

## **BSE/TSE 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

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Please be advised that all materials used to manufacture SDM<sup>®</sup>12, Diluted Nitroglycerin USP (1.95% Nitroglycerin on Lactose Monohydrate) are of synthetic, inorganic or vegetable origin, with the exception of the lactose monohydrate diluent which originates from cow's milk (bovine).

The Guidance Note (EMA/410/01 Rev. 3) advises that milk derivatives are unlikely to present any risk of TSE contamination, and are therefore considered compliant with the requirements of the European Medicines Agency (EMA) Note. Copperhead has received confirmation from our supplier that the lactose we receive is in compliance with the guidance note.

The glycerin and all other materials used by Copperhead Chemical Company Inc. to manufacture the nitroglycerin component of SDM<sup>®</sup>12 are of non-animal origin.

I trust this meets your needs but please feel free to contact me should you have any further questions. I can be reached via email at [dclarke@copperheadchemical.com](mailto:dclarke@copperheadchemical.com).

Sincerely,



Dawn Clarke  
Regulatory Affairs Manager

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