

AFLATOXIN Statement

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

Manufacturing Facility:

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

Aflatoxins are naturally occurring mycotoxins produced by two species of the fungi *Aspergillus* and are known to be genotoxic and carcinogenic. Aflatoxins can occur in foods such as groundnuts, treenuts, corn, rice, figs and other dried foods, wheat, spices and crude vegetable oils, as a result of fungal contamination before and after harvest. They can also be found in feedstocks for agricultural animals which have the potential to pass the toxins into eggs and milk products.

Copperhead confirms that all materials used in the manufacture of SDM[®]17 are of synthetic, inorganic or vegetable origin and are free of the above potential allergens and aflatoxins, with the exception of the lactose monohydrate diluent which originates from cow's milk.

Copperhead's manufacturer for the lactose monohydrate (NF) diluent used in SDM[®]17 has provided an aflatoxin statement and has confirmed it meets the following requirements (dry basis):

| Aflatoxin Test | Requirement |
|-----------------------|-------------------------------|
| M1 | <0.05 micrograms per kilogram |
| B1 | <2.0 micrograms per kilogram |
| B1, B2, G1, G2 | <4.0 micrograms per kilogram |

Sincerely,



Dawn Clarke
Regulatory Affairs Manager

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