



CORNING

THE EVOLUTION OF THE PHARMA ECOSYSTEM: PRODUCT PERFORMANCE NOW MEETS SUSTAINABILITY

Here, Bettine Boltres, PhD, Director Scientific Affairs and Technical Solutions, Glass Systems at West Pharma, and Shivani Polasani, Product Development Manager at Corning, discuss how the pharma industry can progress towards a more sustainable future and consider the role that the Corning/West collaboration can play in supporting pharma's sustainability goals.

In an industry where compassion and empathy for humankind are deeply rooted and values widely subscribed to, it should come as no surprise that the pharma industry is making significant efforts to address the sustainability conundrum. Whether as a pharmaceutical manufacturer or drug containment provider, the industry's primary role is to enhance and help save the lives of patients, ensuring that the safety and efficacy of the drugs used are safeguarded without compromise. That said, there is now an equally vital imperative – to support the global impetus to reduce carbon dioxide equivalent (CO₂e) emissions and help to create a more sustainable planet.

The question is therefore not if, but how, we can work towards a more sustainable future while protecting the interests of the patients we serve. The answer, specifically in injectables, has unequivocally been answered by the work undertaken by the West Pharmaceutical Services and Corning Incorporated collaboration.

THE SIZE OF THE CHALLENGE SHOULD NOT BE UNDERESTIMATED

According to Deloitte, the global greenhouse gas emissions directly generated by the pharma industry are estimated to be around 52 megatonnes of CO₂e per year.¹ This figure does not include indirect energy-related emissions through the entire supply chain, such as transportation, cold chain, etc, which contribute further to the final figure.

Another report estimates that the industry generates about 48.55 tonnes of CO₂e per US\$1 million (£821,000) in revenue generated, which is 55% higher than the emission intensity estimated for the automotive industry, i.e. 31.4 tonnes of CO₂e per \$1 million generated.²

If we take the injectables segment, Corning estimates that over 150,000 tonnes of Type 1 borosilicate glass is used annually in the global production of pharmaceutical vials. Due to complex regulations, most



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"The simple reality is that pharma and its supply chain partners must continue to do more work together to achieve greater sustainability heights while ensuring that the safety and efficacy of the drugs manufactured is maintained."

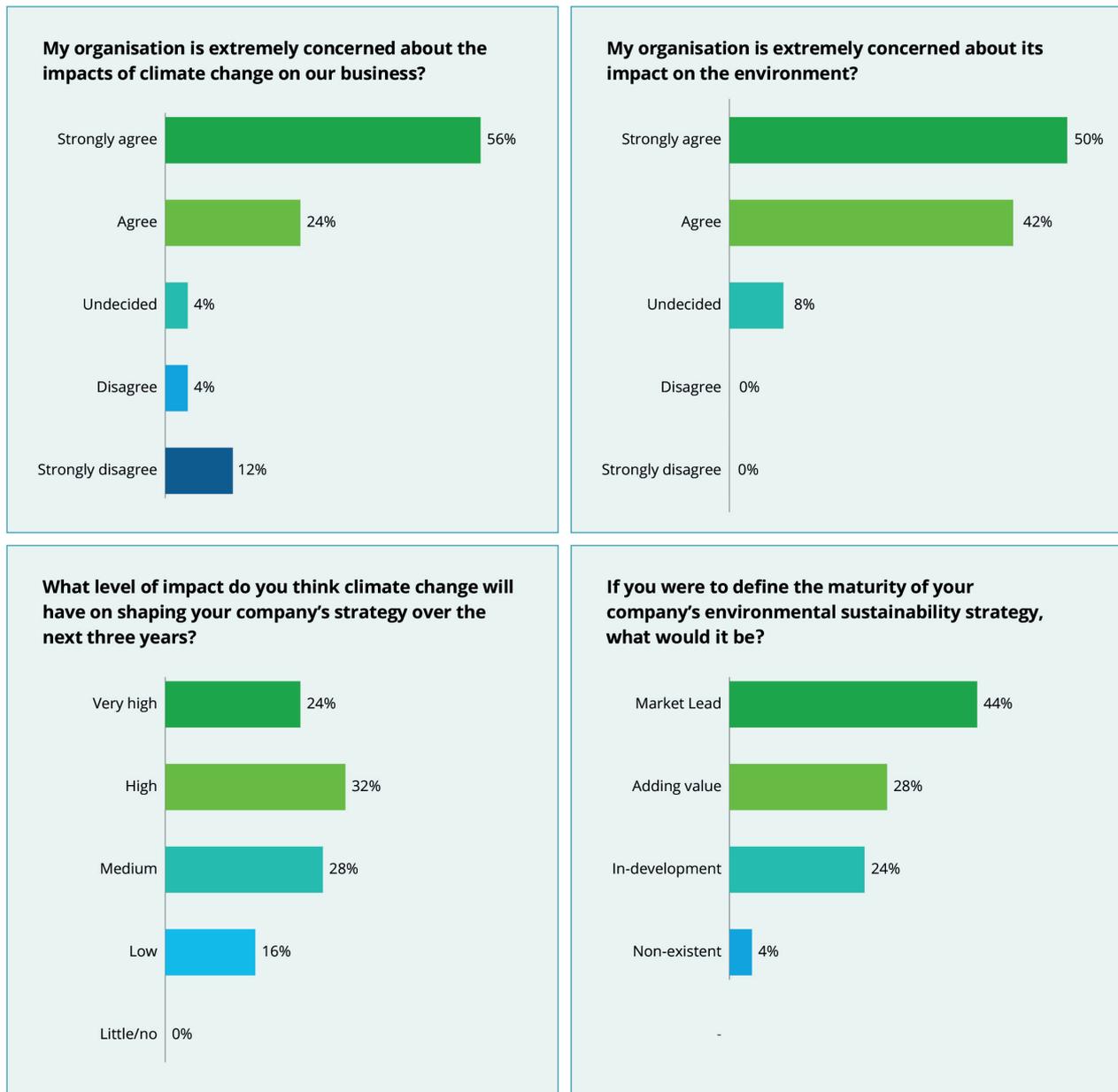


Figure 1: Pharma's attitudes towards sustainability.⁴

of this glass is discarded as medical waste each year, filling landfills across the world, according to internal estimates based on Corning Type 1 glass tubing production and awareness of industry capacity.

The simple reality is that pharma and its supply chain partners must continue to do more work together to achieve greater sustainability heights while ensuring that the safety and efficacy of the drugs manufactured is maintained. West believes that sustainability should be considered an integral component along with safety, efficacy and the manufacturability of pharmaceutical drugs.

In response to this imperative, many pharma companies have adopted ambitious plans with measurable goals; however, such a transformative change does not happen

overnight and, for some, bridging the gap between high aspirations and meaningful, measurable action can be challenging.

THE HEAT IS ON

A greater number of consumers and investors are paying real attention to a brand's sustainability track record and overall values when it comes to company reputation and ethics. Beyond product performance, more and more are now actively discerning which brands to purchase or invest in based on criteria such as sustainable packaging, reduced waste in manufacturing, a commitment to ethical manufacturing standards and reducing overall global warming potential (GWP).³

This attitude is not lost on pharma

executives. Indeed, in one report, 80% of sustainability leaders in pharma said that they "strongly agreed" or "agreed" that their organisation was extremely concerned about the impact of climate change on their business, with 92% reporting that they were concerned about their organisation's impact on the environment.⁴

As global warming continues to threaten the planet, there is therefore no question that the heat is on to address the GWP of all manufacturing operations, including pharmaceuticals. There is, of course, another important dynamic to this imperative – how to ensure any improvements made in terms of sustainability do not compromise the safety, efficacy and operational efficiency embedded in the manufacturing of pharmaceutical products (Figure 1).

PERFORMANCE MUST MEET SUSTAINABILITY

Building on the recent collaboration with West and Corning, which brings together more than 200 years of experience, the team is now taking on this challenge and is excited to bring Corning® Viridian™ vials to the market, directly addressing the thorny challenge of meeting performance and sustainability together in a system-level containment solution. The exclusive supply and technology agreement provides pharma partners with access to some of the most innovative products in parenteral drug delivery.

Corning® Viridian™ Vials are a transformative innovation that reduce glass waste and manufacturing emissions without compromising manufacturing efficiency. Indeed, data demonstrate that Viridian™ Vials reduce material waste by 20%, while reducing CO₂e emissions by up to 30%.* Additionally, filling-line data with Optima (a leading manufacturer of fill-finish equipment based in Schwaebisch Hall, Germany) demonstrates the ability of Viridian™ Vials to increase fill-finish efficiency by up to 50%.** It can also reduce cosmetic rejects and lower glass particle generation by up to 96% (Figure 2).

As a design that included sustainability from first principles, the Viridian™ Vial is a market first. The metrics have been

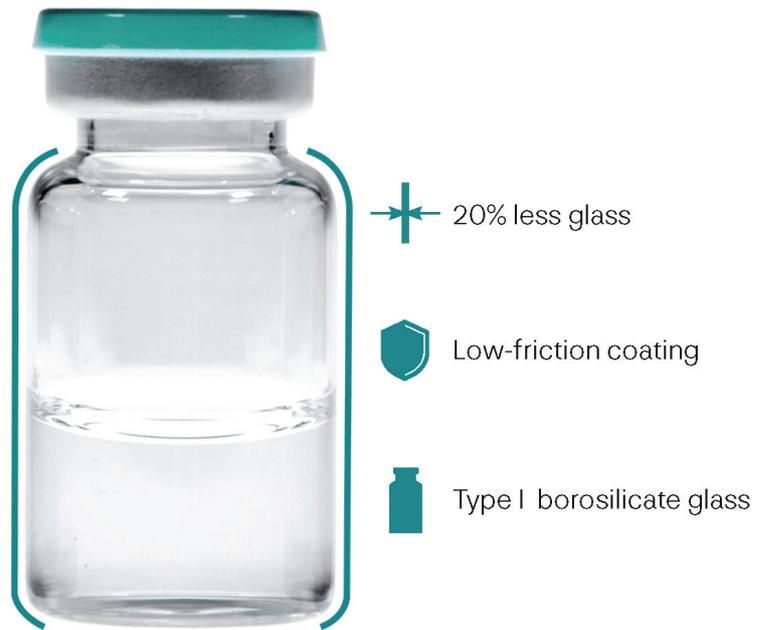


Figure 2: Viridian Vials' protective external coating can reduce damage that leads to cracks, breaks and cosmetic rejects.

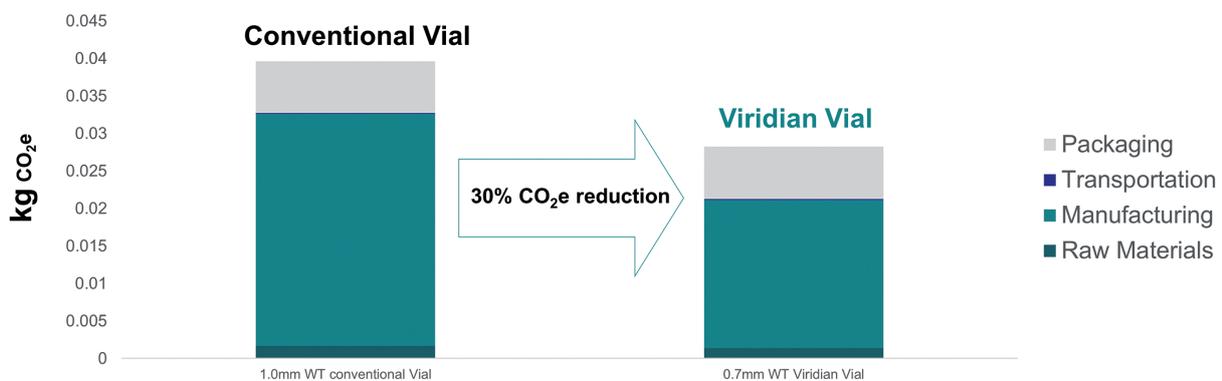
achieved by reducing the wall thickness of the vial, reducing the overall mass from the conventional 2R that weighs 4.4 g. There is another added sustainability advantage too – a thinner wall creates additional capacity in the vial itself, enabling the use of potentially fewer vials to meet demand.

Taking the additional step to substantiate emission reduction claims, Corning worked with Sphera, a leading provider of Environmental, Social and Governance

performance and risk management software, to conduct a cradle-to-gate, third-party lifecycle assessment (LCA), which compared Corning® Viridian™ vials with conventional borosilicate vials. The report discusses how Viridian™ Vials can reduce CO₂e emissions by up to 30%. Furthermore, the report additionally shows that even compared with conventional vials manufactured with 100% renewable electricity, Viridian™ Vials can reduce

30% Reduction in vial manufacturing emissions

Cradle-to-Gate: Emissions from raw material extraction to vial shipment



CORNING • Assumes use of Non-renewable electricity for production of 1.0mm wall thickness conventional vials

Figure 3: Third-party LCA of 2R standard conventional vials with 1.0 mm thickness vs Viridian Vials with 0.7 mm wall thickness.

Reducing Corning's Scope 1, 2, and 3 emissions enables lower Scope 3 emissions for customers

Example: Assumes renewable electricity sources for Viridian Vials and none for conventional vial | up to 30% reduction in CO₂e

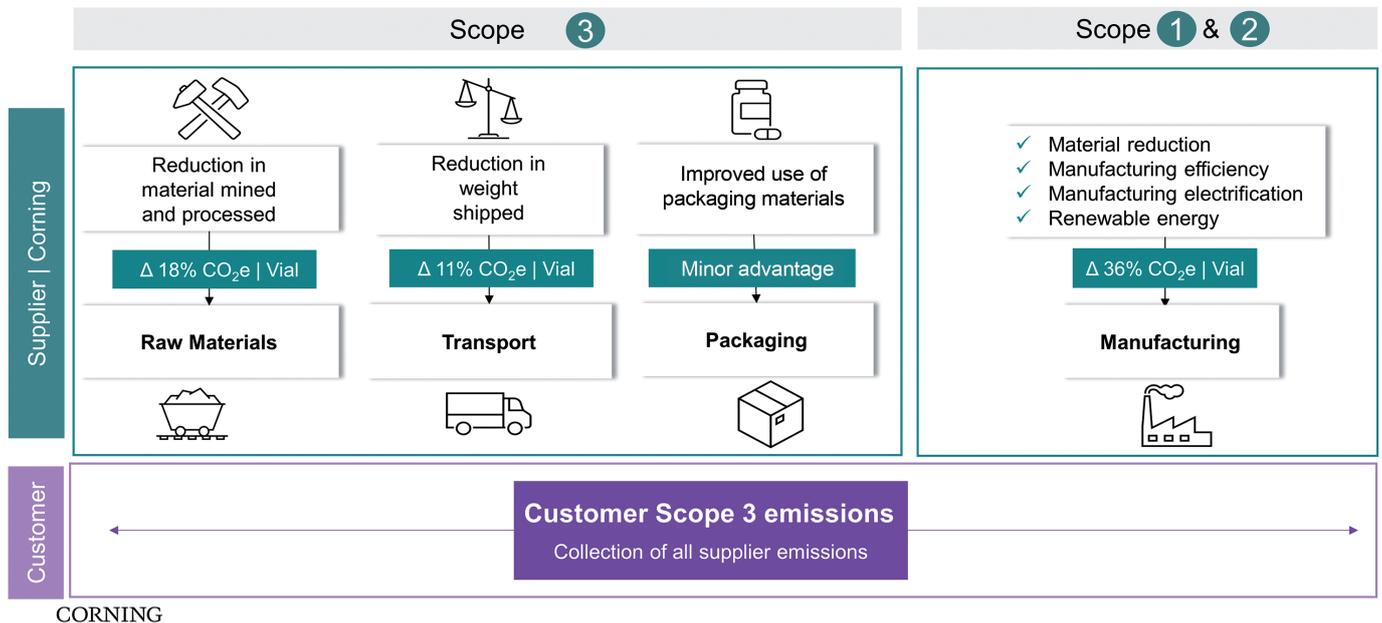


Figure 4: Reducing Corning's scope 1, 2 and 3 emissions enables lower scope 3 emissions.

emissions by up to 15%. The LCA is currently undergoing independent peer review to further validate the claims.

LOWER GWP, SAME SPECIFICATION, NO COMPROMISE

Breaking down the per-vial CO₂e improvement by category, the LCA shows a reduction of 0.3 g of CO₂e from raw material extraction, 11.2 g of CO₂e from manufacturing (tube forming, converting and coating) and 0.03 g of CO₂e from tube and vial transportation. If these data were extrapolated to 10 million vials, Viridian™ Vials could save up to 114,000 kg of CO₂e, which is equal to consuming more than 12,900 gallons of fuel, and eliminate around nine tonnes of glass from landfill waste (Figure 3).⁵

Additionally, Viridian™ Vials, being borosilicate glass, are compliant with USP <660> Type I hydrolytic resistance testing and Ph. Eur. 3.2.1. They also meet ISO standards regarding outer and neck dimensions to mitigate the need for change parts on customer filling lines that already use ISO standard borosilicate vials (Figure 4).

A PRODUCT IS NO GOOD IF YOU CAN'T HANDLE IT

In the development of Viridian™ Vials, it was essential that vial performance

was not impacted by the product design. To this end, Viridian™ Vials can be seamlessly integrated into current fill-finish production facilities without the need for change parts on filling-line equipment and with equivalent or better vial breakage rates. The important point here, as the Optima data demonstrate, is that a thin-wall vial will have a high breakage rate and will not maintain performance rates without Corning's protective coating.

Viridian™ Vials are equipped with Corning's proprietary exterior coating that ensures the vial has a low coefficient of friction and maintains glass strength through fill-finish processing and transportation. This provides the basis for improved throughput and reduces the likelihood of vial damage, rejects and glass particles. Indeed, the external coating used on Corning® Valor® Vials and Viridian™ Vials can improve filling-line efficiency by 20% to 50%,⁶ with a reduction in the likelihood of damage that leads to cracks and breaks and a 96% reduction in glass particles.⁷ Improved efficiency also supports a reduction in pharmaceutical production costs.

PROVING PERFORMANCE

In collaboration with Optima, two vial types were tested; a standard uncoated 2R borosilicate vial (4.4 g) and a 2 mL

Viridian™ Vial (3.5 g). The vials were run at 450 vials per minute and recirculated >120 times, simulating >200,000 vials processed for each group. The trial resulted in no breakages being observed in washing, depyrogenation, accumulation, singulation or while at the star wheels. The Viridian™ Vials demonstrated a lower tip over rate compared with conventional vials. There were no functional issues with washing or depyrogenation and no need for modification of fill-finish processes not additional change parts required.

THE PHARMA SUPPLY CHAIN HAS AN OBLIGATION TO DO MORE

When reporting emission data, the international standard is to classify energy usage and emissions into three categories, scope 1, 2 and 3. The three scopes are a way of categorising the different kinds of emissions that a company creates in its own operations (scope 1 and 2) and in its wider value chain (scope 3). The Greenhouse Gas Protocol defines it as "Developing a full [greenhouse gas] emissions inventory – incorporating scope 1, scope 2 and scope 3 emissions – enables companies to understand their full value chain emissions and focus their efforts on the greatest reduction opportunities".⁸

While scope 1 covers emissions that an organisation owns or directly controls, scope 2 emissions are those that a company indirectly causes and come from the energy it purchases. Scope 3 encompasses emissions that an organisation is indirectly responsible for, up and down its value chain. Pharmaceutical companies are looking for suppliers to develop innovative solutions to support scope 3 emission reductions. Recently, much of the narrative at industry events has been about engaging the supply chain in helping pharma manage its scope 3 commitments.

Of course, in this setting, innovation needs to be “feasible”, meaning a drop-in solution that is accessible and balanced with pragmatism – the time/cost/risk paradigm is a paramount consideration for pharma. This is where Viridian™ Vials really deliver true value – they deliver demonstrable benefits with careful consideration to maintaining specification and operational efficiency. But this is just the beginning; the Corning/West collaboration will continue to innovate and further improve to support pharma’s sustainability efforts.

CONCLUSION

The supply chain has responsibility to work in partnership with pharma to better support its scope 3 commitments. There are, of course, many ways to achieve that goal, such as to improve operational efficiencies to increase the speed of manufacturing and reduce energy consumption, or invest in renewable energy, among others. To change the game regarding sustainability, there needs to be a measured and innovative approach. The first-of-its-kind Viridian™ Vial was created not only from a product perspective but from a wider ecosystem

standpoint, delivering real gains in sustainability while positively impacting the overall sustainability credentials of the manufacturing environment. Hence, designing for sustainability does not need to cost the earth or compromise on traditional key performance indicators. The heat is on, but there is now a tangible opportunity to contribute to dialling down the temperature and delivering on those scope 3 sustainability aspirations.

* *Corning in-house data – independent LCA by Sphera.*

** *Corning in-house data.*

ABOUT THE COMPANIES

West Pharmaceutical Services is a leading provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps to ensure the safe, effective containment and delivery of life-saving and life-enhancing medicines for patients. With 10,000 team members across 50 sites worldwide, West helps to support customers by delivering approximately 47 billion components and devices each year.

Corning is one of the world's leading innovators in materials science, with a 170-year track record of life-changing inventions. Corning applies its unparalleled expertise in glass science, ceramic science and optical physics, along with its deep manufacturing and engineering capabilities, to develop category-defining products that transform industries and enhance people's lives. Corning succeeds through sustained investment in research, development and extension, a unique combination of material and process innovation and deep, trust-

based relationships with customers who are global leaders in their industries. Corning's capabilities are versatile and synergistic, which allows the company to evolve to meet changing market needs, while also helping its customers capture new opportunities in dynamic industries. Today, Corning's markets include optical communications, mobile consumer electronics, display, automotive, solar, semiconductors and life sciences.

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ABOUT THE AUTHORS

Bettine Boltres, PhD is Director Scientific Affairs and Technical Solutions, Glass Systems, supporting the scientific exchange between West and the pharmaceutical industry. This complements her work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging and wrote the book *When Glass Meets Pharma*. Since January 2019, she has been a member of the PDA Board of Directors. Since 2015, Dr Boltres has been an active member of the USP Packaging and Distribution Expert Committee, as well as the European Pharmacopoeia Commission Group of Experts 16 (elastomers), and the GLS Working Party (glass) and convenor of the ISO TC76/WG 4 on elastomers and member of the WG 2 on rigid containers.

Shivani Polasani, Product Development Manager, Corning Pharmaceutical Technologies, has over 10 years of experience in product and process development, spanning diverse early-stage technologies at Corning’s Sullivan Park Research and Development Facility. Ms Polasani currently leads a group focused on the development of product requirements, measurement methods and understanding product applications. She joined Corning in 2011 and has worked in R&D and Corporate Engineering. Ms Polasani holds a BS in Biochemistry from SUNY Geneseo (NY, US) and an MS in Chemistry from the University of Maryland (US).



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Corning® Viridian™ Vials are your drop-in solution to eco-conscious Type I pharmaceutical packaging. Experience a 30% reduction in cradle-to-gate Scope 3 emissions related to vial manufacturing and a notable decrease in material waste, all while ensuring accelerated and efficient fill-finish operations. Viridian Vial's innovative external coating enhances performance, delivering up to 50% increased fill-finish efficiency and a 96% reduction in glass particles.

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