

## **Polymorphism Statement**

**SDM<sup>®</sup>12, Diluted Nitroglycerin USP  
(1.95% Nitroglycerin on Lactose Monohydrate)**

### **Manufacturing Facility:**

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

---

Copperhead Chemical advises that SDM<sup>®</sup>12, 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<sup>®</sup>12, has also confirmed that it does not exhibit polymorphism as it is 100% alpha-monohydrate.

Sincerely,



Dawn Clarke  
Regulatory Affairs Manager

Email: [dclarke@copperheadchemical.com](mailto:dclarke@copperheadchemical.com)

Issued: January 30, 2019