

QUALITY CONTROL AND TRACE ELEMENT MONITORING OF PHOSLOCK[®] PRODUCTION

1. BACKGROUND

Phoslock[®] was developed by the leading Australian Government Research organisation, the CSIRO, during the 1990's to bind Filterable Reactive Phosphorus (FRP) in water bodies. Phoslock Water Solutions Ltd (PWS) acquired the license to manufacture Phoslock[®] in 2002 and developed suitable commercial production processes and raw material/finished product test protocols that meet or exceed industry and regulatory requirements for waterbody restoration products.

Commercial production of Phoslock[®] commenced in China in 2005. This was due to the strategic location of the active ingredient, lanthanum. China is the largest producer of rare earth compounds in the world and these commodities are used in many high value electronic goods and pharmaceutical applications.

Manufacturing of Phoslock[®] is conducted under the strict supervision of PWS. It is monitored and controlled under specifically developed QA/QC practices. Batch testing of raw materials and the finished product is conducted by approved ISO¹ accredited laboratories in China, Australia and the USA.

The Phoslock[®] production facility and manufacturing processes in China are certified in accordance to the NSF/ANSI² Standard 60 – Nth American Drinking Water. A detailed review of the manufacturing facility is conducted biannually by the NSF auditors to: audit all manufacturing steps; assess equipment and facilities used to produce Phoslock[®]; assess cleaning, sanitation and calibration processes; review of manufacturing batch records, laboratory production test records; and to assessment of quality control testing of the finished product.

A certification of renewal is issued at the completion of the audit and review of laboratory analysis (as supplied by an independent Analytical Laboratory).

¹ International Organization for Standardization

² National Sanitation Foundation/American National Standards Institute

2. MANUFACTURING DOCUMENTATION

The commercial production of Phoslock® follows Good Manufacturing Practice. This is compiled, refined and adopted in accordance with commercial and regulatory requirements.

All stages of production are recorded and checked by factory process operators. This includes both the raw materials and finished product, processing operation times, batch numbers of raw materials and finished goods.

1. *Batch Number Recording*

The batch number is generated using a numerical system that identifies the date of manufacture and the raw materials used in production. Batch records and process testing data are retained in accordance with GMP. Raw materials and Phoslock® samples are retained at the factory with composite samples being dispatched to PWS, Australia.

2. *Packing and Shipping*

Finished Phoslock® granules are bagged into 25 kg sacks or 1 tonne bulk bags, stamped with a batch number, and stacked on new heat treated shipping pallets. Pallets are capped with cardboard covers and stretch wrapped to ensure the stability and integrity of goods during transportation.

When goods are prepared for shipment, the batch numbers are recorded and a Certificate of Analysis, that states the material specification, are generated (refer Appendix A).

3. *Phoslock® Specification*

Phoslock® is manufactured to conform to the following specifications:

- (a) Optimal removal of filterable reactive phosphorous (FRP)
- (b) Negligible to non-detectable levels of soluble trace elements – refer to Section 4 of ANZECC ³ Guidelines, 2000.

³ Australian and New Zealand Environment Conservation Council

Table 1: Phoslock[®] specification conformance is assured through production sampling and testing

Physical/Chemical Property	Target Value
Appearance	Tan coloured granules
Particle Size	0.2mm – 3mm, Dust < 100 µM
Total Lanthanum content by XRF analysis (mg/g)	50±5
P uptake capacity	>90% of the soluble Phosphorus of a solution that contains 1 ppm FRP/P in 24 – 72 hrs
Specific Gravity	1.1
pH (1% Solution)	7 - 8
Moisture Content	< 10%

4. Trace Element Analysis – Contaminant Monitoring

Comparison between the typical analysis of Phoslock[®] granules and ANZECC/ARMCANZ recommended trace elemental concentrations for sediments indicate that trace elements are well below the “Low” ANZECC/ARMCANZ recommended levels.

Concentrations of rare earth elements other than lanthanum measured in Phoslock[®] are at or below detection limits due to the purity of the lanthanum feedstock used in the manufacturing process.

Raw material suppliers maintain strict quality control of the ingredients. Suppliers are separately audited during the biannual NSF/ANSI audit and are required to sign off on “Do Not Change Supplier” agreements.

⁴ Australian and New Zealand Environment Conservation Council/ Agriculture and Resources Management Council of Australia and New Zealand

Trace elemental composition of Phoslock[®] granules.

ANZECC/ARMCANZ Guidelines for trace element concentrations in sediments in aquatic environments (ANZECC Guidelines, 2000).

Chemical Element	Phoslock [®] (µg/g)
As	12.0±2.47
Cr	32.4±8.5
Cu	3.7±2.8
Ni	5.8±2.9
Pb	13.5±4.3
Zn	79.5±5.7

Chemical Element	Low (µg/g)	High (µg/g)
As	20	70
Cr	80	370
Cu	65	270
Ni	21	52
Pb	50	220
Zn	200	410

5. Activity Testing

Phoslock[®] is tested for the presence of Radionuclides by the Australian Nuclear Science and Technology Organisation (ANSTO) and Eurofins Eaton Analytical, Inc., (the largest potable water testing laboratory in the USA). Gross Alpha and Gross Beta radioactivity are reported as non-detectable in Phoslock[®].



Water Quality Association Gold Seal Certificate

Phoslock Water Solutions Limited

Suite 403, 25 Lime Street
Sydney NSW 2000,

Facility: Leshan Primet New Materials Co. Ltd



Certification Date: March 11, 2014

Authorized By: *Thomas P. Palkon*

Thomas P. Palkon
Director of Product Certification



Water Quality Association
4151 Naperville Road
Lisle, IL 60532, USA



This Certificate, or any part thereof, may not be used in a misleading manner and validation of its use is contingent upon the Official WQA web-listing.

Revision: 01/07/2013

FORM 12046

Water Quality Association Official Gold Seal Listing	
Granted to the following Company:	<i>Phoslock Water Solutions Limited Suite 403, 25 Lime Street Sydney NSW 2000,</i>
For the Facility Located at:	<i>Leshan Primet New Materials Co. Ltd Wu Tong Qiao Leshan City, Sichuan</i>

The WQA Gold Seal Certification Department has issued certification for the following model(s) to the standard(s) below. Only models that appear in the official listing are authorized to bear the WQA Gold Seal.

NSF/ANSI 60 (05/02/2011): Drinking Water Treatment Chemicals - Health Effects is within WQA's ANSI and SCC approved scope of accreditation Drinking Water Treatment Chemicals Scheme

Phoslock Phoslock Phosphate
Sequestering Agent

Notice: To request any changes to the certified model(s), please request a Change to Certified Product (CCP) form. Examples include any change to the wetted parts or formulations such as supplier or material types, literature, or a change in company name. This list is not all inclusive. Failure to submit documentation regarding changes may result in non-compliance with the standard(s) as well as de-listing of the affected models.