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Buy [Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products](#) 1 by Ball, Douglas J., Norwood, Daniel L., Stults, Cheryl L. M., Nagao, Lee M. (ISBN: 9780470173657) from Amazon's Book Store. Everyday low prices and free delivery on eligible orders.

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xi The establishment of data-based safety thresholds for leachables and extractables in orally inhaled and nasal drug products (OINDPs) is an important scientific advancement that helps OINDP manufacturers make knowledge-based safety and risk assessments for extractables and leachables and ensure the safety of their products for patient use.

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Addressing the concepts, background, historical use, and development of safety thresholds and their utility for qualifying leachables and extractables in OINDP, the Leachables and Extractables Handbook takes a practical approach to familiarize readers with the recent recommendations for safety and risk assessment established through a joint effort of scientists from the FDA, academia, and industry.

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The well-known proverb "Don't judge a book by its cover" is, at first glance, confirmed by Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products.

[Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults, and Lee M. Nagao](#)

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A safety assessment for extractables or leachables is the process by which the effect of extractables or leachables on user health is established. As the issues associated with a direct assessment the leachables' effect on patient safety are significant, safety effects are typically assessed indirectly.

[Identification, analysis and safety assessment of](#)...

• SCT: Safety Concern Threshold is defined as the threshold below which a leachable would have a dose so low as to present negligible safety concerns from carcinogenic and non-carcinogenic toxic effects. The safety concern threshold (SCT) for extractables and leachables has been defined as 0.15 µg/day.

[Extractables and Leachables--An Introduction](#)

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