Sustainability and Single-Use Systems: From Vision to Action

Magali Barbaroux, Sustainability Committee Chair Vachette, Elisabeth - Sartorius Narendar, Yeshwanth – Saint Gobain Mitchel, Matt - Avient





ECISUTVI



2023 Sept. 10-13 Boston MA Hyatt Regency Hotel

Single-Use Technologies : Established, Emergent, Agile, Sustainable?

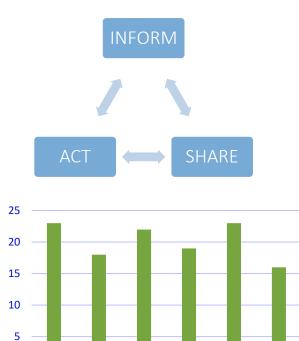
REGISTRATION IS OPEN

https://engconf.us/conferences/biotechnology/single-use-technologies-vi/

Conference Chairs Magali Barbaroux (Sartorius) Sheryl Kane (Takeda) Seongkyu Yoon (U-Mass Lowell)

BPSA Sustainability (technical) Committee

Board Sponsor : Brian Chung, Solvay | Committee chair : Magali Barbaroux, Sartorius



Mission

- Provide members information on how SUT support biomanufacturing call for sustainability & takes actions to prove BPSA seriously tackle sustainability concerns.
- Allow members to be informed on environmental sustainability tools and trends in the biomanufacturing and polymer industry, to share ideas and good practices.

Members

- Approx. 42 active members (attended at least one monthly meeting) (33 in 2022)
- Average of 20 attendees | meeting (18 in 2022)



FFP

MAR

Attendance 2023

JAN

IUN











Thank you

Baillie, Megan - Barrentine, Robert - Bogen, Jon - Calmels, Caroline - Chen, Joy - Chung, Brian - Clark, Chris - Cook, Hubert - Collins, Francois - Cormier, Bryce - Cousin, Olivier - Daumke, Ralph - Ettie, Derek - Flanagan, Shannon - Grube, Kallee - Hanson, Colin - Heiler, Dianne - Horowski, Brian - Horst, Kendall - Jarmey-Swan, Claire - Jermyn, Christian - Kamph, Evan - Kuyl, Pierre - Love, Calum - Mariner, Amanda - McCool, Jeanette - Miles, Merete - Mitchell, Matt - Narayanan, Ravi - Narendar, Yeshwant - Ouellette, Matthew - Petrich, Mark - Roalandt, Elke - Shih, Cherry - Snyder, Mitchell - Springael, Sabine - Strohben, Bill - Tan, Chor Sing - Vachette, Elisabeth - Young, Don

Active contributors :

 Avient, Burkert, Corning, Cytiva, Daikin, DPS, DuPont, Entegris, GSK, GEA, Gore, High Purity England, , ILC Dover, KrystalBio, NewAge, Nordson Medical, Meissner, Pfizer, PendoTECH, Qosina, Repligen, RubiusTherapeutics, Saint-Gobain, Sartorius, Sealed Air, Solvay, ThermoFisher, Watson Marlon, Wood





Content :

- Context and ideality
- Case studies, illustrations
- Q&A



Bio-Process Systems Alliance Advancing Single-Use Worldwide



The UN's sustainable development goals context

- Triple bottom line: People Planet Profit
- 17 Interconnected goals
- Corporate Challenge
 - Identify THE driving goal
 - As we can, contribute to others
 - Activities must be transparent
 - Can't be achieved alone







Reasons for Industry Adoption of SU Technologies

- Improved consistency in manufacturing processes
- Flexibility to design a purpose-built facility and the ability to amend SU technologies as needed
- Fast process deployment and changeover
- Less initial investment in fixed equipment enabling significant cost-savings
- Reduced water use due to the elimination of steaming and cleaning procedures
- Smaller facility footprint reduces the requirement for HVAC, the most significant factor for energy usage in the facility





Biotech industry environmental landscape

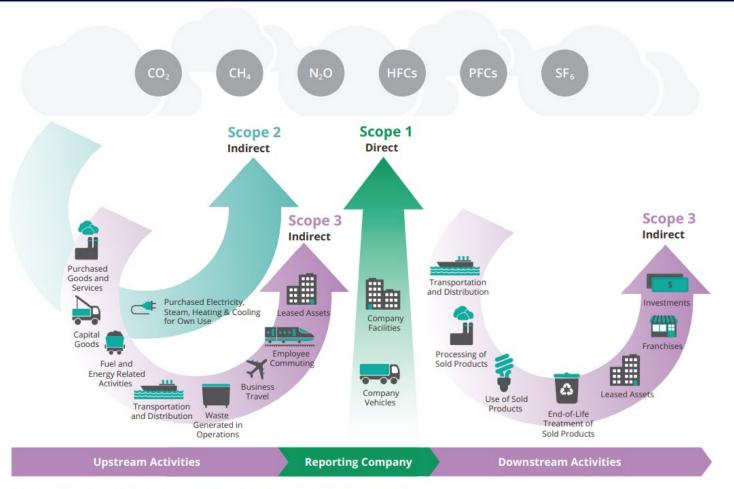


European Federation of Pharmaceutical Industries and association PIE = pharmaceutical in environment -https://www.efpia.eu/about-medicines/developmentof-medicines/regulations-safety-supply/environment-health-safety-and-sustainability/

- A 2019 study found that the climate footprint of healthcare was representing 4.4% of total global emissions ⁽¹⁾
- Total amount of carbon emitted | year by public companies in the biotech and pharma industry is more than the semiconductor or forestry and paper industry sector.⁽²⁾
- Fast-growing global biotech and pharma industry = significant contributor to climate change but beginning to move in the right direction, with some of the largest companies demonstrating leadership on emissions reductions⁽³⁾
 - (1) <u>https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_090619.pdf</u>
 - (2) <u>https://www.mygreenlab.org/blog-beaker/my-green-lab-measures-carbon-impact-of-biotech-and-pharma</u>
 - (3) The Carbon Impact of Biotech & Pharma, October 2022 (mygreenlab.org)



Toward Carbon Neutrality



 For most industries — biotech and pharma is no exception — scope 3 emissions are significantly larger than scope 1 and 2 combined.

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To understand the true carbon impact of an industry, critical to evaluate the entire carbon footprint, including scope 3 emissions in the upstream and downstream value chain

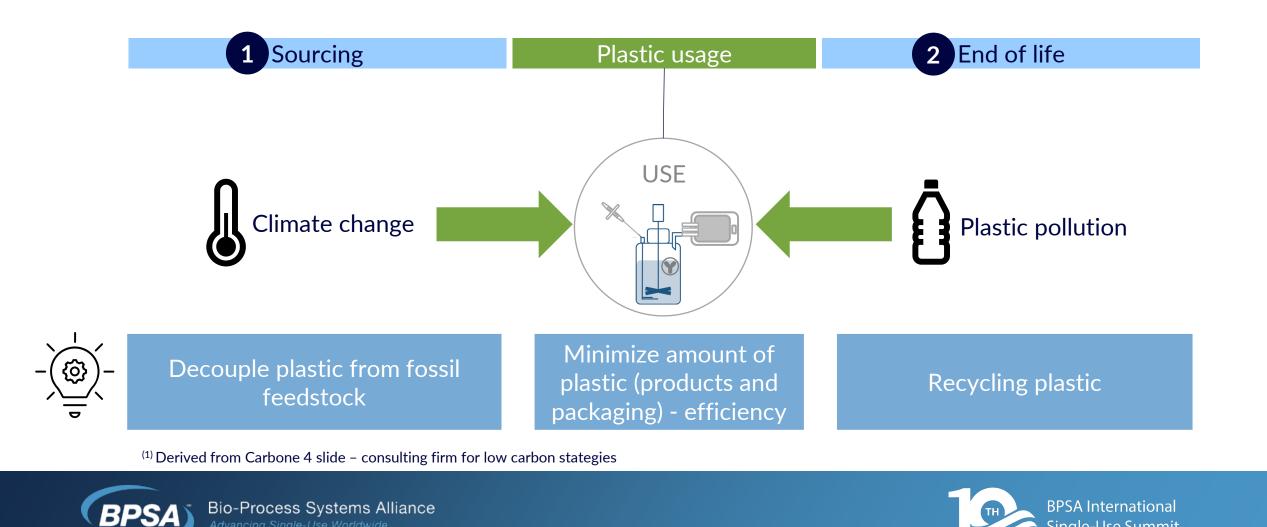
Credit: Greenhouse Gas Protocol — Corporate Value Chain (Scope 3) Accounting and Reporting Standard



Bio-Process Systems Alliance Advancing Single-Use Worldwide



Toward (Plastic) Circularity



Single-Use Summit

Advancing Single-Use Worldwide

References*

- 1. Aseptic Virtual conference, March 2021, Upstream Cell-based Vaccine Production: Improving the Environmental Footprint, Whitford, Barbaroux
- 2. World Economic Forum 2016 The New plastic Economy
- 3. UNEP SINGLE-USE PLASTICS A Roadmap for Sustainability
- 4. Medical plastic market is estimated to 7.7 million tons in 2020 (www.grandviewresearch.com/industry-analysis/medical-plastics-market) for a global market of 400 million de tons, e.g.1,9%.
- 5. Health-care waste (who.int)
- 6. www.nationalgeographic.com/science/2019/10/can-medical-care-exist-without-plastic/
- 7. www.the-scientist.com/news-opinion/ucl-to-phase-out-single-use-plastics--including-pipette-tips-66637
- 8. Whitford, William; Petrich, Mark; Flanagan, William. "Environmental Impacts of Single-Use Systems." Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition, edited by Regine Eibl and Dieter Eibl, John Wiley & Sons, 2019, 271-285.
- 9. J. Ignacio, From Single-Use to Re-Use in the MedecineMaker, June 2018
- 10. BPSA "The Green Imperative" series BioProcess Intl 2020 and 2021
- 11. W. Flanagan, "Single-use and sustainability: quantifying the environmental impact," BioProcess Online, 2016.
- 12. European Commission : A circular economy for plastics, Insights from research and innovation to inform policy & funding decisions
- 13. K. Budzinski, et al., "Introduction of a process mass intensity metric for biologics," New BIOTECHNOLOGY 49 (2019) 37-42.
- 14. Kristi Budzinski *et al.* Streamlined life cycle assessment of single use technologies in biopharmaceutical manufacture. *New Biotechnology*, 2022.
- 15. Luu, D and al, Recycling of Post-Use Bioprocessing Plastic Containers—Mechanical Recycling Technical Feasibility. Sustainability (Switzerland) 2023
- 16. Sartorius Driving Environmental Sustainability in the Biopharmaceutical Industry White Paper Environment | Sartorius

*Last access to web sites – July 7th 2023





SVISCIS

Simplifying Progress

Examples of circularity initiatives

Elisabeth Vachette

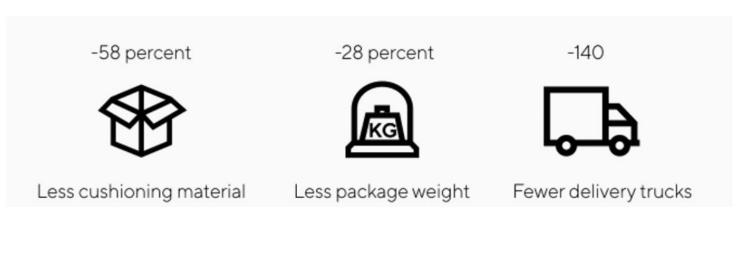


Initiatives to improve packaging

- Same Safety, Less Waste: new Packaging For MaxiCaps Sterile Filters
- Smaller, lighter, and recyclable with no compromise on quality more complicated that what it looks !



Eva Schäfers presents the old (left) and new packaging (right).





Initiatives to improve waste management (Aubagne)



Sorting is a critical success factor for recycled polymer value, especially for color "Plastics packaging waste recycling rates are 80x higher (and plastics waste 13x higher) when collected separately compared to mixed waste⁽²⁾

- (1) Figure taken from: Vachette, Elisabeth & Fenge, Christel & Cappia, Jean Marc & Delaunay, Lucie & Greller, Gerhard & Barbaroux, Magali. (2014). Robust and convenient single-use processing: The superior strength and flexibility of flexsafe bags.
- (2) Plastics the Facts 2022 Plastics Europe



Collaboration in recycling post use non biohazardous film

Working group : Sanofi, Sartorius and Veolia.

Objective :

Challenge widespread thought that SUTs cannot be recycled in standard waste streams for plastics⁽¹⁾ and collaboratively answer the following questions :

- Is there any application where post used bags are not considered bio-hazardous ?
- How to technically recycle a SUT bag, composed of a mechanically recyclable film⁽²⁾ (sorting strategy) ?
- What will be the quality of the recycled content⁽³⁾ ?
- What impact on environmental profiles of SUT end of life ?

Identified opportunity : bioprocessing bags used for media and buffer preparation and storage

- Still represent the largest amount today.
- Most buffers and media are not hazardous fluids.
- Flexsafe[®] Bag chamber designed to be recyclable | biggest weight contributor in simple bags.
- Materials for the constitution are well known and characterized.

(1) most frequent objections : mixed plastic, multilayer films, bio-hazardous post-use products, recycling has a higher footprint than waste to energy.)
(2) Recommended recycling option in the recycling hierarchy
(3) Laboratory scale on representative

Order of magnitude "Simple" bag mass distribution (measured) Bag chamber 43,7 % Plastic packaging 14,1 % Carboard packaging 31,9 % Connectors & tubes 10,3 %



Methodological approach



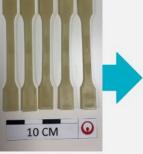












Post-use

Manual dismantling

cutting

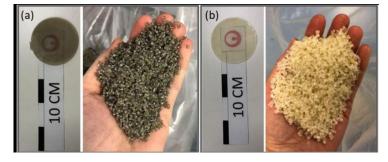
Shear Crushing #1

Shear Crushing #2

Grinding

Injection Molding

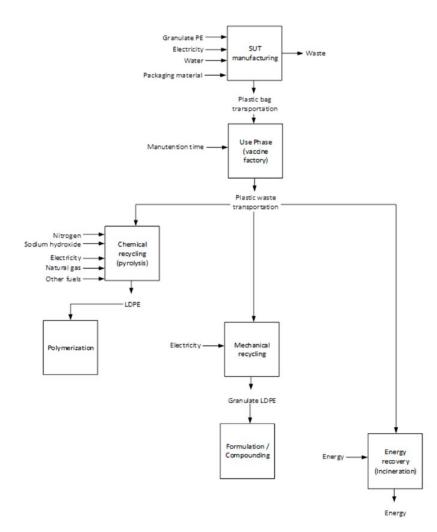
- Quantitative physical | mechanical tests and analysis (FTIR, DSC, TGA, density, MFI, color, tensile, flexural, and Charpy choc)
- Results show that recycled PE can go to applications with similar performance requirements than the one of virgin material (films, bags, pipes and fittings, profiles, and flexible sheets)
- Confirmed that sorting is a critical success factor for recycled polymer value, (color doesn't impact mechanical properties, but negative impact on value)



On the left, cable ties mixed.



Theoretical Environmental Profiles of Different End of Life Scenarios



Comparative LCA⁽¹⁾ (theoretical framework), shows mechanical recycling for end of life presents the advantage of keeping material in the loop without a significant statistical difference compared to incineration with regards to the climate change indicator.

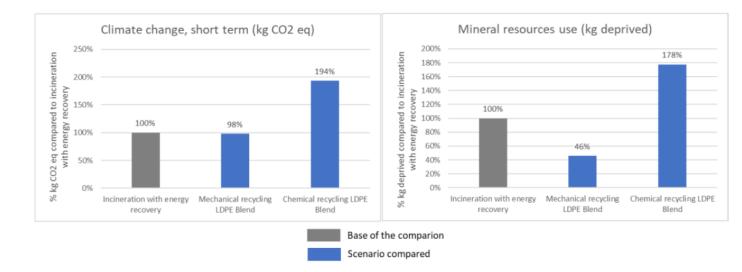


Figure 10. Comparative LCA results of mechanical treatment vs. incineration vs. chemical treatment for 1 kg of SUA treated, for two mid-point indicators, climate change short term and mineral resources use (IMPACT World + Midpoint V1,01).

⁽¹⁾ Data assumptions available for upload : <u>https://www.mdpi.com/article/10.3390/su142315557/s1</u>.



Conclusion

- Recycled Flexsafe[®] bag chambers could technically be used for films, bags, pipes and fittings, profiles, and flexible sheets provided an appropriate sorting and massification solution is identified.
- The comparative LCA, based on a theoretical framework, shows that mechanical recycling for end of life presents the advantage of keeping material in the loop without a significant statistical difference compared to incineration with regards to the climate change indicator.
- Several challenges remain
 - Trade-off between the quality and quantity of the recycled plastic needs to be further evaluated.
 - Cost and efficiency of sorting is another area that needs to be addressed.
 - Lack of accurate data (e.g., production volume, energy consumption, quantities of emissions) related to the emergence of this new circular scheme product limits the value of the LCA*
- Published in open-source Sustainability 2022, 14, 15557

*A whole environmental impact assessment, with different logistic scenarios to ensure the economic viability from a cost perspective, would require a more detailed cradle-to-cradle LCA, with more accurate data (raw materials, SUA production, location use, waste treatment streams), with relevant stakeholders, when the recycling scheme at scale will be defined.



CIRCULARITY AT SAINT-GOBAIN Case study from Ceramics used in Glass Production

Yeshwanth Narendar Vice-President R&D and Innovation Saint-Gobain Life Sciences

TOGETHER, WE CREATE A BETTER LIFE

______SAINT-GOBAIN

SAINT-GOBAIN – OPERATES ACROSS MULTIPLE MARKETS

Materials based solutions across our markets

LIFE SCIENCES	CONSTRUCTION INDUSTRY	CONSTRUCTION CHEMICALS	MOBILITY	SURFACE SOLUTIONS	CERAMICS
BIOPROCESS SOLUTIONS	VETROTEX	CEMENT	SEKURIT ORIGINAL EQUIPMENT MANUFACTURER (OEM)	ABRASIVES	GLASS REFRACTORIES
MEDICAL COMPONENTS	INDUSTRIAL FABRICS EUROPE	CONCRETE	AUTOMOTIVE GLASS REPLACEMENT	Europe, Middle-East, Africa North America	ZIRCONIA
INDUSTRIAL AND CONSUMER SOLUTIONS	CONSTRUCTION PRODUCTS EUROPE	Precast Ready-mix concrete Decorative Concrete	SEKURIT TRANSPORT	Latin America Asia-Pacific	PERFORMANCE CERAMICS AND REFRACTORIES
ELECTRONICS	CONSTRUCTION INDUSTRY	Screed	AEROSPACE	India	QUARTZ
	AMERICAS	Gypsum		ADHESIVES AND SEALANTS	CATALYST SUPPORTS
		SPECIALTY BUILDING MATERIALS	ENGINEERED COMPONENTS Bearings	COMPOSITE SYSTEMS	SPECIALTY POWDERS
			Joints Automobile Polymer Solutions	Tape Solutions	VALOREF - RECYCLING
		AN	Omniseal Solutions	Thin Films	

SAINT-GOBAIN

1

2

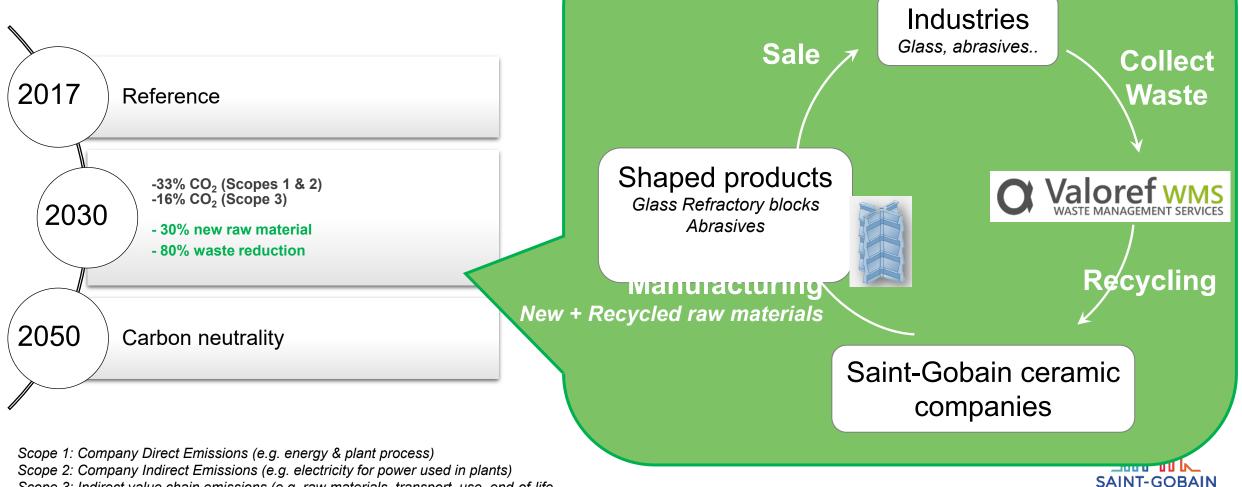
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CIRCULARITY KEY TO ACHIEVE ENVIRONMENTAL OBJECTIVES



Circular economy – Inorganic Materials

Saint-Gobain Objectives



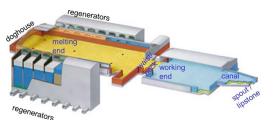
22 Scope 3: Indirect value chain emissions (e.g. raw materials, transport, use, end-of-life

RECYCLING APPROACH FOR GLASS REFRACTORIES



Glass Furnaces

- Building flat glass
- Automotive glass
- Containers (incl. Pharma)
- Glass wool & fibers (insulation)



1000s of tons of ceramics used Furnace Life span of 10-20 years "Valoref started to recycle ceramics used for glass furnaces: Production waste to post use"

3 SERVICES



- \rightarrow Punctual waste collection
- \rightarrow Furnace demolition operation
 - Dedicated team on-site







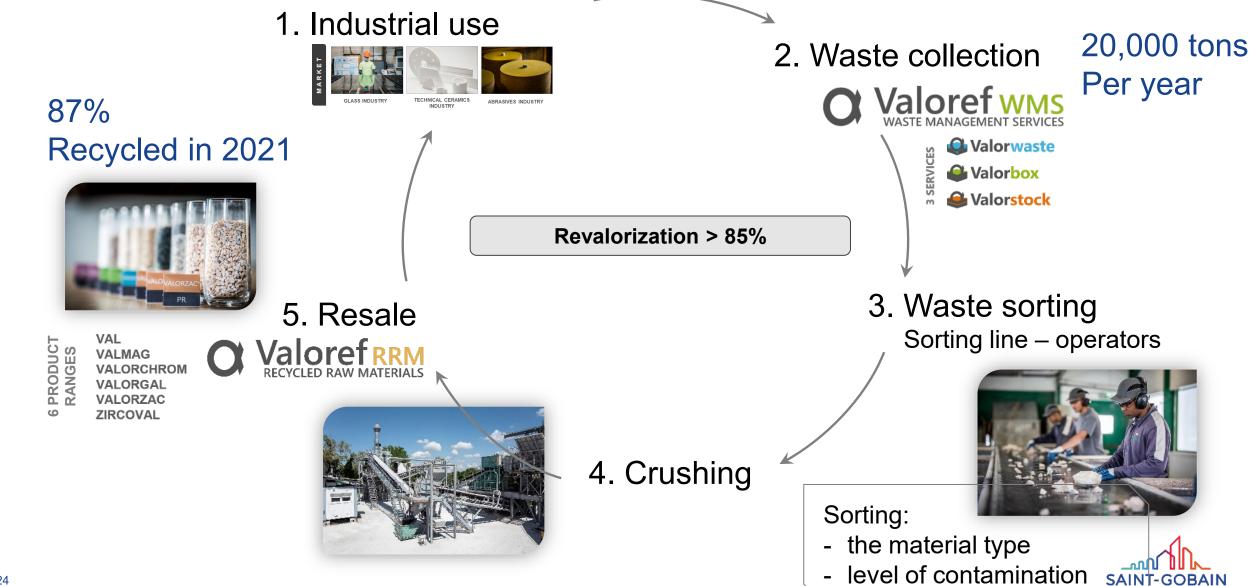
 \rightarrow Regular waste collection









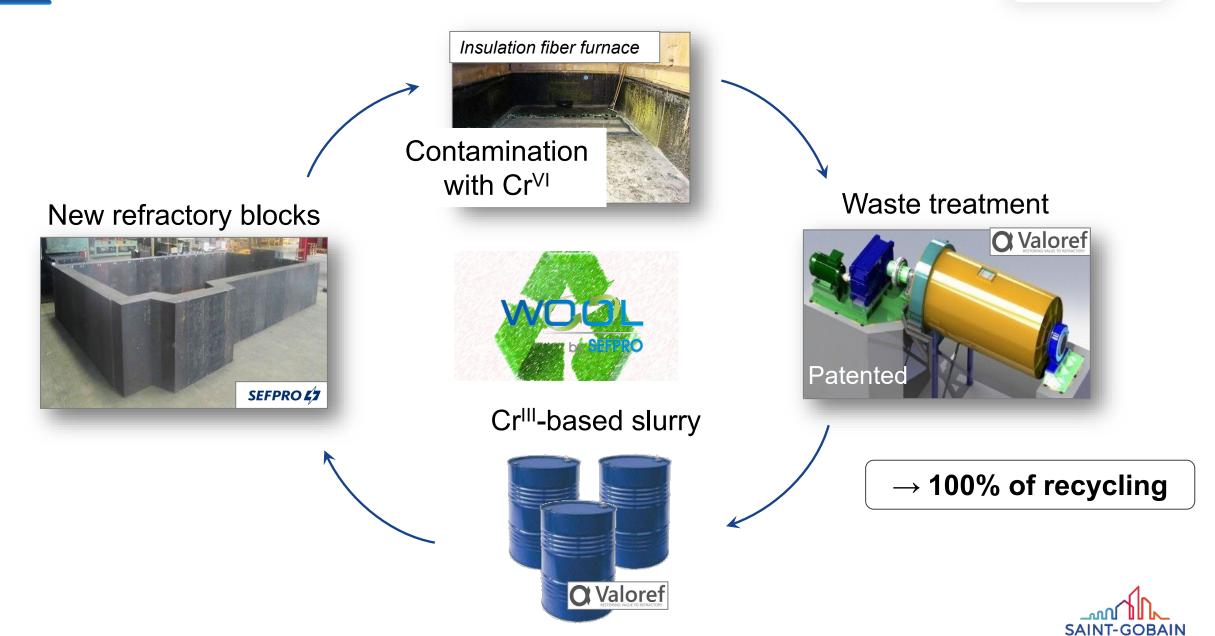


RECYCLING PROCESS

GROW& ΙΜΡΛCT

UNIQUE PROCESS TO VALORIZE CR(VI) CONTAMINATION





DISCUSSION POINTS FOR SUT

Engineered Products "fused"/connected together in a glass furnace -> Separate product into raw materials to enable recycling

Contamination is a common issue -> Develop economical decontamination process to enable recycling

Glass furnace ceramics need to work for 15+ years -> Some recycled raw materials are used for less demanding applications

Testing feasibility of single use plastics recycling -> leveraging Saint-Gobain's presence in Life Science, Industrial and Construction



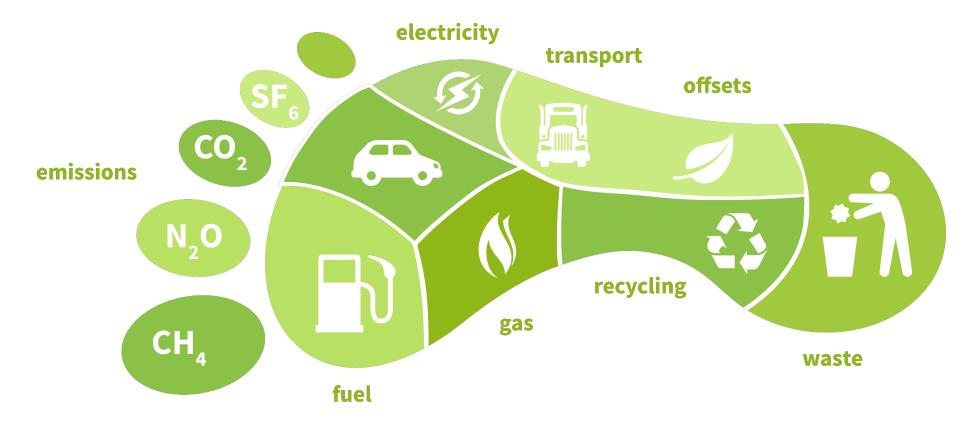




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WHAT IS CARBON FOOTPRINT?

A carbon footprint describes the total climate change impact – greenhouse gas (GHG) emissions – that a product, action, or person has.





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CARBON EMISSIONS DATA

 CO₂ emissions have increased by about 90% over the past 50 years²

2500

companies have set emission reduction targets³

70%

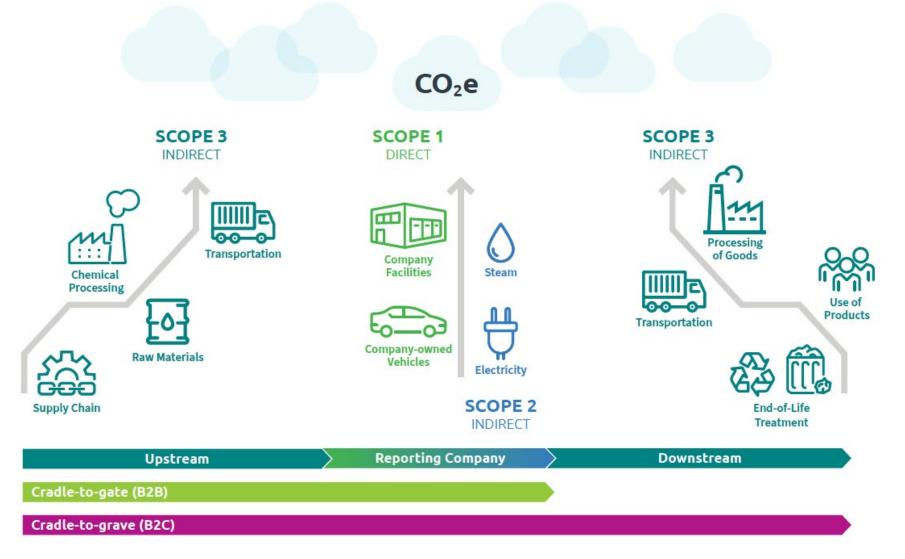
of countries have net zero targets³

1740+

companies set net zero commitments³

Source 2: https://www.epa.gov/ghgemissions/global-greenhouse-gas-emissions-data Source 3. https://sciencebasedtargets.org/companies-taking-action

UNDERSTANDING PRODUCT CARBON FOOTPRINT





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METHODOLOGY

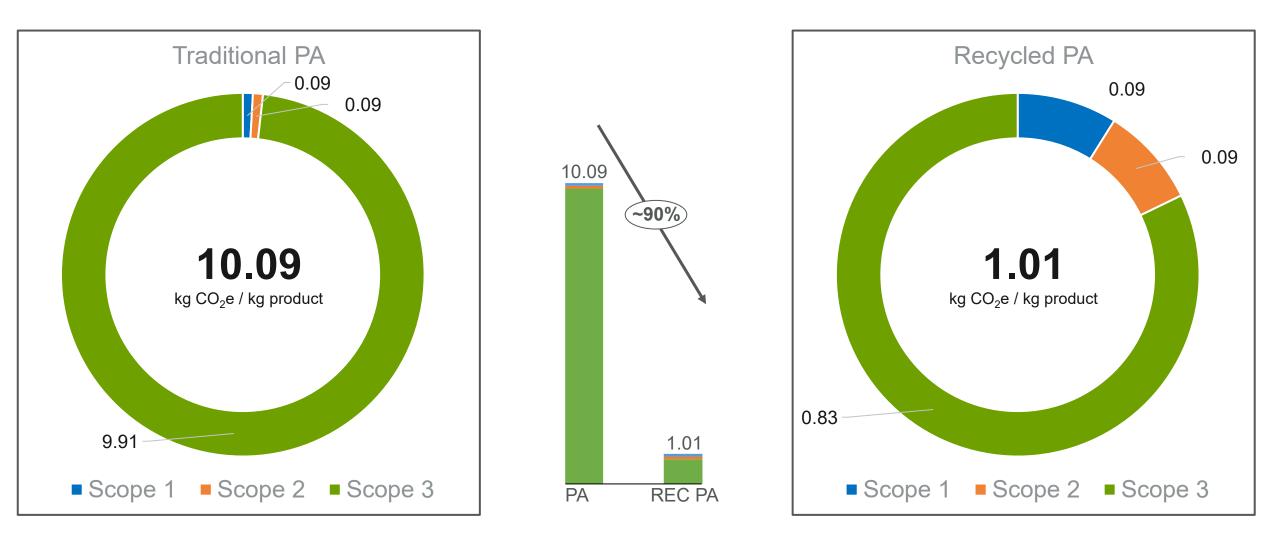
- Follows ISO 14067:2018 Carbon Footprint of Products
 - Specifies principles and guidelines for the quantification and reporting of the carbon footprint of a product
- Third-Party Certified by TUV
 - Certificate confirms that a product meets defined criteria and defined safety-relevant aspects

Certificate+ID:	C01-2023-03-21257059		Product Carbon	102401
Certificate for:	Review of Product Carbon Footprint Method of Avient Corporation	A	Footprint Certified Calculation Method	
	AVIENT	TÜVRheinland		
Certified:	Avient Corporation 33587 Walker Road, Avon Lake OH 44012, United States	TUVRheinland	L	
Accounting Scope:	Methodology for assessing the potential climate change effects for plastics in primary pellet forms, such as color and additive masterbatches, and compounds with reinforced fillers	CERTIFIED	www.tuv.com	
Applied Standard:	ISO 14067: 2018 which is based on ISO 14040:2006 + A1:2020 /ISO 14044:2006 + A1:2018 + A2:2020		ID 0000084994	_
Review Report:	CF-2023-03-21257059			
Valid until:	March 31st 2024			



IMPACT OF RAW MATERIAL

TRADITIONAL PA VS. RECYCLED PA

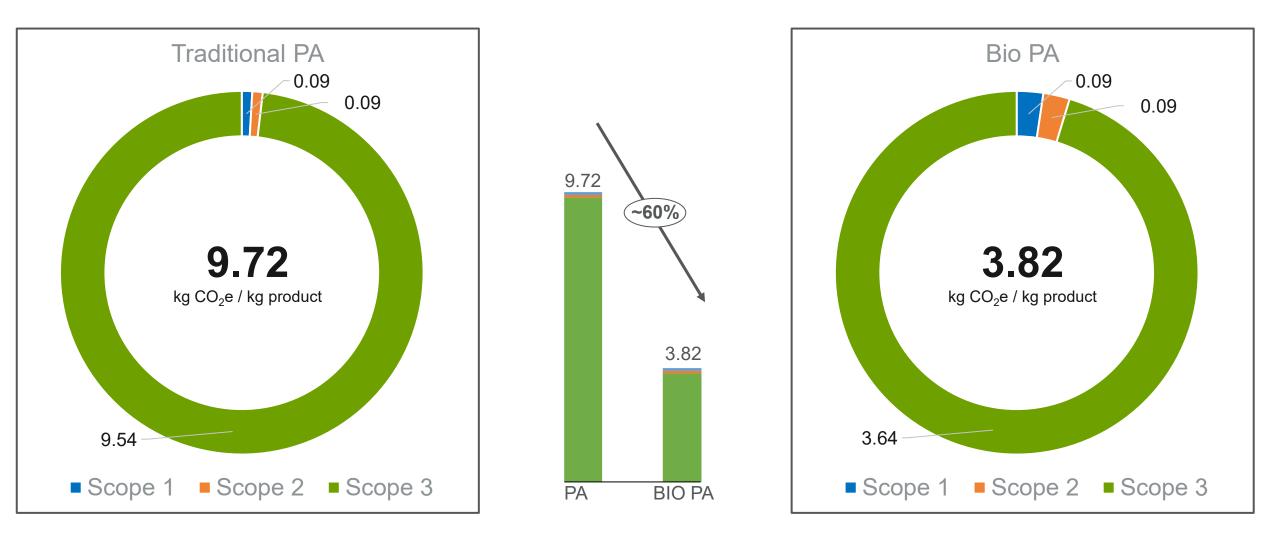




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IMPACT OF RAW MATERIAL

TRADITIONAL PA VS. BIO PA



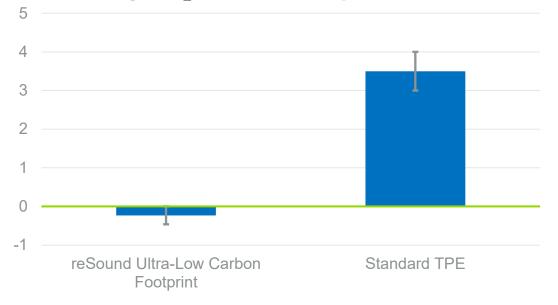


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SUSTAINABLE SOLUTIONS INDUSTRY-FIRST NEUTRAL PCF TPES



reSound[™] Ultra-Low Carbon Footprint TPEs kg CO₂ equivalent / kg product



- Comparable performance
- Globally available

