

Extractables/leachables assessment of COVID vaccines

Part 2: Oxidized BHT

Usually, the primary packaging of COVID vaccines consist of a glass vial and a rubber stopper. Pfizer/BioNtech, AstraZeneca, Moderna and Johnson&Johnson uses halobutyl rubber [1] [2] [3]. Common extractables from halobutyl rubber stoppers are rubber oligomers and the antioxidant BHT [4].

„Butylated hydroxytoluene (BHT) is used as an antioxidant in many products including food, pharmaceuticals, cosmetics, jet fuels, rubber, paint, and petroleum products. It is also on the Food and Drug Administration’s (FDA) list of compounds generally regarded as safe (GRAS)” [5].

However, as antioxidant it protects the elastomer against oxidation, while being oxidized itself.

One oxidation product is BHT-quinone methide (BM-QM), an electrophilic compound with high reactivity toward thiol and amino groups [5], [6].

ASAS Labs has initiated a project to investigate the interaction rubber extractables with nucleosides like adenosin, uridine and guanosine as model substrates for RNA. The reactivity of rubber oligomers among nucleosides was already demonstrated [7]. In part 2, the reactivity of nucleosides towards oxidized BHT was investigated.

Reaction products for each nucleoside were observed. The adducts were identified using high resolution accurate mass spectrometry. Details can be found [here](#).

[1]: <https://www.anaphylaxis.org.uk/covid-19-advice/pfizer-covid-19-vaccine-and-allergies/>

[2]: <https://www.sps.nhs.uk/articles/advising-individuals-with-allergies-on-their-suitability-for-moderna-covid-19-vaccine/>

[3]: <https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf>

[4]: <https://ddfevent.com/media/12249/simon-kervyn.pdf>

[5]: [Maren Gulsrud Willcockson 2011](#)

[6]: [Pro-electrophiles: A source of protein-reactive extractable not covered by most screening methods](#), A.Stratmann, S.A. Watt, L. Martens

[7]: [Extractables/leachables assessment of COVID vaccinesPart 1: Rubber oligomers](#)