



Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 1950001695
Batch Size 207,000 KG

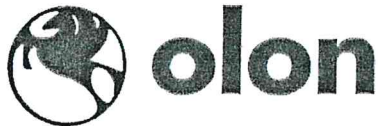
Manufacturing date 07/06/2019
Re-test date 25/05/2024
Certificate Nr. 040000007666

<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	%	6,5
LOSS ON DRYING	<= 10,0	%	6,8
OXALATE	≤ 0,35 %		≤ 0,35 %
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,02
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	%	0,02 (NOTE)
Any other Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,05 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,14
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	< LOQ (50)
-Dimethylformamide (HPLC)	<= 100	ppm	24
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 June 25, 2019

Agnese Messina
Qualified Person
Released June 26, 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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Impurity B (rel. sub. HPLC USP)	$\leq 0,10$	%	< Disregard limit (0,05)
Any other Impurity (rel. sub. HPLC USP)	$\leq 0,10$	%	0,06 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	$\leq 0,30$	%	0,06
ASSAY (pot.) (calculated on the dried basis)	99,0 - 101,0	%	99,9
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	99,1

NOTE

Any other imp. (RRT 1,09) EP

NOTE

Any other imp.1 (RRT 1,16) EP

NOTE

Any other imp.2 (RRT 1,45) EP

NOTE

RRT 1,6 (any other impurity) USP

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).

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