

RE: NITROSAMINE RISK STATEMENT –

August 10, 2021

Nitrosamines are a family of compounds which are formed by the reaction of secondary amines, amides, carbamates, derivatives of urea with nitrite or other nitrogenous agents with the nitrogen in the +3 state. The common nature of the precursors and the simplistic nature of the nitrosation reactions under acidic pH have made nitrosamines a potential source of concern.

Repligen does not use raw materials characterized as a nitrosamine, according to EMA/189634/2019.

Repligen has performed risk assessments against the Bill of Materials (BOMs) from a OPUS 45 cm column design for likelihood of Nitrosamine Impurities which represents a worst-case assessment to cover all Materials of Construction used in OPUS 2.5-80 cm column designs.

It must be advised however, that Repligen does not perform routine analysis for the presence of these compounds. All final assessments for the risk of nitrosamine impurities must be conducted by the end-user of these products.

Sincerely,



Name: Kevin Fitzgerald

Title: Director, Quality

References

FDA WATCH: Nitrosamines, How to address these unwelcome guests in the pharmaceutical world; May 2019