

BSE/TSE Statement

SDM[®]17, 10% Nitroglycerin on Lactose Monohydrate, USP

Manufacturing Facility:

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

Please be advised that all materials used to manufacture SDM[®]17, 10% Nitroglycerin on Lactose Monohydrate, USP 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 (EMEA/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[®]17 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.

Sincerely,



Dawn Clarke
Regulatory Affairs Manager

Issued: January 22, 2019