

## PRESS ARTICLE

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### **SIDEL ANNOUNCES FDA APPROVAL OF ITS ASEPTIC COMBI PREDIS BLOW FILL SEAL FILLER FOR LOW ACID PRODUCT MANUFACTURING IN THE U.S.**



**Sidel has received Food and Drug Administration (FDA) approval for its Aseptic Combi Predis™ FMa blow fill seal filler following tests run at a dairy customer in North America. This means that the Sidel Aseptic Combi Predis FMa PET filler is validated for low acid manufacturing and commercial distribution in the United States market. The Sidel Aseptic blow fill seal solution is the world's first aseptic PET filling equipment with dry preform sterilisation approved by FDA.**

“We are particularly proud of this FDA acceptance”, explains Guillaume Rolland, Sensitive Products Director at Sidel. “It confirms our Aseptic Combi Predis design is compliant with the FDA’s current Good Manufacturing Practice (cGMP) requirements.” This FDA approval officially qualifies the Sidel aseptic solution with dry preform sterilisation technology to produce and distribute shelf-stable low acid products in PET bottles for the US market.

#### **Independent evaluation from experienced organisation**

The Process Authority for the Sidel aseptic filler was Dover Brook Associates (DBA). DBA applied their 30 years of professional experience in sterile processes to validate the scheduled processes of the Aseptic Combi Predis. Using a scientific-based approach of specific tests and acceptance criteria, DBA was able to prove that the scheduled processes were in compliance with the predicate rules and expectations of the FDA so that the equipment could produce a commercially sterile low acid product.

The successful completion of this extensive and exhaustive evaluation process confirms the performance of the other 100 Combi Predis lines in operation worldwide. Sidel’s key accounts, along with co-packers and local brands, have been manufacturing low and high acid products using PET line applications for nearly 10 years. This regulatory acceptance demonstrates how the Sidel patented technology is 100% safe for the packaging of UHT milk, soymilk, coconut water, or teas in PET bottles, sold through the ambient chain market in the US and the rest of the world.

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### **A scientific approach for regulatory validation**

The Sidel Aseptic Combi Predis merges dry preform sterilisation with aseptic blowing, filling and sealing functions within a single production enclosure and respects the fundamental concept which underpins state-of-the-art aseptic packaging rules: producing a commercially sterile product, filled in a sterile zone, in a previously sterilised package. It differs from traditional aseptic technology because the package sterilisation takes place at the preform rather than at the bottle phase.

DBA conducted a detailed review of the design, critical factors, and the sterile zone boundaries. The stringent validation tests were performed on a commercial filler producing aseptic UHT milk, and all the tests were successfully passed. "We accumulated more science from these tests performed with DBA. They challenged and validated the process and the technology itself", explains Arnaud Poupet, Aseptic Product and Platform Manager at Sidel. DBA concluded that the minimised sterile zone provided a safe and successful aseptic process that produced a commercially sterile, hermetically sealed bottle. "DBA's testing demonstrated that the sterile zone during the blowing process was the critical component, not the blow-moulding zone itself, which was due to the Sidel patented dry-preform sterilisation technology", comments Poupet. The scheduled processes require minimal critical factors, which have to be monitored during the production, cleaning and sterilisation phases of the aseptic process. The critical parameters are continuously monitored to ensure full production sterility, beverage integrity and food safety. "Our best warranty for food safety is simplicity, because a line with a small sterile zone and minimal critical factors is managed more safely, easily and effectively," continues Poupet.

"We partnered with one of the major dairy producers in North America who was confident of the safety and efficiency of the Aseptic Combi Predis. He invested in the solution to introduce new UHT liquid dairy products in PET bottles. Under the coordination of DBA, we went through a rigorous FDA qualification process at the FDA registered customer site", explains Poupet. The Aseptic Combi Predis approved by the FDA is very similar to the existing machines installed for aseptic production in customers' plants worldwide.

### **A proven technology successfully implemented worldwide**

Sidel's reputation is built on a long history and experience with sensitive products: 40 years in aseptic beverages and dairy bottling solutions, more than 35 years in PET packaging and 50 years in blowing. Sidel was a pioneer in preform sterilisation, allowing the first production of PET bottles for UHT milk on a Sidel aseptic Combi with this dry preform sterilisation technology in 2002. With its proven and patented solution, Sidel Predis, Sidel continues to enjoy a leading position in sensitive beverages and liquid dairy production technology. Sales of Sidel Predis have grown steadily as companies throughout the world have recognised the benefits it offers: safety and simplicity, cost-effectiveness, no water and use of very few chemicals (offering significant environmental advantages). More than 100 Combi Predis installations worldwide are a clear endorsement of this technology by major beverage and dairy companies, many of which produce leading national and international brands. The high level of customer satisfaction is ultimately the best indicator of the reliability of the technology.

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### About Sidel

Our purpose is to help brands protect the product inside, preserve the planet outside and touch the lives of millions of people every day.

We do so by offering complete and modular PET, can and glass packaging solutions, including people, services and equipment.

Sidel has over 165 years of industrial experience. With 30,000 machines installed in more than 190 countries, we have been helping producers fill beverage bottles for over 85 years, blow them for more than 50 and label them for more than 40. We have over 40 years of aseptic packaging expertise, and were one of the first companies to introduce PET bottles to the beverage industry over 35 years ago.

Part of the Tetra Laval group, Sidel has offices worldwide, including 8 production sites and 8 training centres. All our experts are committed to creating the optimum liquid-packaging solution.

We call it **A Better Match** - for our world, our customers and ourselves.

Find out more at [www.sidel.com](http://www.sidel.com) and connect with us



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