

WholeSeal®

BRAND of Laboratory Non-Porous Coating



Long Valley, NJ: Medical Device Packaging Consultant and inventor Donald Barcan has developed an application to enhance the testing of POROUS medical device packages. He calls the material "WholeSeal® (patented)", which is applied to the exterior of the porous side of the package. Upon drying, the porous package becomes non-porous for the purpose of testing the package for seal integrity or for defects on the other side of the package, such as pinholes. The process has been tested and shown to detect imperfections below 25µ in size and limited to the sensitivity of the test equipment.

THE PROBLEM:

Currently, testing porous packages for either seal integrity or package integrity usually involves using dye testing or underwater bubble testing (ASTM F1929 & F2096) or some variation. These tests are messy and are limited to the size of defect that can be detected and also rely on good operator technique. A major problem is that the tests are qualitative not quantitative. There are other test methods for package and seal integrity, as described in ASTM F2228 & F2338, but these tests require expensive test equipment.

THE SOLUTION:

WholeSeal® is an aqueous polyurethane emulsion which can be applied by brush or roller and air dries producing an impervious thin film. This coating is effective when applied to a spun-bonded polyolefin or paper. Drying can be speeded up by using an air dryer or low temperature oven. Once dry, the package can be tested for leaks using current pressure decay technology such as ASTM F2095. Specifications can be written around a specific quantitative leak rate. This coating will also extend the time available to do dye testing because the dye will not penetrate the coated side as quickly as the uncoated porous material. Trials have also shown the coating to be effective using underwater bubble testing.

ATTENTION: PACKAGE ENGINEER, QC, & LAB MANAGER

WholeSeal™ is perfect for package development and the evaluation of distribution & handling defects. We will send you a small trial sample free of charge for your evaluation. Please send an e-mail to wholeseal@2dbi.com requesting a sample. Please allow several weeks for delivery and include name, address, AND telephone number. If your need is more urgent, please include your FedEx account number and we will send it per your instructions.



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