

**ALLERGEN DISCLOSURE FORM**

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

A. Does this product contain or originate from the following sources?

No	Origin of Source	Yes	No	Comments/Additional Notes
1	Alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
2	Animal Derivates <b>*Refer to comment</b> *If yes, which ingredients and which animal? *What is the country of origin for this animal?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	*Contains lactose made from cow's milk sourced from the United States. See item C below for TSE statement.
3	Corn	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4	Eggs	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
5	Gluten or Wheat Based Materials	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
6	Grain (wheat, barley, spelt, oats, rye)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
7	Iodine	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
8	Lactose <b>*Refer to comment</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	*Lactose is a component of SDM®12
9	Latex <b>*Refer to comment</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	*Latex is not a component of the SDM®12 formulation, however the NG used for SDM®12 comes into contact with a hose made from natural rubber.
10	Mercury	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
11	Milk/Dairy Based Materials <b>*See comment</b>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	*Lactose made from cow's milk is a component of SDM®12.
12	Mustard	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
13	Peanuts	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
14	Preservatives	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
15	Seafood/Fish/Shellfish *If yes, what is the specific source?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
16	Soy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
17	Starch (e.g. corn, potato, rice, legumes) *If yes, what is the specific source?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
18	Sugar (e.g. dextrose, fructose, sucrose) *If yes, what is the specific type?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
19	Sulfa/Sulfites/Sulfates <b>*See comment</b>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	*None detected, but may contain trace amounts of sulfates
20	Tree Nuts (e.g. almonds, pecans, walnuts) *If yes, what is the specific source?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

B. Is this product Kosher? Yes  No

C. If you answer yes to #2, please provide a statement regarding TSE/BSE compliance:


All materials used to manufacture SDM®12 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®12 are of non-animal origin.

Other Comments: The current source of glycerin, which is used in the manufacture of nitroglycerin, may be derived from palm, palm kernel and/or coconut oils. However, the manufacturer states that the glycerin is "highly processed, distilled and purified" and that "any protein residue in the crude oils is removed by the processing, thus removing the allergens."

Company name and Address: Copperhead Chemical Company Inc., 120 River Road, Tamaqua, PA 18252

Questionnaire completed/certified by: Dawn Clarke, Regulatory Affairs Manager

Signature:



Date: 30-Jan-2019