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

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Tel. HQ: +39 02 9523.1
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Olon S.p.A. - Sede Legale
Strada Rivoltana Km 6/7
Rodano (MI)

Lote: 0100920

Certificate of Analysis

Product name **SODIUM CROMOGLICATE**

		Manufacturing date	03/08/2020
Product Code	C4050	Re-test date	02/08/2025
Batch Number	2050002201	Certificate Nr.	100000011468
Order	1192161	Batch Size	188,000 KG
Quantity	50,000 KG	Ref. Order	PO 2019 - 1/352

Test	Specification	M.U.	Result
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 BY_5	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	0,00
WATER	<= 10,0	%	6,3
LOSS ON DRYING	<= 10,0	%	5,9
OXALATE	≤ 0,35 %		≤ 0,35 %
--	-		-
RELATED SUBSTANCES	-		-
Impurity 1 (rel.sub. HPLC)	<= 0,10	%	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	%	0,03 (NOTE)
Any other Impurity 2 (rel.sub. HPLC)	<= 0,10	%	0,02 (NOTE)
Sum of all Impurities (rel.sub. HPLC)	<= 0,30	%	0,12
--	-		-
RESIDUAL SOLVENTS:	-		-
-Methanol (GC)	<= 200	ppm	60

Andrea Rebora QC Manager Approved September 01, 2020	Agnese Messina Qualified Person Released September 01, 2020

'Emission'	Agnese Messina	Qualified Person	September 04, 2020

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Test	Specification	M.U.	Result
-Dimethylformamide (HPLC)	<= 100	ppm	7
--	-		-
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)
Impurity B (rel. sub. HPLC USP)	<= 0,10	%	< Disregard limit (0,05)
Any other individual unspecified impurity and Cromolyn tricarboxylic acid analog (rel. sub. HPLC USP)	<= 0,10	%	0,06 (NOTE)
Sum of all Impurities (rel. sub. HPLC USP)	<= 0,30	%	0,06
--	-		-
ASSAY (pot.) (calculated on the dried basis)	99,0 - 101,0	%	100,2
ASSAY (HPLC) (calculated on the anhydrous basis)	98,0 - 101,0	%	98,7

NOTE
RRT 1,14 (any other impurity EP)
NOTE
RRT 1,45 (any other impurity EP)
NOTE
RRT 1,07 (any other impurity 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).

Andrea Rebora QC Manager Approved September 01, 2020	Agnese Messina Qualified Person Released September 01, 2020		
'Emission'	Agnese Messina	Qualified Person	September 04, 2020