

Melamine Statement

**SDM[®]12, Diluted Nitroglycerin USP
(1.95% Nitroglycerin on Lactose Monohydrate)**

Manufacturing Facility:

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

Copperhead Chemical has determined that the lactose monohydrate used in the manufacture of SDM[®]12 is listed as one of the at-risk components identified as vulnerable to melamine contamination in the FDA Guidance for Industry titled “Pharmaceutical Components at Risk for Melamine Contamination”. Following is Copperhead’s statement regarding the issue of testing for the absence of melamine in lactose as required by the guidance:

1. Copperhead Chemical Company has assessed the supply chain for the Lactose Monohydrate NF used in the manufacture of SDM[®]12 and has determined that the component is not at risk of containing any melamine contaminant.
2. Certification is received from the manufacturer of the Lactose Monohydrate NF that each lot of the lactose is absent of melamine.
3. At the present time, Copperhead Chemical is not aware of the existence of a validated method for determining melamine in lactose.

Copperhead does not believe there to be any risk of melamine contamination in any of its lactose products given the supply source and manufacturing integrity of our lactose manufacturers. None of the other materials used in the manufacture of SDM[®]12 are at risk for melamine contamination.

Sincerely,



Dawn Clarke
Regulatory Affairs Manager

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