Sterilization of Medical Plastics

Hans de Brouwer & Pierre del Pozo - SABIC



With the support of:

Classification: General Business Use

SABIC AT A GLANCE



1976
Company established

28,000+
Employees around the world

140+
Countries served

11,000+
Patent portfolio

Top 2
Chemical Brand Value*

4.9
US$ bn
Estimated Brand Value*

74.1
US$ bn
Total assets

0.6
US$ bn
Net income from continuing operations

37.3
US$ bn
Annual revenue

135
New products introduced

60
Manufacturing/compounding sites worldwide

20
Technology & Innovation Centers

*Brand Finance, 2025.

Classification: General Business Use

HEALTHCARE INDUSTRY

THE WORLD IN 2050

AROUND 9.7 BILLION PEOPLE ARE EXPECTED TO BE LIVING ON OUR PLANET*



2BN
WORLD'S POPULATION BE ELDERLY BY 2050*

6.3%
CAGR GLOBAL HEALTHCARE MARKET GROWTH BY 2026**

6.4MMT
GLOBAL POLYMERS USAGE FOR HEALTHCARE APPLICATIONS BY 2026**

MEGATRENDS PUSHING THE INDUSTRY TO FOCUS ON SOLUTIONS FOR FUTURE

- SUSTAINABILITY
- SAFETY & REGULATORY
- DESIGN & COST EFFICIENCY
- IMPROVED FUNCTIONALITY
- CUSTOMERS & PATIENTS CONVENIENCE

*- The United Nations DESA report, "World Population Prospects: The 2021 Revision"; Euromonitor | Nielsen | Bloomberg
**- AMI2020 SABIC2021 Global Demand, IHS CISQ2021, BI Petrochemicals analysis

SABIC'S BROAD MATERIALS PORTFOLIO FOR THE HEALTHCARE INDUSTRY

Manufactured by SABIC Group
Manufacture by SABIC - ETP West

	AMORPHOUS	CRYSTALLINE
HIGH PERFORMANCE	PEI, PES, PPSU	LCP, PEEK, PPS
ENGINEERING THERMOPLASTICS	PSU, PC, PC/PBT, PC/PET, PC/ABS, PC/ASA, ABS, ASA	PPA, PBT, POM, PA
COMMODITY	PS, PVC	PP, HDPE, PET, LDPE



LEXAN™ HP (PC) resin
- Excellent processability
- Transparency
- Excellent impact resistance



CYCOLOY™ HC (PC/ABS) resin
- Excellent processability
- Colorability and aesthetics
- Good impact resistance



CYCOLAC™ HMG (ABS) resin
- Cost effective offering good mechanical properties
- Colorability and aesthetics



PCG PET resins
- Thin wall
- processability

VALOX™ HX (PBT) resin
- Good dielectric strength
- Excellent chemical resistance





XYLEX™ HX (PC/PET) resin
- Good processability
- Good chemical resistance
- Transparency



SABIC® PCG (PP and PE) grades
- Cost effectiveness
- Versatility
- Processability





SABIC'S HEALTHCARE PRODUCT POLICY

- Easily identifiable healthcare product nomenclature
  - CYCOLAC™ HM resins
  - CYCOLOY™ HC resins
  - LEXAN™ HP resins
  - VALOX™ HX resins
  - XENOY™ HX resins
  - XYLEX™ HX resins
  - SABIC® HDPE PCG resins
  - SABIC® LDPE PCG resins
  - SABIC® PP PCG resins
  - SABIC® PET PCG resins
- Biocompatibility assessed (according to ISO 10993 or USP Class VI)
- Food contact compliance according to FDA and/or EU Reg. No. 10/2011 for most healthcare grades
- FDA Drug Master File and/or Device Master File listing
  (letter of authorization provided as needed)
- SABIC healthcare products are subject to formula lock and stringent management of change process. SABIC healthcare products are manufactured under GMP rules (No.2023/2006 (Commission Regulation EC, 22 December 2006) or FDA 21CFR174.5).
- Long-term supply options available



SABIC does **not** support applications which remain implanted **beyond 29 days**

STERILIZATION METHODS AND RESIN PERFORMANCE

STERILIZATION: WHAT & WHY

- Sterilization: a process that removes, kills, or deactivates all forms of life (particularly microorganisms such as fungi, bacteria, spores, and unicellular eukaryotic organisms) and other biological agents (such as prions or viruses) present in fluid or on a specific surface or object
- Centers for Disease Control estimates average of 2 million Healthcare Associated Infections (HCAI) occur annually in the U.S. On any given day, about one in 31 hospital patients has at least one HCAI
- The estimated direct annual cost of treating HCAIs in the United States ranges from $ 28 billion to $ 33 billion
- WHO: 136 million cases of HCAI occur worldwide every year. 1 in 10 patients
- Sterilization is essential to prevent such infections



Sources: www.cdc.gov ; www.who.int

STERILIZATION & DISINFECTION METHODS

			INDUSTRIAL USE	PROFES. USE	GENERAL USE
ETHYLENE OXIDE	GAS	Compatible with polyolefins. Concerns around residues & EHSS			
HYDROGEN PEROXIDE	GAS	new method, alternative to EO (dry conditions)			
OZONE	GAS	similar function to H_2O_2			
GAMMA	RADIATION	High equipment cost. Industrial procedure. Requires Co-60 source.			
ELECTRON BEAM	RADIATION	High equipment cost. Industrial procedure.			
X-RAY	RADIATION	High equipment cost. Industrial procedure.			
UV-C	RADIATION	effective method against several microbial species.			
DRY HEAT	TEMPERATURE	material at elevated T: 150-180 °C			
AUTOCLAVING	TEMPERATURE	steam sterilization at 104 – 138 °C as heating			
DISINFECTANT (WIPES)	CHEMICAL	Aldehydes, Quartenary ammonium salts, variety of other chemicals			

A BOOST IN UV-C APPLICATIONS

Scientists consider indoor ultraviolet light to zap coronavirus in the air

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A robot emitting ultraviolet light is seen at the Nice International airport on May 7, 2020
PHOTO: AFP

Add as a preferred source on Google

Published May 08, 2020, 08:40 AM

NEW YORK (NYTIMES) - As society tries to rebound from the coronavirus pandemic, some scientists hope a decades-old technology could zap pathogens out of the air in stores, restaurants and classrooms, potentially playing a key role in containing further spread of the

Source: New York Times

Sport | Culture | Lifestyle

ney Markets Project Syndicate B2B Retail

This article is more than **5 years old**

UV cabinet that zaps Covid 'could become fixture of UK homes'

Electricals firm Beko among those tapping into demand for professional levels of hygiene

Coronavirus - latest updates
See all our coronavirus coverage



Beko Hygienic Shield cleaning cabinet. Photograph: Beko/MSL Group

A "disinfection" cabinet that zaps coronavirus could be this Christmas's must-have gadget as manufacturers tap into demand for professional levels of hygiene in the home.

The UV cleaning cabinet, which resembles a microwave and costs £199, is

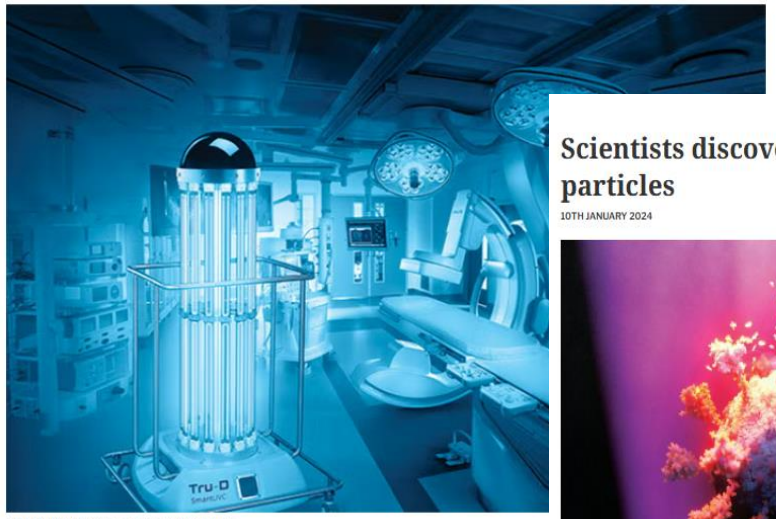
Source: The Guardian

ENVIRONMENTAL SERVICES

Study addresses barriers to using UV disinfection

Duke researchers give tips to successfully implement UV disinfection systems in hospitals

Apr 4, 2018 | Jamie Morgan



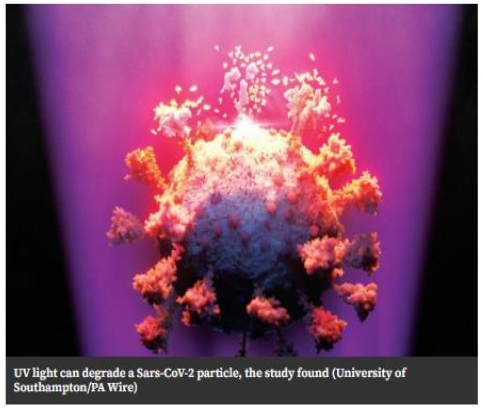
Tru-D disinfecting an operating room
Tru-D SmartUVC

In the Benefits of Enhanced Terminal Room (BETR) Disinfection study, rese set out to prove what many concerned with infection prevention have long s

Source: Health Facility Managment

Scientists discover how UV light degr particles

10TH JANUARY 2024



UV light can degrade a Sars-CoV-2 particle, the study found (University of Southampton/PA Wire)

By PA News Agency

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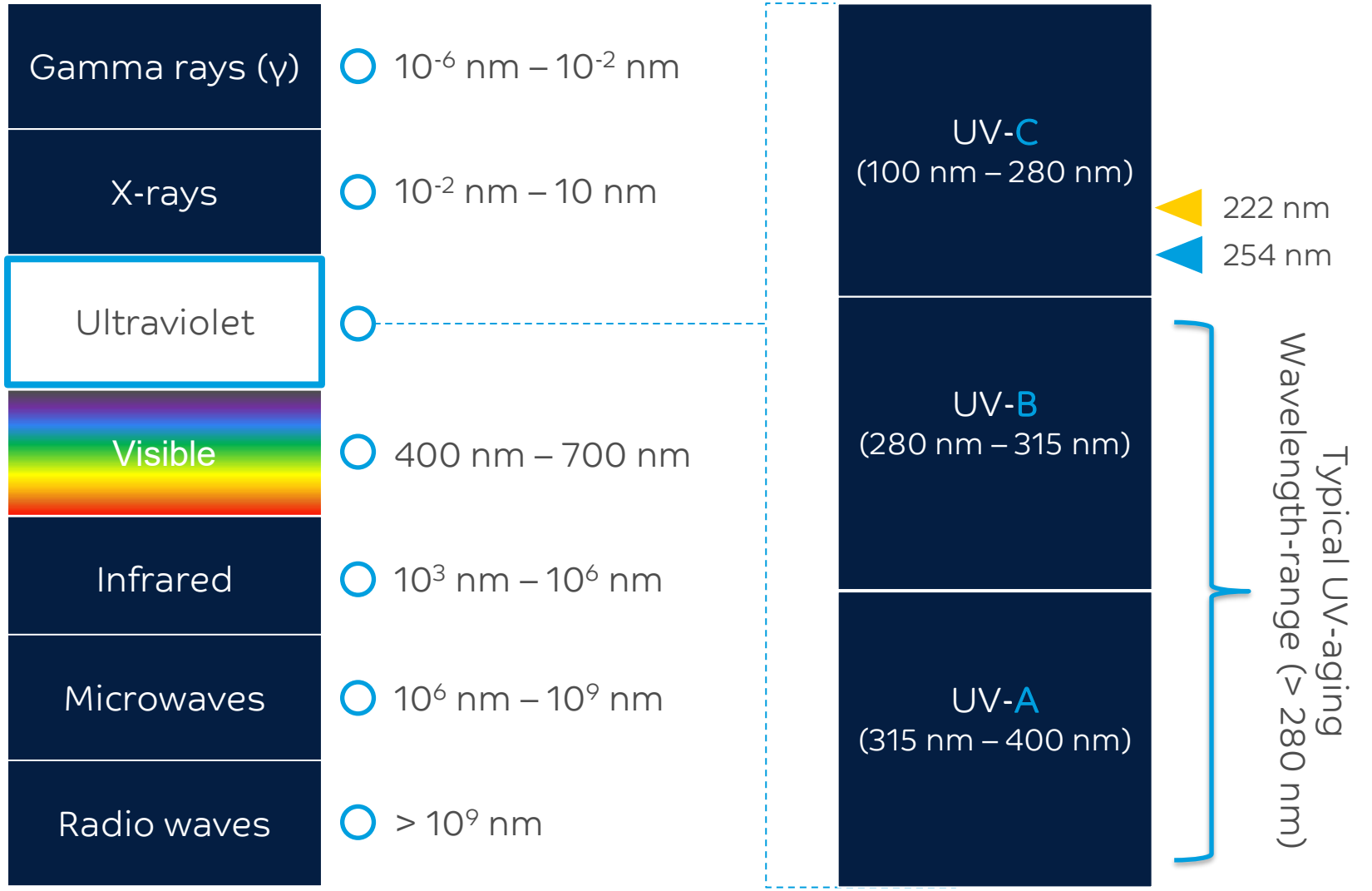
0 comments

Source: Gazette & Herald

THE ELECTROMAGNETIC SPECTRUM

UV radiation

- **UV-A**: Long-wave, black light, not absorbed by the ozone layer; soft UV
- **UV-B**: Medium-wave, mostly absorbed by the ozone layer: intermediate UV
- **UV-C**: Short-wave, germicidal, completely absorbed by the ozone layer and atmosphere: hard UV



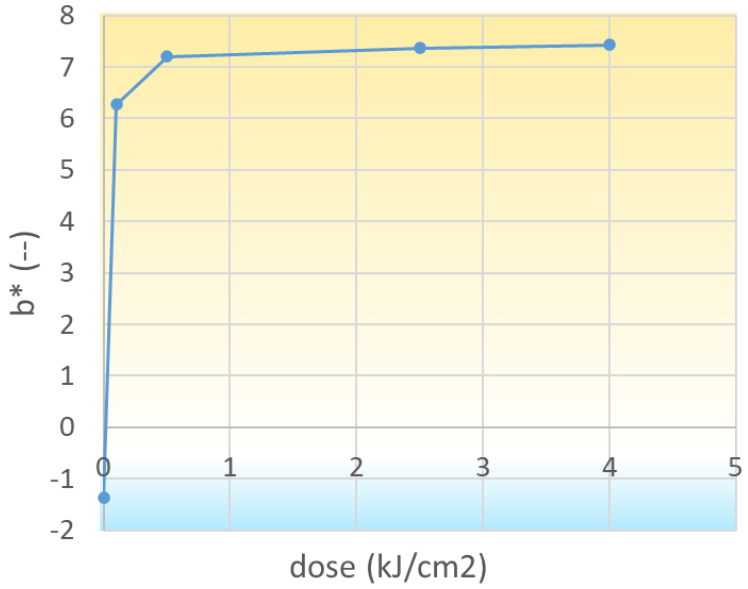
WHAT ARE RELEVANT DOSE RANGES ?

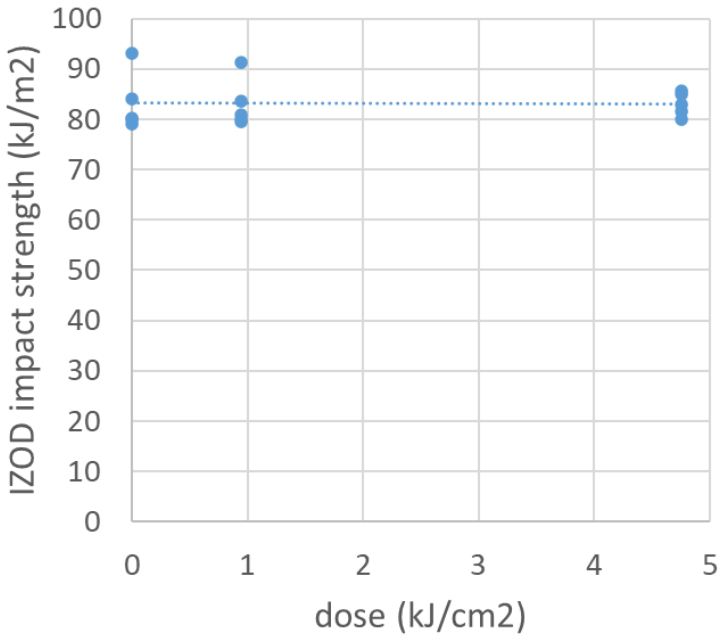
		Hospital Furniture Guideline (2014)	Medical Device Mfg (2020)
Intensity	(mW/cm^2)	1	1
Duration	(min.)	1.5	2
Cycles	(day^{-1})	8	24
Exp. Lifetime	(years)	5	10
Total Dose	(kJ/cm^2)	1.1	8.6

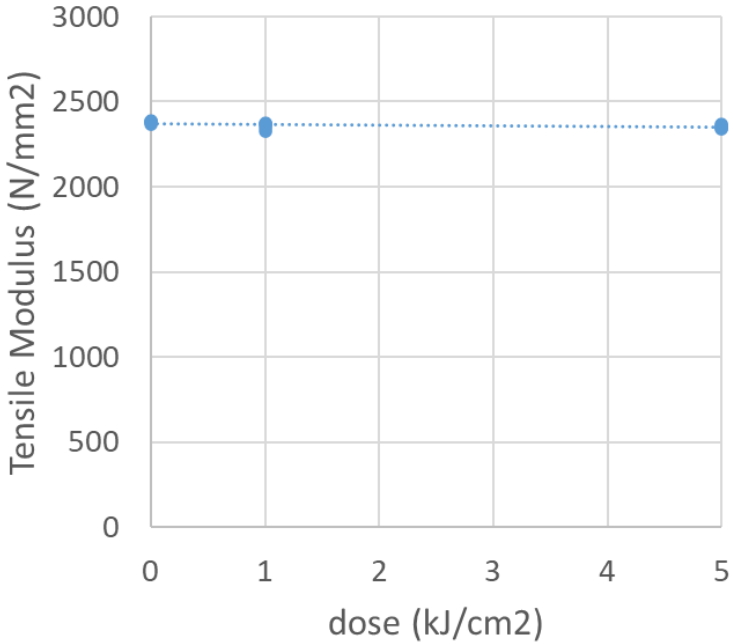




POLYCARBONATE DISCOLORATION & MECHANICAL PERFORMANCE



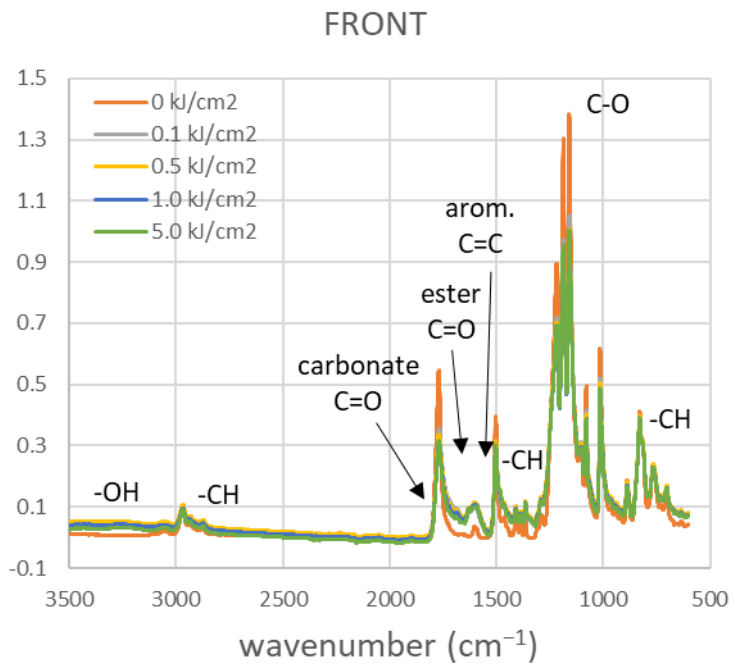


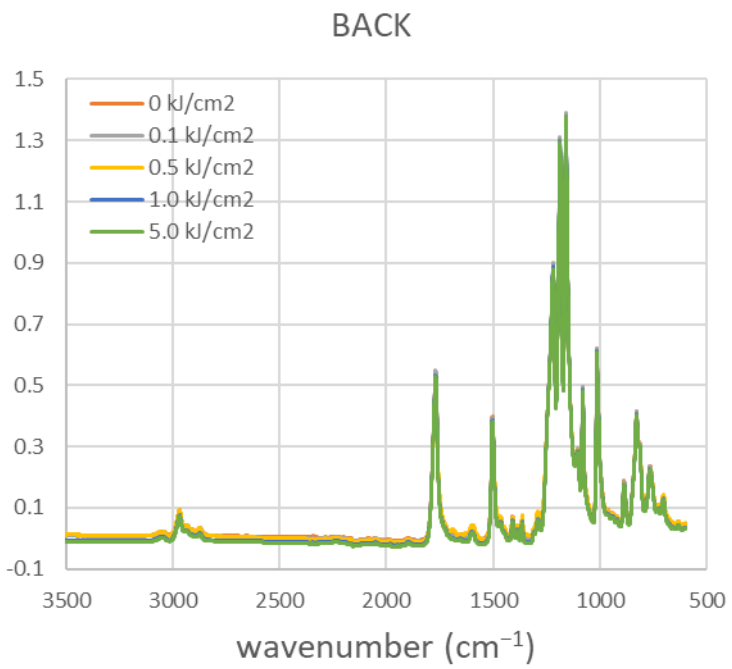


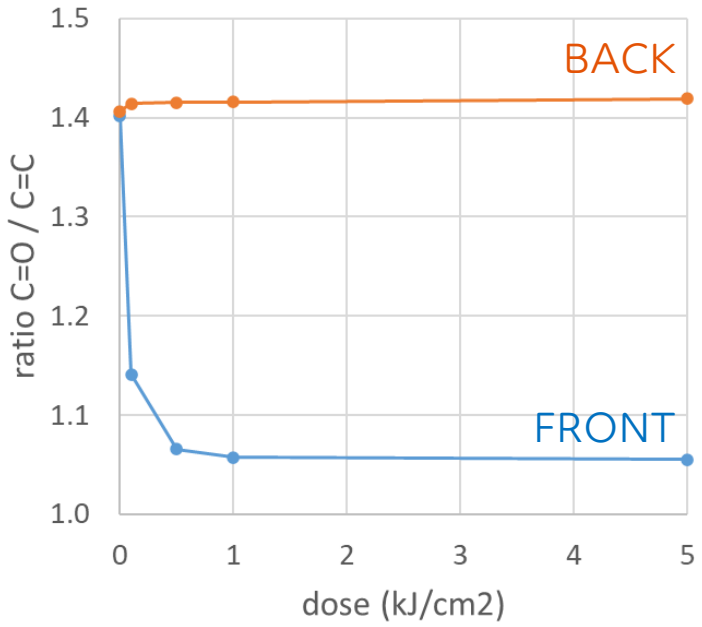


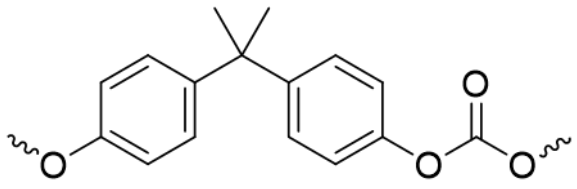
Rapid discoloration to plateau at low dose, but stable mechanics

POLYCARBONATE DEGRADATION MECHANISMS









polycarbonate

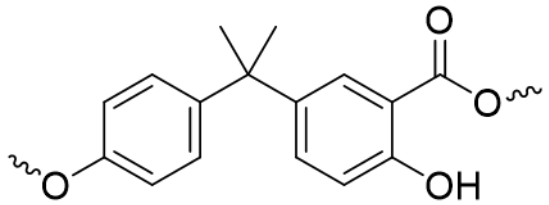
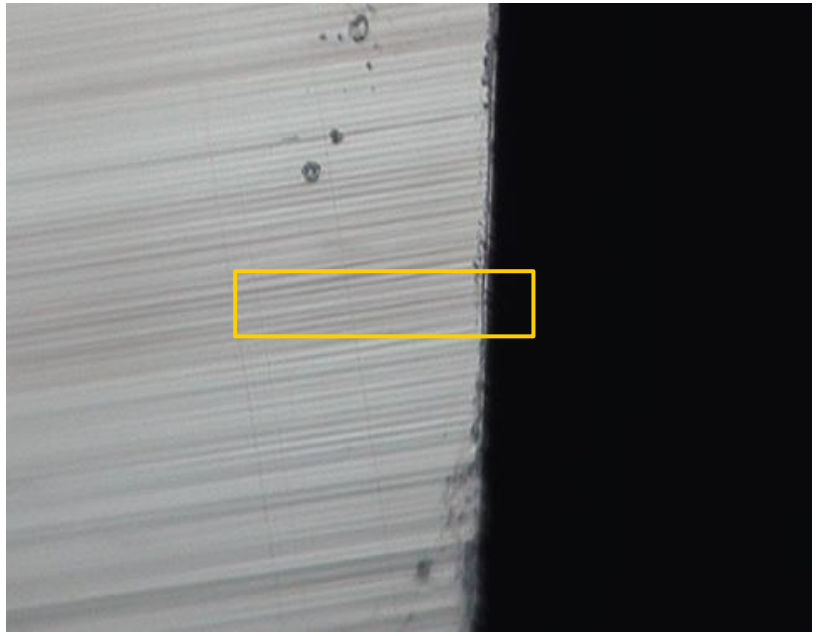
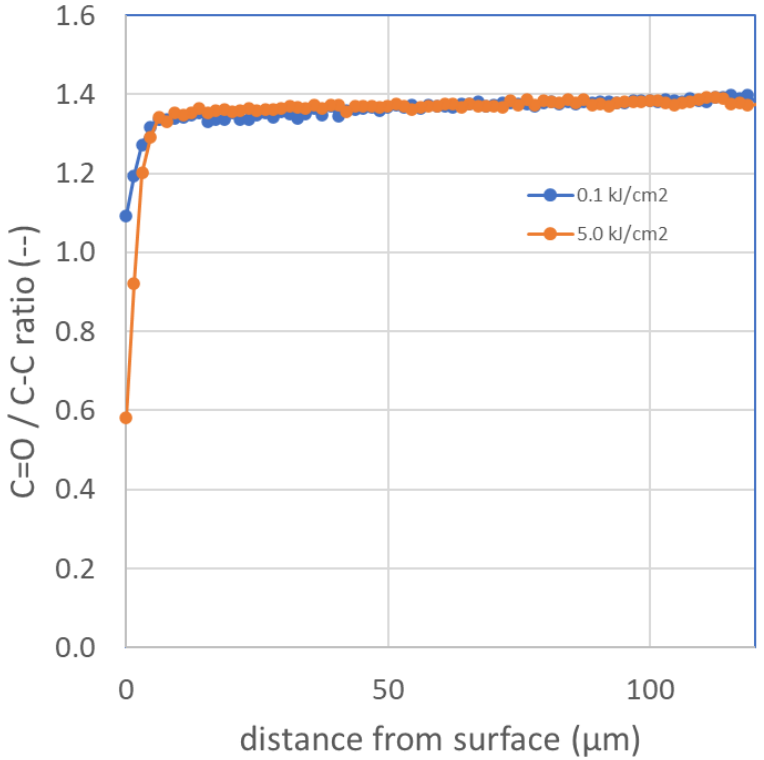


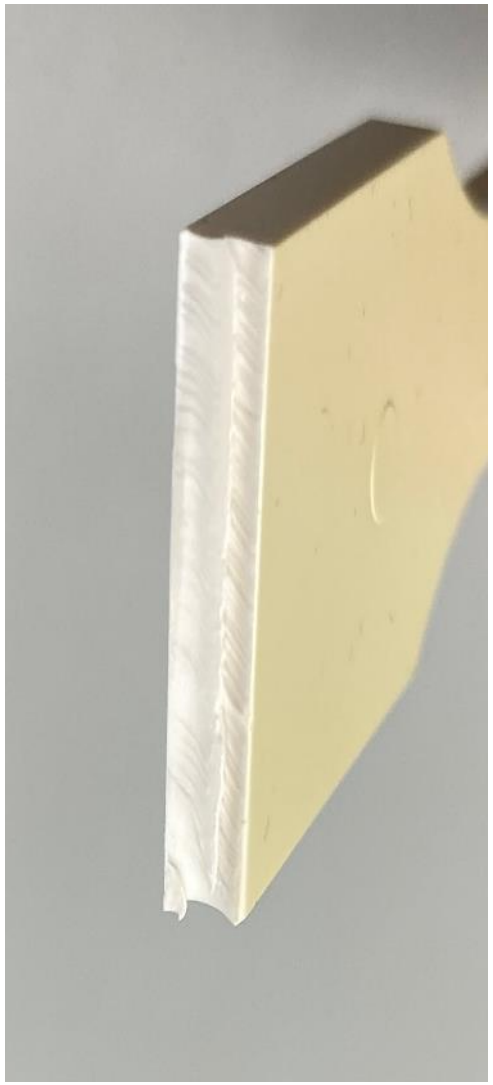
Photo-Fries rearrangement



PENETRATION DEPTH OF UVC INTO POLYCARBONATE

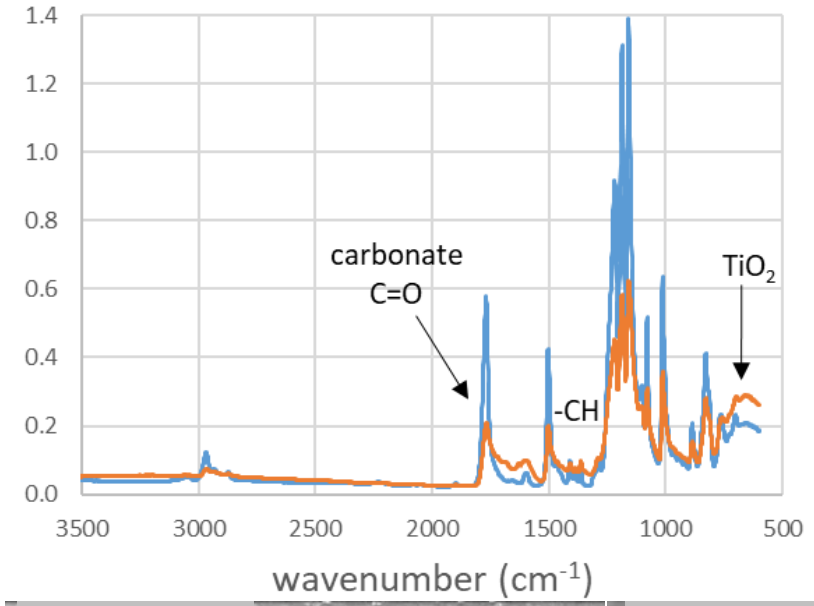


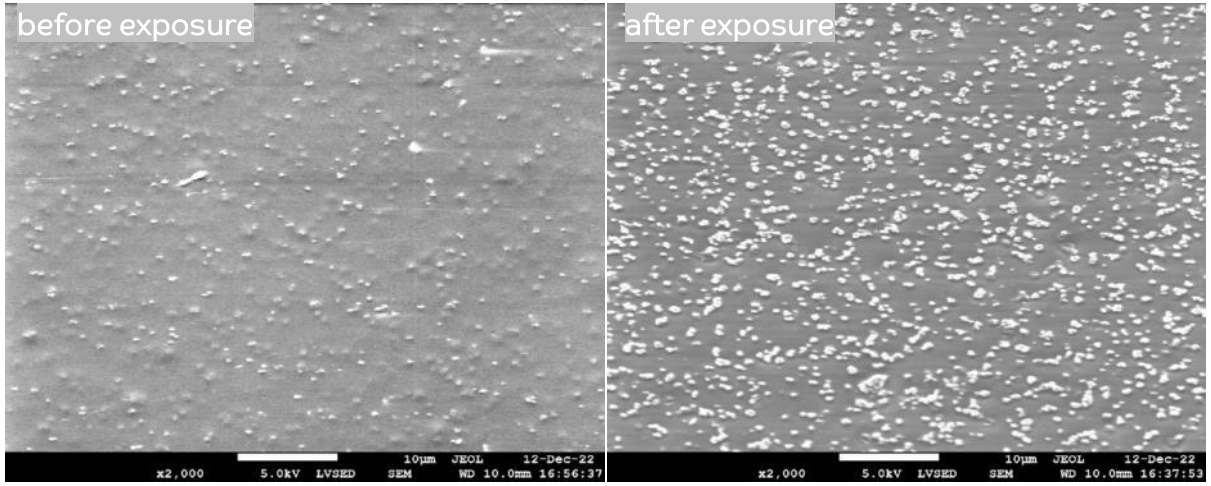


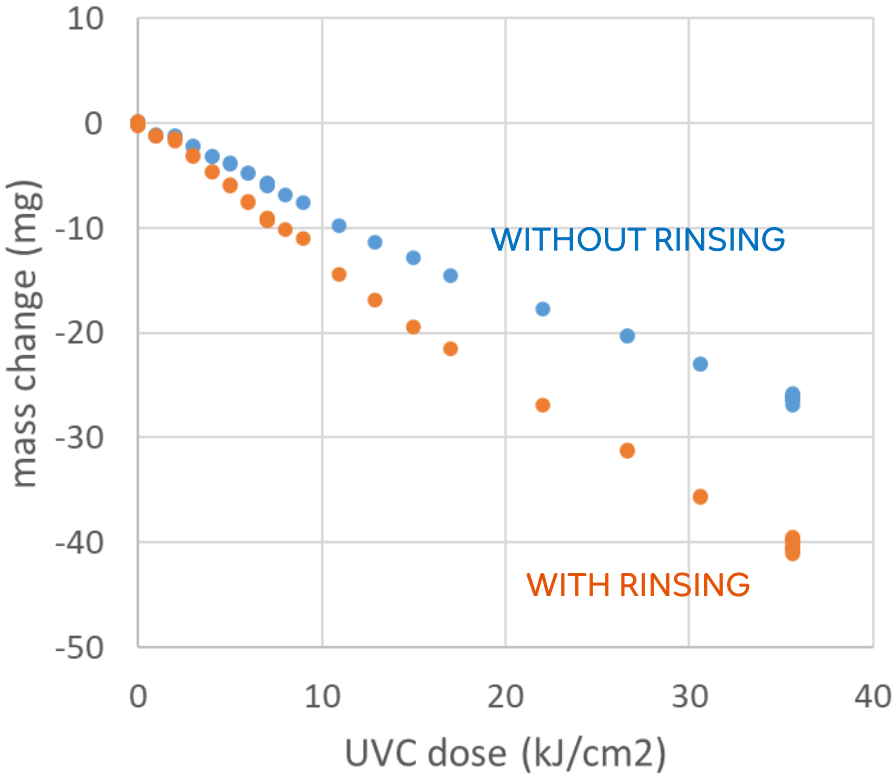


Degraded layer is only 3-5 µm thick

SURFACE EROSION IN PIGMENTED FORMULATIONS

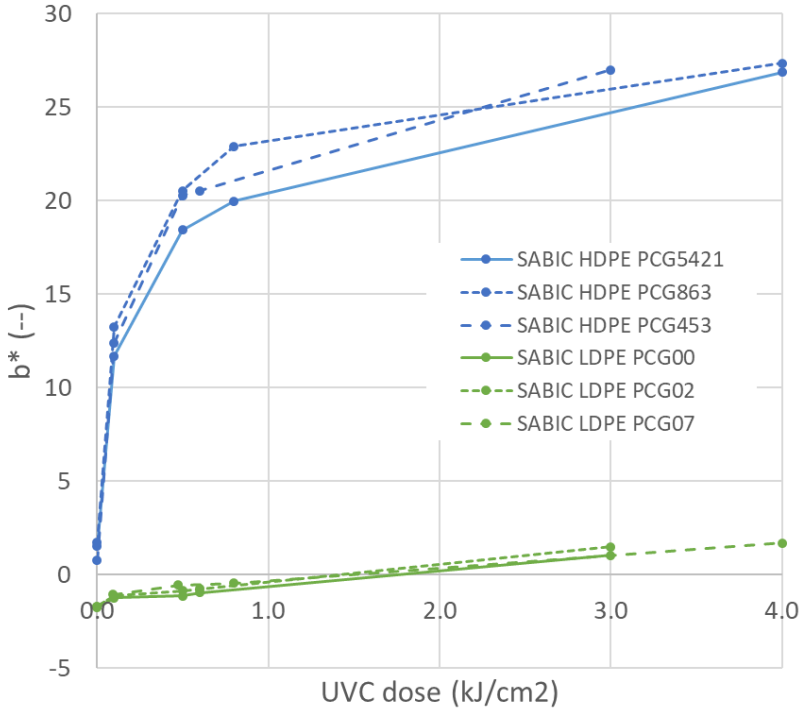






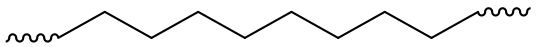
- Mass loss is continuous and linear
- Part of the degradation products is easily soluble in MeOH

DIFFERENT BACKBONE MATERIALS SHOW ALTERNATE PROFILES

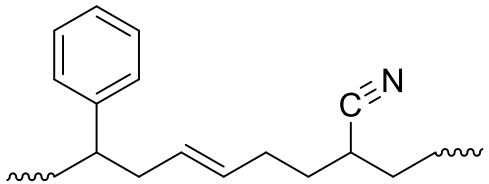


	target dose of 1kJ/cm2						target dose of 5kJ/cm2					
	Δimpact (%)	ΔE_t (%)	$\Delta\sigma_y$ (%)	$\Delta\sigma_b$ (%)	$\Delta\varepsilon_y$ (%)	$\Delta\varepsilon_b$ (%)	Δimpact (%)	ΔE_t (%)	$\Delta\sigma_y$ (%)	$\Delta\sigma_b$ (%)	$\Delta\varepsilon_y$ (%)	$\Delta\varepsilon_b$ (%)
PC	4	0	0	-3	1	-5	6	0	0	-1	1	-1
PC/PBT	4	0	0	1	0	8	2	0	0	0	0	9
PC/PCTG	4	0	0	5	0	7	3	1	0	2	0	1
PC/PET	1	0	0	0	2	10	2	0	1	0	3	48
PC/ABS	1	0	0	-6	0	-19	4	0	0	-5	0	-13
ABS	-10	0	0	6	0	-36	-10	0	1	6	0	-32
HDPE	0	-1	1	-10	-1	4	-22	2	2	81	-10	-82
LDPE	1	3	2	1	26	-2	0	8	1	0	13	1
LLDPE	2	-4	1	2	0	8	0	-9	2	-13	-6	-11
PP_h	5	2	0	13	0	-16	-15	2	-9	10	-13	-83
PP_r	1	1	0	24	-7	-26	-50	3	-5	25	-8	-81
PP_icp	-20	1	0	-1	-1	-52	-35	3	-7	10	-12	-72
GF-PBT	3	0	0	0	0	2	6	1	0	1	0	3
GF-PP	3	2	0	-12	-2	-1	-2	-1	-1	0	-1	-4

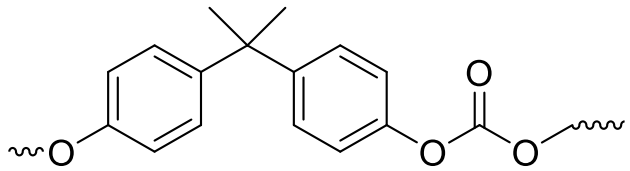
>10% change
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PE



ABS



PC

CONCLUSIONS

- There are different exposure regimes for (1) disposables, (2) durable medical devices, furniture and (3) construction materials for UVC luminaires



- **Durable devices**:
  - PC and PC blends show discoloration but retain mechanical performance
  - mineral filled materials retain mechanical properties very well
  - a thin degraded surface layer slowly erodes while protecting the bulk material
  - surface chemistry is changing. Part of the degradation products is soluble in methanol.



- **Disposables**: PE and PP have good low dose UVC stability (< 1 kJ/cm2)

- **Other learnings:** UVC as surface modification technique

LET'S COLLABORATE



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QUESTIONS ?



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