

From: [REDACTED]
To: [REDACTED] - PG Impfstoffe COVID-19 /114.BMG; [REDACTED] - 121 / PG Impfstoffe.BMG
Cc: [REDACTED] - L2.BMG; COVID-19-vaccines; [REDACTED] -Stab Lageführung COVID19.BMG; [REDACTED]
Subject: Impact Röntgenstrahlung
Date: Mittwoch, 6. Oktober 2021 17:28:26
Attachments: [BNT-Europe.png](#)
[LI-In-Bug.png](#)
[Twitter_Social_Icon_Rounded_Square_Color.png](#)

Liebe [REDACTED]

Sie hatten bei unserem letzten Jour Fixe eine Frage zu Röntgenstrahlung gestellt, dazu können wir folgende Informationen übermitteln:

[REDACTED]
[REDACTED] Similar biologics showed reasonable chemical and colloidal stability when exposed to multiples of the possible X-ray radiation levels resembling cosmic radiation or personal, baggage, or cargo screening methods. Independent studies have demonstrated the protective effect of disaccharides, such as sucrose, in protecting radiation-induced DNA damage in cells, and the cellular functionality by gamma-rays.² Important to note that x-rays are generally low energy compared to gamma-rays, hence less penetrating.³

Based on the rationale and references cited above, it is BioNTech's position that exposure to X-ray during routine transportation of frozen BNT162b drug product can be assigned a low risk for affecting product quality.

References:

[REDACTED]
² Yoshinaga et. al., *Biosci. Biotech. Biochem.*, 61 (1), 160-167, 1997.

³ IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. *Ionizing Radiation, Part 1: X- and Gamma (γ)-Radiation, and Neutrons. Lyon (FR): International Agency for Research on Cancer; 2000. (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 75.) X-radiation and γ -radiation. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK401331/>*

Mit besten Grüßen

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