

Olon Spa Stab. Casaleto Lodig
Via Livelli 1
26852 Fraz. Mairano (LO)

PEC: olon@pec.olonspa.it
Tel. HQ: +39 02 9523.1
Tel. Plant: +39 0371 739901

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



Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

Product Code C4050
Batch Number 1850002645
Order 1180903
Quantity 1,000

Manufacturing date 14/09/2018
Re-test date 13/09/2023
Certificate Nr. 100000000873
Ref. Order PO B-2180195

Test	Specification	M.U.	Result
DESCRIPTION: white or almost white hygroscopic crystalline powder	complies		complies
IDENTIFICATION (IR)	complies		complies
IDENTIFICATION (UV)	complies		complies
IDENTIFICATION (sodium reaction)	complies		complies
ACIDITY/ALKALINITY	complies to Ph.Eur.		complies
ACIDITY/ALKALINITY	complies to USP		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	0,04
WATER	<= 10,0	%	6,7
LOSS ON DRYING	<= 10,0	%	6,5
OXALATE	≤ 0,35 %		≤ 0,35 %
Each Impurity (rel.sub.TLC)	≤ 0,5 %		≤ 0,5 %
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	%	0,05 (NOTE)
Any other Impurity 1 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,11
RESIDUAL SOLVENTS:			
-Methanol (GC)	<= 200	ppm	< LOQ (50)
-Dimethylformamide (HPLC)	<= 100	ppm	9
ASSAY (pot.) (calculated on the dried basis)	99,0 - 101,0	%	99,5
ASSAY (UV) (anhydrous basis)	98,0 - 101,0	%	100,1

Andrea Rebori
QC Manager
Approved October 10, 2018

Agnese Messina
Qualified Person
Released October 10, 2018

Emission December 13, 2018

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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Specification

M.U.

Result

RRT 1,15 (any other Imp.)

NOTE

RRT 1,17 (any other Imp.1)

NOTE

RRT 1,45 (any other Imp.2)

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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Modello: C4050-STD / 1
December 13, 2018