sub>10</sub>

Parameter	Test Method	Specification	Unit
<b>Organoleptic test</b>			
Appearance of solution		Clear, < Y <sub>6</sub>	
Appearance		White to slightly yellow, lumpy, waxy powder	
<b>Physical parameter</b>			
Loss on drying		≤ 1,0	%
pH value		3,50 â 4,00	
<b>Identity</b>			
Assay		98,5 â 101,0	%
Identification	TLC	positive	
Identification		Test for citrates: positive	
Infrared absorbtion spectrometry		conform to the reference	
Melting Point (identity)		74,0 â 78,0	Â°C
UV spectroscopy		conform to the reference	
<b>Impurities</b>			

Heavy Metals (as Pb)		≤ 10	ppm
Readily carbonizable substances		â€ BY <sub>5</sub>	
Sulphated ash		≤ 0,1	%
Impurity	TLC	≤ 0,10	%
Impurity	HPLC	B1: ≤ 0,15	%
Impurity	HPLC	B2: ≤ 0,15	%
Impurity	HPLC	C: ≤ 0,15	%
Impurity	HPLC	D: ≤ 0,10	%
Impurity	HPLC	each other: ≤ 0,10	%
Impurity	HPLC	sum: ≤ 1,0	%
<b>Residual Solvents</b>			
Acetone		≤ 5000	ppm
Petroleum Ether		≤ 5000	ppm
Toluene		≤ 890	ppm
<b>Elemental Impurities</b>			
Chlorides (Cl)		≤ 50	ppm
<b>Microbiological data</b>			
Aerobic microorganisms		≤ 1000	CFU/g
Escherichia Coli.		neg.	
Yeast and Mould		≤ 100	

**Supplemental information:**

**Shelf life:** 2 years

**Version of manufacturer:** 8

**Conclusion:** The above mentioned product complies with tests of AP 016/F076/C.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 26. Sep. 2021

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