

TECHNOLOGY HIGHLIGHT

Nitrosamine Mitigation Simplified with NEW N-SorbSM Drop-In Molded CoreTech



Stop Nitrosamine Formation Before it Starts Without Disrupting Your Packaging Line

Nitrosamine-related recalls are on the rise, regulators are tightening Acceptable Intake (AI) limits, and reformulation can take months. But there's another option that can help you solve this challenge today without changing your packaging line. Aptar's N-SorbSM technology is an active material science solution that captures and neutralizes nitrosamine precursors in the packaging headspace before they can react. By inhibiting nitrosamine formation at the source, N-SorbSM delivers proactive protection without disrupting your manufacturing process.

Powered by the company's proprietary Activ-PolymerTM platform technology, N-SorbSM offers a simple and elegant solution to a chemically complex problem. Originally engineered as an Activ-FilmTM material, the technology is now being deployed as a molded drop-in component — N-SorbSM CoreTech — that can be seamlessly implemented on existing bottle-based packaging lines.

Customizable Protection: Designed for Complexity

Nitrosamine impurities can arise through multiple pathways and is mechanistically complex. Formation is often driven by formulation-specific interactions between nitrosating agents (such as nitrites), secondary amines from APIs or excipients, and environmental triggers like humidity, heat, or residual solvents. N-SorbSM technology is adaptable to your drug's unique risk profile, enabling a targeted mitigation strategy that gives you confidence in meeting compliance and assuring patient safety.

Data Review

The graph below shows the results of a study exploring how N-SorbSM technology can reduce nitrite concentration in placebo tablets. The experimental method was as follows:

- 2 in² of N-SorbSM mitigation film
- Film and 11 tablets (66% MCC, 33% Lactose, 1% Mg. St.)
- Sealed in foil bag
- Aged 180 days at 25°C
- Characterization by Greiss reaction on LC-UV/VIS (LOQ = 0.1 ppm)

All N-SorbSM films reduced nitrite concentration with N-SorbSM B delivering a >84% reduction (Figure 1).

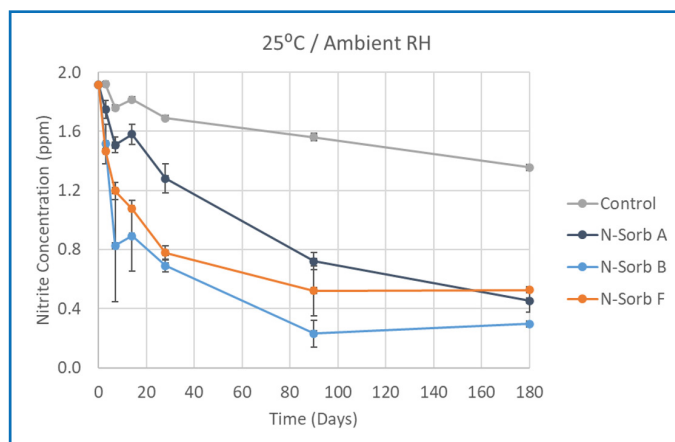


Figure 1: Nitrite Concentration in placebo tablets in the presence of N-SorbSM films

KEY ADVANTAGES

✓ Seamless Integration

N-SorbSM CoreTech is inserted during the bottle filling process using the same methodology for dropping in a typical desiccant canister. No equipment changes are required. This enables fast and frictionless deployment across oral solid dose lines.

✓ Targeted Nitrosamine Control

N-SorbSM CoreTech is custom-engineered to capture the nitrosamine precursors or volatile nitrosamines impacting your specific formulation. Additionally, the rate at which these target molecules are scavenged is customized to provide stable protection over time with maximum capacity.

✓ Speed to Market

N-SorbSM technology, including the new CoreTech format, can help companies solve their nitrosamine challenges without reformulation or sourcing new packaging materials. The new format not only avoids the lengthy reformulation process, but its simple drop-in format overcomes potential implementation challenges.

✓ Regulatory & Quality Alignment

The N-SorbSM technology platform has been accepted into the FDA's Emerging Technology Program (ETP), which allows Aptar to work directly with the FDA, ensuring a development and validation plan for N-SorbSM technology that can potentially meet and exceed regulatory expectations. Data from ongoing testing efforts conducted as part of the ETP discussions have shown that N-SorbSM has the potential to reduce nitrosamine levels below the Acceptable Intake (AI) limits set by the FDA and other regulatory authorities (EMA, Health Canada, Japan's PDMA).

✓ Powered by Proven & Trusted Technology

N-SorbSM technology is built on Aptar's Activ-PolymerTM platform, which has been used successfully to protect pharmaceutical drugs, medical devices, implants, diagnostic tests, and other sensitive products for decades. Companies around the globe trust our technology to prevent degradation, mitigate impurity risk, and extend shelf life of their products in order to keep their promises to their customers.

Let's Talk!

Whether you have an urgent nitrosamine challenge you need to solve or are working on future sensitive formulations and want to future-proof your drug, N-SorbSM can give you a strategic edge. Contact us today to request technical data, pilot samples, or a consultation on how N-SorbSM can be tailored to your formulation's specific risk profile.

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