

Residual Solvents

SDM[®]27, Diluted Nitroglycerin USP (10% Nitroglycerin in Propylene Glycol)

Manufacturing Facility:

Copperhead Chemical Company Inc., 120 River Road, Tamaqua, PA 18252

According to General Chapter <467> “Residual Solvents” of the current United States Pharmacopoeia (USP), all drug substances (APIs) and drug products are to be subject to relevant control of solvents likely to be present in the substance or product. To assist our customers in determining the Residual Solvents content of their drug products, Copperhead Chemical includes the following statement on the Certificate of Analysis that we provide with each shipment of SDM[®]27 manufactured at our facility in Tamaqua, PA:

“Residual Solvents: Only the Class 3 solvent ethyl acetate is likely to be present in SDM[®]27 at a maximum level of 70 ppm.”

While no organic solvents are used in the synthesis or purification of nitroglycerin, Copperhead employs Ethyl Acetate, NF as a cleaning agent for the tank and auxiliary equipment used to blend SDM[®]27, and there is a potential for this solvent to be present in the resultant active pharmaceutical ingredient. While we continually work towards eliminating all trace of the residual solvent, we can at the present time assure that the content of ethyl acetate in SDM[®]27 will be less than 70 ppm (0.007%).

Our supplier of Propylene Glycol, USP has advised that no Class 1, 2, 3, Table 4 or any other solvents not listed in USP/NF General Chapter <467> are used or produced in the manufacture of this component of SDM[®]27.

We wish to draw your attention to the fact that the USP default method for Class 3 solvents of Loss on Drying <731> is not suitable for use with SDM[®]27 due to the volatility of nitroglycerin. The test method employed by Copperhead is an in-house test method, TM-P211. A copy of the test method is available to customers upon request.

Sincerely,



Dawn Clarke
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