

Polymorphism Statement

**SDM[®]17, Diluted Nitroglycerin USP
(10% Nitroglycerin on Lactose Monohydrate)**

Manufacturing Facility:

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

Copperhead Chemical advises that SDM[®]17, Diluted Nitroglycerin USP does not exhibit polymorphism.

The active nitroglycerin is a liquid above 13°C and for that reason polymorphism is not considered to be of concern; in addition, there are no polymorphic structures reported in the literature for solidified nitroglycerin.

The supplier of the lactose monohydrate, used as the diluent in SDM[®]17, has also confirmed that it does not exhibit polymorphism as it is 100% alpha-monohydrate.

Sincerely,



Dawn Clarke
Regulatory Affairs Manager

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