Nitrosamines declaration

Formula Hill:	$C_6H_{14}O_6$
Molar Mass:	182,17 g/mol
CAS Nº:	69-65-8

Date of print: 17 April 2024

108185 D(-)-Mannitol, Ph. Eur., for parenteral use

Outcome of the Risk Assessment on the above-mentioned product based on the requirements defined in the guidance on the EMA webpage based on the EMA Assessment report “Nitrosamines impurities in human medicinal products” (EMA/369136/2020), “Questions and answers for marketing authorization holders (EMA/409815/2020) and the US FDA Guidance for industry “Control of Nitrosamine Impurities in Human Drugs”.

We hereby confirm that nitrosamines are not used as intentionally added ingredients. Based on the characteristics of the raw materials and the manufacturing process, DC Fine Chemicals declares that, at the best of our knowledge:

- The route of synthesis of the product in object does NOT include nitrite salts, alkyl nitrites or any other nitrosating agent.
- Secondary amines, tertiary amines, quaternary alkyl ammonium salts or alkyl amides e.g. DMF, DMAc, NMP, TEA, DIPEA, NMM, TBA etc.. are not present in the synthesis, including starting materials.
- Nitrite (NO2) or nitrate (NO3) are not potentially present in any raw materials used, including water.
- There is not a potencial presencial of nitrosamines in any of the raw materials used in the route of synthesis (eg. Solvents, reagents…)
- No amide solvents, are used during the process.
- No catalysts are used during the process.
- No amines or ammonium salts can be formed in the synthesis process of the product.
- Neither solvents nor organic products are used for equipment cleaning.
- No nitrosamines are handled in the facilities (including manufacturing plant and equipment).

Based on evaluation of the manufacturing steps, we declare that risk for contamination of the above-mentioned product with nitrosamines is negligible.

Dra. Miriam Miguel (miriam@dcfinechemicals.com)
Qualified person

Electronic document valid without signature