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Publication: Comprehensive extractables and leachables sensitization analysis...

Interesting paper on sensitizers in parenteral drug products.:

„Comprehensive extractables and leachables sensitization analysis and practical application of a risk-based approach to sensitization assessment for parenteral drug products“

Regulatory Toxicology and Pharmacology, Volume 157, March 2025, 105776

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Somewhat hidden in the supplementary data, there are information on rubber oligomer C₂₁H₃₉Br (CAS 2518227-14-8): "No *in vivo* data, Predicted extreme sensitizer". However, in the paper, this compound is not further mentioned. For other compounds also classified as extreme or strong sensitizers, it is mentioned "Not expected as leachables in aqueous conditions due to rapid hydrolysis" (e.g. diisocyanates) and "No observations as E or L" (e.g. Dibutyl fumarate).

Well, C₂₁H₃₉Br is a common extractable from bromobutyl rubber and it will not hydrolyse in aqueous solutions (the compound is insoluble in pure water but soluble in presence of co-solvents or detergents). What is the appropriate threshold for this compound?