

PROPOSITION 65 STATEMENT

Sodium Hydroxide Solution GMP

BioSpectra does not intentionally add or use any substances listed under California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) known to the State of California to cause cancer, birth defects, or other reproductive harm, to the BioSpectra manufacturing process of Sodium Hydroxide Solution, Bio Pharma Grade.

BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the raw material supplied to BioSpectra may contain trace impurities known to the State of California to cause cancer or reproductive toxicity based on this evaluation, including Arsenic, Cadmium, Chromium, Lead, and Nickel.

Sodium Hydroxide, Bio Pharma Grade has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D, with results for the specified elements detailed in the table below.

Listed Component	Supplier-Stated Maximum Content (ppm by wt.)	Proposition 65 NSRL / MADL (µg/day)			BioSpectra Analysis Results
		Inhalation	Oral	Other	
Arsenic (As)	0.1	0.06	N/A	10 (except inhalation)	< 0.15 ppm
Cadmium (Cd)	0.5	0.05	4.1	N/A	< 0.02 ppm
Chromium (Cr)	1	0.001	8.2	N/A	< 11 ppm
Lead (Pb)	0.5	N/A	15	0.5	< 0.05 ppm
Nickel (Ni)	3	N/A	N/A	N/A	<0.20 ppm

Current Product Number
NAHY-4126

For further information, please contact info@biospectra.us


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