olon s.p.a.

Revision 4050-00

SODIUM CROMOGLICATE

Batch N°:	**1750001654**	**ANALYSIS CERTIFICATE N°**	**172751**	**Date:**	**16/01/2018**
Kg:	197.00	Formula:	$C_{23}H_{14}Na_2O_{11}$	M.W.:	512.3
Man. date:	12/12/2017	Retest date:	Dec/2022	Complies with:	Ph.Eur. BP USP JP
Solubility:	*soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform*				

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white or almost white hygroscopic crystalline powder	complies
IDENTIFICATION	(1): IR spectrum (2): UV spectrum (3): sodium reaction	complies complies complies
ACIDITY OR ALKALINITY	(1): complies to Ph. Eur. test (2): complies to USP test	complies complies
APPEARANCE OF SOLUTION	a 2.0% solution in water is not more intensely coloured than *reference solution* BY_5	complies
CLARITY OF SOLUTION	a 2.0% solution in water is not more opalescent than *reference suspension II*	complies
COLOUR OF SOLUTION	Abs at 440 nm not more than 0.05 (5.0% solution)	0.01
WATER	not more than 10.0%	7.8%
LOSS ON DRYING	not more than 10.0%	7.0%
OXALATE	not more than 0.35%	complies
HEAVY METALS	not more than 20 ppm	complies

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

Q.C. Manager ..... 17/9/18 **Q.A. Manager** ..... 16/01/18 **Qualified Person** ..... 17 APR 18

OLON SpA
Sede Legale-Direzione e Uffici
Strada Rivoltana km. 6/7
20090 Rodano (MI)

Telefono 02.9523.1
Fax 02.9523.5111
5381-5181-5933-5333
PEC: olon@pec.olonspa.it

Stabilimento di Casaletto Lodigiano
Via Livelli,1-26852 Casaletto Lodigiano
Fraz.Mairano (Lodi) –Italy
Tel.+39 0371 739901 –Fax +39 0371 73108

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SODIUM CROMOGLICATE

Batch N°:	**1760001654**	**ANALYSIS CERTIFICATE N°**	**172751**	**Date:**	**16/01/2018**
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Man. date:	12/12/2017	Retest date:	Dec/2022	Complies with:	Ph.Eur. BP USP JP
Solubility:	*soluble in water; practically insoluble in ethanol (96 per cent) and in chloroform*				

TESTS	SPECIFICATIONS	RESULTS
RELATED SUBSTANCES (TLC)	each impurity not more than 0.5%	no impurities detected
RELATED SUBSTANCES (HPLC)	(1): impurity 1 not more than 0.10%	< 0.01%
	(2): impurity 2 not more than 0.10%	< 0.01%
	(3): impurity 3 not more than 0.10%	< 0.01%
	(4): any other impurity not more than 0.10%	RRT 0.97: 0.01% RRT 1.15: 0.05% RRT 1.24: 0.01% RRT 1.29: 0.01% RRT 1.45: 0.02%
	(5): sum of all impurites not more than 0.30%	0.10%
ASSAY	99.0% to 101.0% with reference to the dried substance (pot.)	100.0%
	98.0% to 101.0% calculated on the anhydrous basis (UV)	99.8%
RESIDUAL SOLVENTS	(1): methanol not more than 200 ppm (GC)	< LOQ
	(2): dimethylformamide not more than 100 ppm (HPLC)	38 ppm

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

Q.C. Manager ..... **Q.A. Manager** ..... **Qualified Person** .....

17/1/18 17/01/18

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