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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
Rodano (MI)

Lot: 9040319



Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 1950000772
Batch Size 186,000

Manufacturing date 12/03/2019
Re-test date 06/03/2024
Certificate Nr. 040000003399

<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
DESCRIPTION: white or almost white hygroscopic crystalline powder	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (UV)	complies		complies
IDENTIFICATION (HPLC retention time)	complies		complies
IDENTIFICATION (sodium reaction)	complies		complies
ACIDITY/ALKALINITY	complies to Ph.Eur.		complies
ACIDITY/ALKALINITY	complies to JP		complies
APPEARANCE OF SOLUTION: a 2.0% solution in water is not more intensely coloured than reference solution BYs	complies		complies
CLARITY OF SOLUTION: a 2.0% solution in water is not more opalescent than reference suspension II	complies		complies
COLOUR OF SOLUTION: Abs at 440 nm (5.0% solution)	<= 0,05	AU	0,02
WATER	<= 10,0	%	7,3
LOSS ON DRYING	<= 10,0	%	6,9
OXALATE	≤ 0,35 %		≤ 0,35 %
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Impurity 2 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Impurity 3 (rel.sub. HPLC)	<= 0,10	%	< Disregard limit (0,01)
Any other Impurity (rel.sub. HPLC)	<= 0,10	%	0,06 (NOTE)
Any other Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,04 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,01 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,16
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)
-Dimethylformamide (HPLC)	<= 100	ppm	< LOD (1)
ORGANIC IMPURITIES	-		-
2-Acetylresorcinol (rel.sub. HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Impurity A (rel. sub.USP)	<= 0,10	%	< Disregard limit (0,05)

Andrea Rebora
QC Manager
Approved April 02, 2019

Agnese Messina
Qualified Person
Released April 02, 2019

Capitale Sociale € 40.000.000 i.v. - R.I. Milano Cod. Fisc. e P.IVA n. 08101100167 - R.E.A. Milano n. 1201640
Società del Gruppo P. & R. S.p.A. soggetta all'attività di direzione e coordinamento della Società capogruppo P. & R. S.p.A.
Strada Rivoltana Km 6/7 - 20090 Rodano (MI) - ITALY capitale sociale € 12.000.000,00 i.v. - C.F. e P.I. 00651030181



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<u>Test</u>	<u>Specification</u>	<u>M.U.</u>	<u>Result</u>
Impurity B (rel. sub. HPLC USP)	$\leq 0,10$	%	< Disregard limit (0,05)
Any other Impurity (rel. sub. HPLC USP)	$\leq 0,10$	%	0,05 (NOTE)
Any other Impurity 1 (rel.sub. HPLC USP)	$\leq 0,10$	%	0,07 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	$\leq 0,30$	%	0,12
ASSAY (pot.) (calculated on the dried basis)	99,0 - 101,0	%	100,6
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	100,5
<u>NOTE</u>			
RRT 1,15 (any other impurity)			
<u>NOTE</u>			
RRT 1,45 (any other impurity 1)			
<u>NOTE</u>			
RRT 1,2 (any other impurity 2)			
<u>NOTE</u>			
RRT 1,25 (any other impurity)			
<u>NOTE</u>			
RRT 1,75 (any other impurity 1)			

Solubility: soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform.

Complies with: Ph.Eur. BP USP JP

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Andrea Rebora
QC Manager
Approved April 02, 2019

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