TOPAS® COC

PAN (Barex®) Replacement

TOPAS® Cyclic Olefin Copolymer (COC)
Your Clear Advantage.

Permeability of TOPAS® COC & Barex®

TOPAS
Advanced Polymers

	Conditions	Units	Barex®210	TOPAS® 8007	TOPAS® 6013
Water Vapor	100°F, 100% RH	g-mil/100 in^2-24 hr	5.00		
Water Vapor	23°C; 85% RH	g-mil/100 in^2-24 hr		0.07	0.10
	38°C; 90% RH	g-mil/100 in^2-24 hr		0.24	0.40
Nitrogen	73°F, 100% RH	cc-mil/100 in^2-24 hr	0.2		13
	23°C; 0% RH	cc-mil/100 in^2-24 hr		<2.6	
Oxygen	73°F, 100% RH	cc-mil/100 in^2-24 hr	0.8		
	23°C; 50% RH	cc-mil/100 in^2-24 hr		63	107

- TOPAS COC offers superior moisture, good nitrogen and poor oxygen barrier compared to Barex.
- TOPAS COC is not expected to replace Barex in all applications, but following data show it is a very good replacement for many leading ones.

TOPAS® COC – Food & Medical Approval

TOPAS Advanced Polymers

USA

- FDA Food Contact Notification (FCN #405), effective 2004, expanded prior FCN to cover all applications including bottles (See http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=fcslisting.)
- FDA FCN #1104 covers E-140 for many conditions of use
- FDA Drug Master File -- DMF #12132
- FDA Device Master File -- MAF #1043

←Access letters available

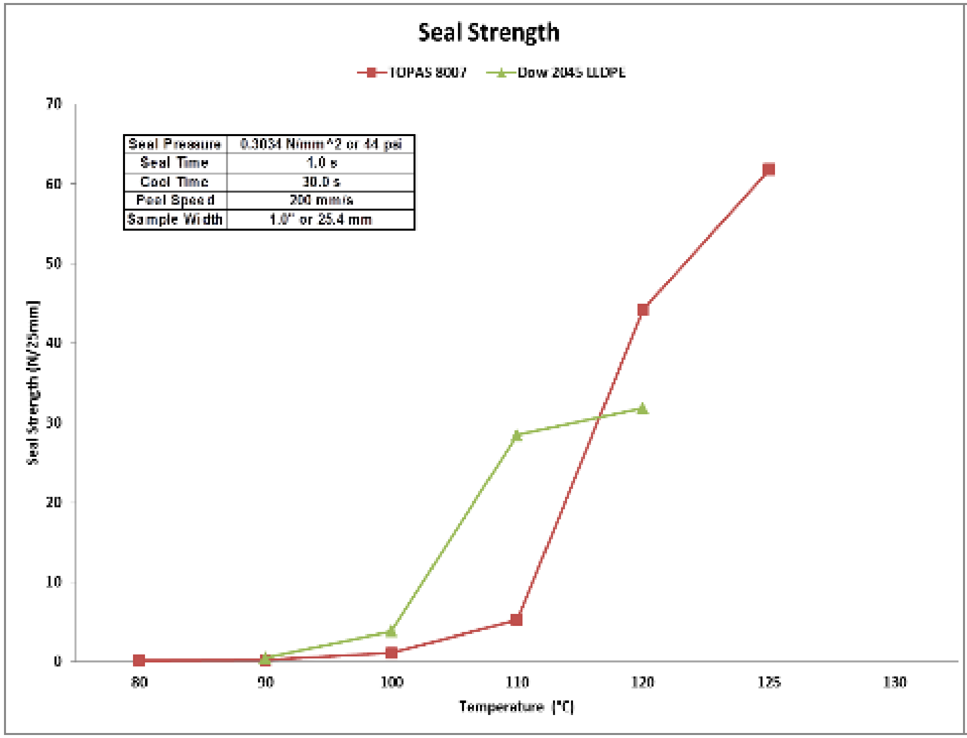
Europe

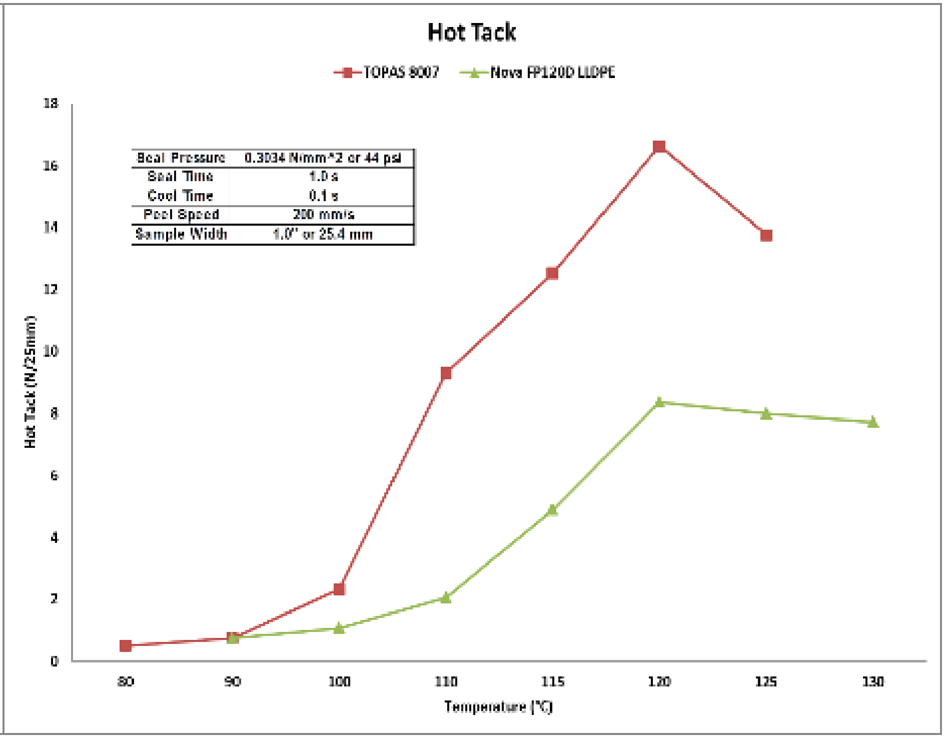
- Monomers and additives are listed in the EU Plastics Regulation 10/2011 (PIM - Plastic Implementation Measure)
- Norbornene has a Specific Migration Limit (SML) of 0.05 mg/kg

TOPAS COC is the ONLY cyclic olefin resin meeting all major global regulatory requirements for food contact and medical use

Contact us for compliance of specific grades!

TOPAS® COC: Heat Sealing





TOPAS COC has heat sealing properties similar to LLDPE

TOPAS® COC Adsorption Case Studies

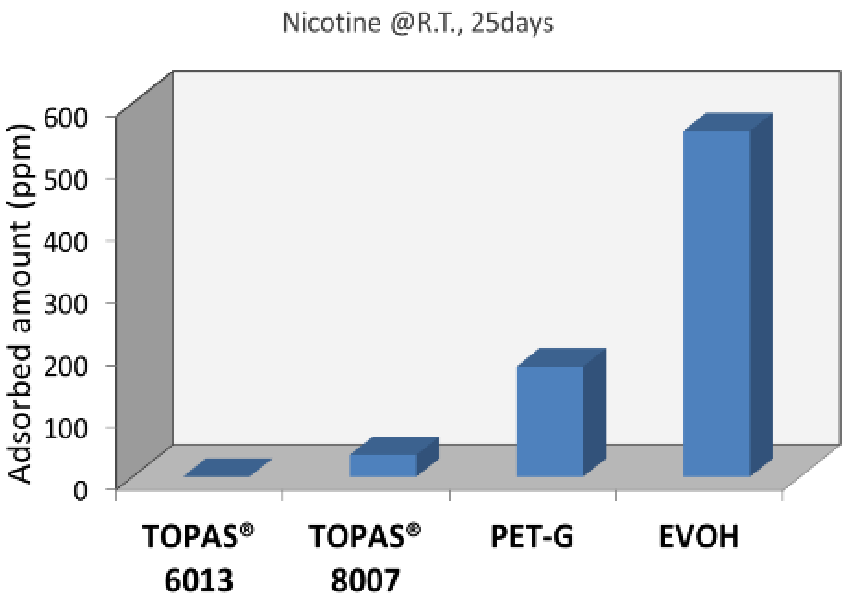
- Case Study 1: Nicotine & Bromhexine Hydrochloride
- Case Study 2: Nicotine Adsorption of COC Blends
- Case Study 3: Tulobuterol & Menthol/Camphor
- Case Study 4: SALONPAS®
- Case Study 5: Lidocaine
- Case Study 6: Triclosan
- Case Study 7: Acetone
- Case Study 8: High SPF Sunblock
- Case Study 9: Eugenol

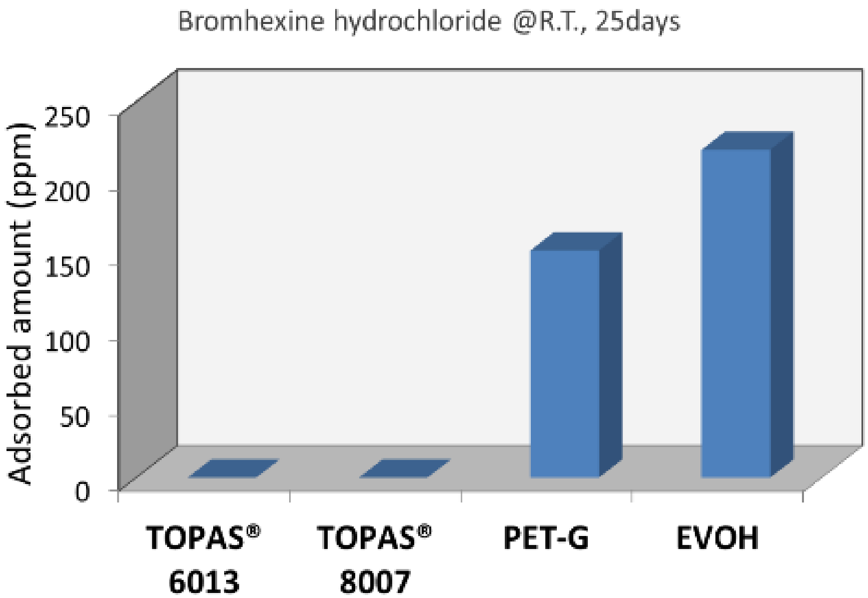
Case Study 1: Nicotine and Bromhexine HCl

- Adsorption Materials:
  - Nicotine: 25 day exposure
    - Nicotinell® patch (35 mg), 3 sheets placed bottom of desiccator
  - Bromhexine Hydrochloride: 25 day exposure
    - 2 grams placed bottom of desiccator

- Experimental Method:
  - Hang test films (40 mm x 40 mm x 30 micron) under lid; store desiccator at room temperature
    - TOPAS COC: 8007F-600 & 6013F-04
    - PET-G: Eastman Eastar GN001
    - EVOH: Kuraray EVAL E105B
  - Analysis: Mitsubishi Chemical Analytech Co., TS-100ND, nitrogen and sulfur detector

Case Study 1: Adsorption Results





TOPAS COC low adsorption of nicotine and bromhexine HCl outperforms PET-G and EVOH

Higher Tg grades of COC have lowest adsorption.

Case Study 2: Nicotine with COC Blends

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Adsorption Materials:

- Nicotine: 24 day exposure
- Nicotinell® patch (35 mg) (Novartis), 6 sheets placed bottom of desiccator

Experimental Method:

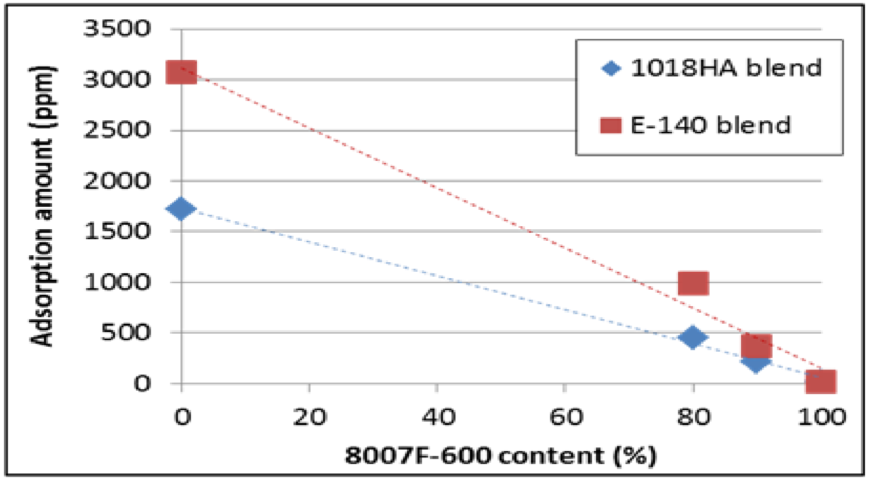
- Hang test films (40 mm x 45 mm x 50 micron) under lid; store desiccator at room temperature
- Materials:
  - TOPAS COC: 8007F-600 & E-140
  - LLDPE: ExxonMobil Exceed 1018HA

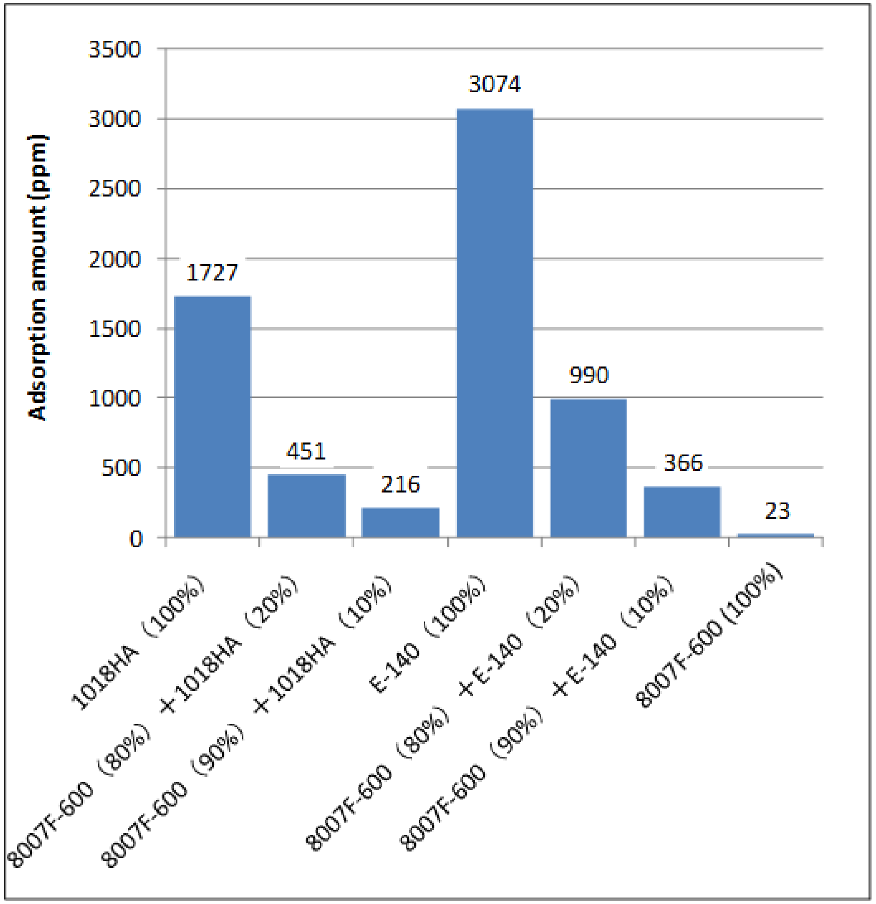
Blends:

- 8007F-600 (90%) + E-140 (10%)
- 8007F-600 (80%) + E-140 (20%)
- 8007F-600 (90%) + 1018HA (10%)
- 8007F-600 (80%) + 1018HA (20%)

Analysis: Total nitrogen method

Case Study 2: Nicotine Adsorption Results





- As expected, LLDPE and COC elastomer adsorb large quantity of nicotine.
- Adsorption of nicotine in COC blended films increase linearly as LLDPE or COC elastomer content increases.
- COC elastomer adsorbs more nicotine than LLDPE because E-140 has more free volume.

Case Study 3: Tulobuterol & Menthol/Camphor

Film samples:

- TOPAS COC: 8007F-600, 7010F-600, 6013F-04, 6013M-07
- PAN: INEOS Barex
- PET-G: Eastman Eastar GN001
- EVOH: Kuraray EVAL E105B
- m-LLDPE: Dow ELITE 5100
- r-PP: Japan Polyethylene Novatec FX4E

- Sample size: 40mm × 45mm × 30µm
- Testing done by Polyplastics, Japan

Case Study 3: Tulobuterol and Menthol/Camphor

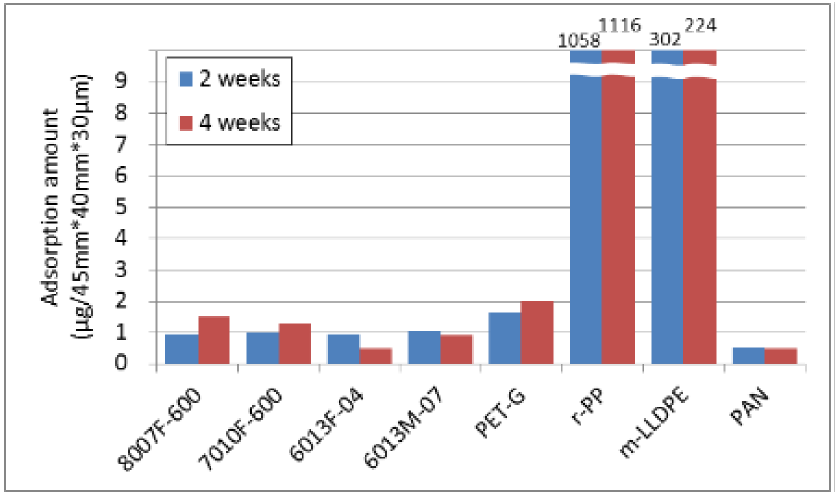
Adsorption Materials & Experimental Method:

- Tulobuterol: 2 weeks
  - 100 mg in petri dish placed bottom of desiccator
  - Hang films under lid, store desiccator at room temperature
  - Measure adsorption by liquid chromatography / mass spectroscopy

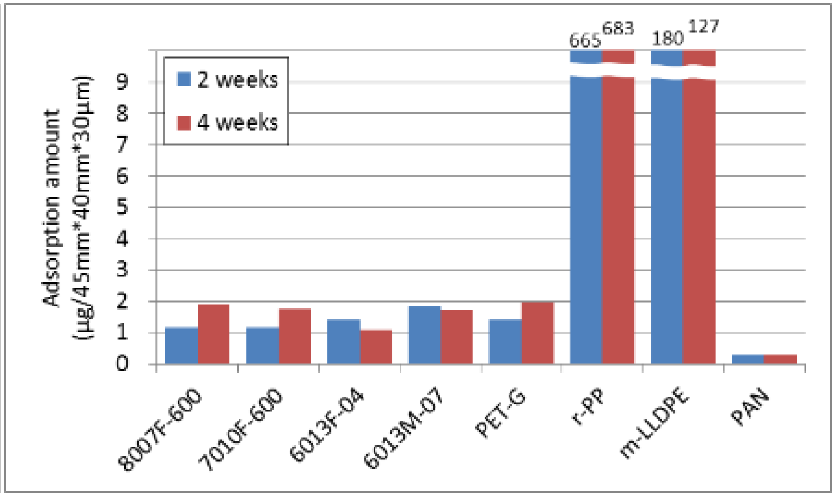
- Methyl salicylate, l-menthol, dl-camphor: 2 & 4 weeks
  - 30 g in petri dish placed bottom of desiccator
  - Hang films under lid, store desiccator at room temperature
  - Measure adsorption by head space gas chromatography

Case Study 3: Adsorption Results

dl-camphor



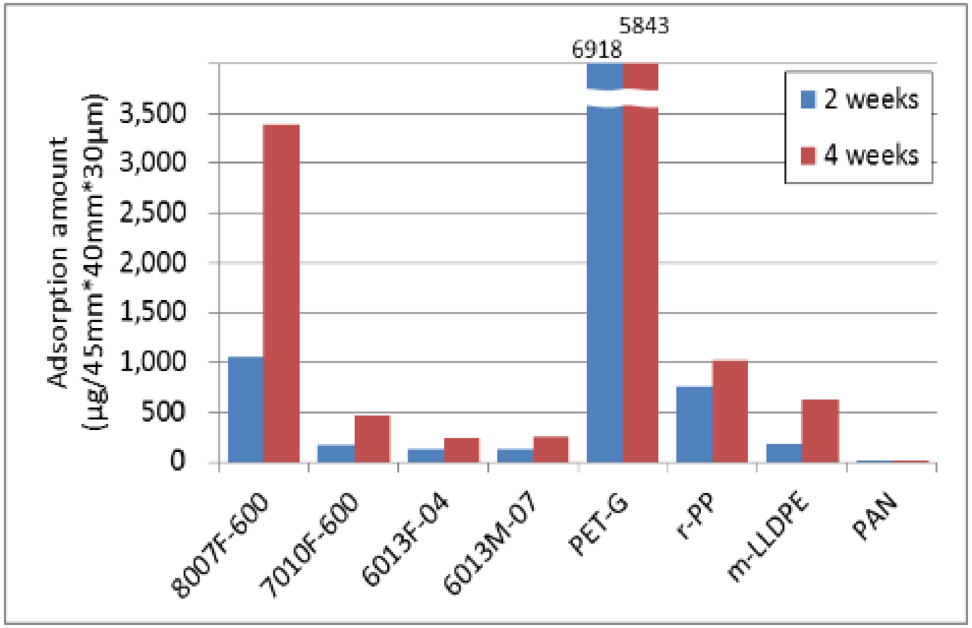
l-menthol



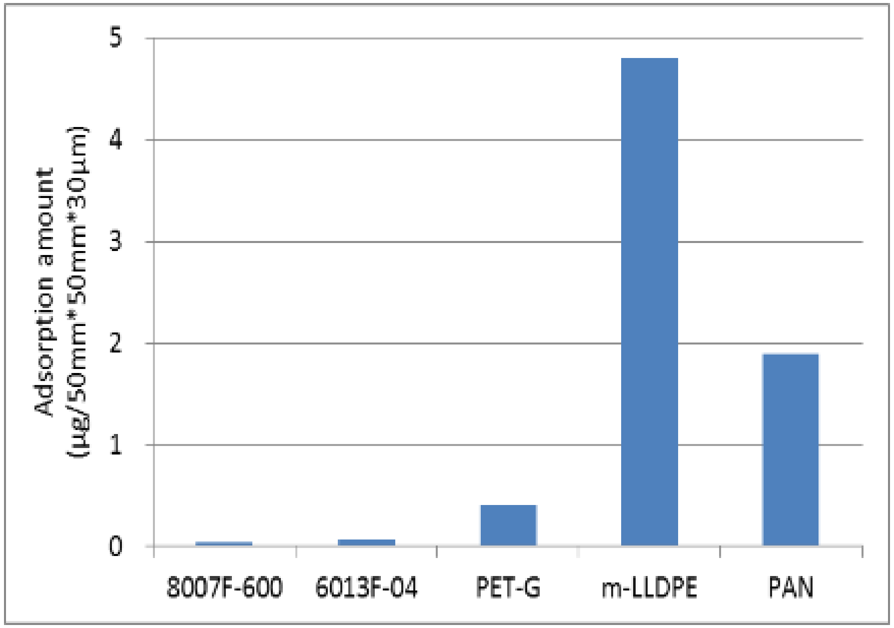
TOPAS COC offers lower adsorption than other polyolefins; independent of glass transition temperature and similar to PAN

Case Study 3: Adsorption Results

Methyl salicylate



Tulobuterol



TOPAS COC outperforms PET-G; higher Tg grades have very low methyl salicylate adsorption; similar to PAN.

TOPAS COC lowest adsorption of Tulobuterol, outperforming PET-G and PAN

Case Study 3: Tulobuterol & Menthol/Camphor

Film samples:

- TOPAS COC: 8007F-600, 7010F-600, 6013F-04, 6013M-07
- PAN: INEOS Barex
- PET-G: Eastman Eastar GN001
- EVOH: Kuraray EVAL E105B
- m-LLDPE: Dow ELITE 5100
- r-PP: Japan Polyethylene Novatec FX4E

- Sample size: 40mm × 45mm × 30μm
- Testing done by Polyplastics, Japan

Case Study 3: Adsorption Summary

	dl-camphor		l-menthol		methyl salicylate		tulobuterol
	2 weeks µg / film	4 weeks µg / film	2 weeks µg / film	4 weeks µg / film	2 weeks µg / film	4 weeks µg / film	2 weeks µg / film
8007F-600	0.96	1.52	1.16	1.89	1054.47	3395.55	0.04
7010F-600	0.98	1.28	1.16	1.74	171.69	463.55	—
6013F-04	0.95	0.50	1.40	1.09	128.41	233.81	0.07
6013M-07	1.04	0.93	1.81	1.73	131.53	253.10	—
EVOH	0.38	0.40	0.45	0.44	2.80	4.29	0.07
PET-G	1.65	2.00	1.39	1.97	6918.81	5843.41	0.41
r-PP	1057.84	1116.32	665.40	682.73	753.20	1022.82	—
m-LLDPE	302.36	223.62	180.10	127.41	180.72	639.06	4.80
PAN	0.51	0.48	0.28	0.30	1.71	6.16	1.90

TOPAS® COC is a compelling PAN replacement option for many chemicals and ingredients

Case Study 4: SALONPAS®

Film sample

- 8007F-500, PAN, PP, LDPE, HDPE
- Sample size : 50mm × 70mm × 50μm

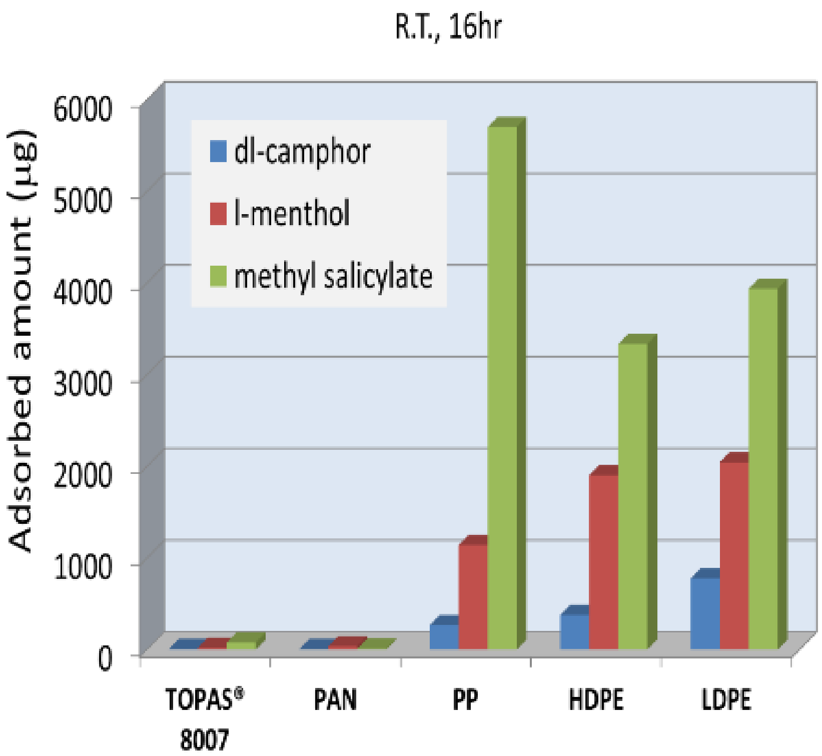
Adsorption materials

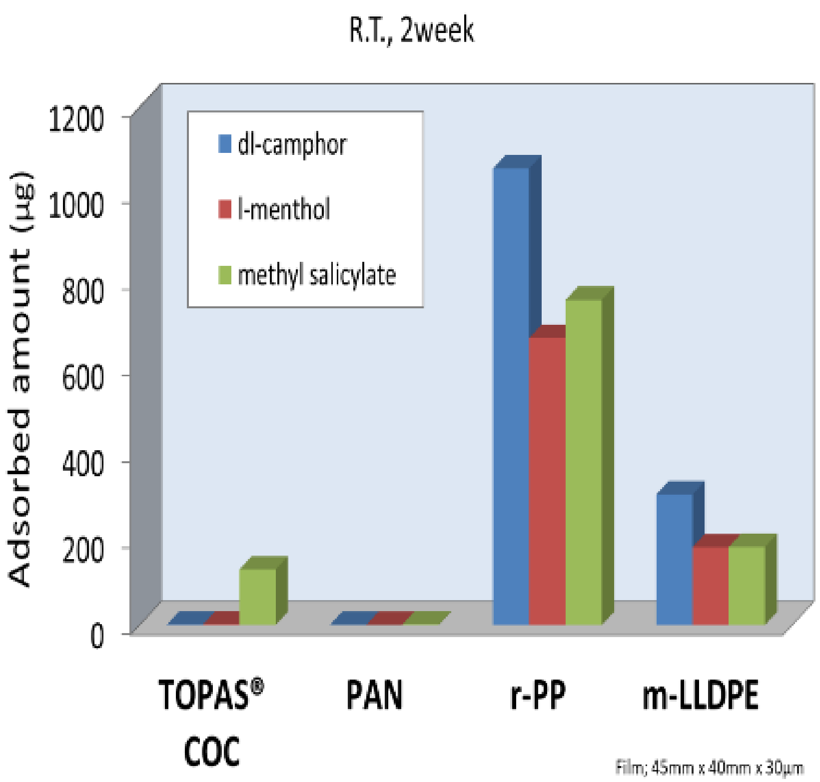
- SALONPAS® produced by Hisamitsu Pharmaceutical
  Ingredients: methyl salicylate, l-menthol, dl-camphor

Experimental method:

- Put two SALONPAS sheets on a film sample
- Wrapped it up in aluminum foil
- Stored it at 23℃ × 16h or 23℃ × 2 weeks
- Analyzed adsorption amount with HS-GC
- Testing performed by Polyplastics, Japan

Case Study 4: Adsorption Results

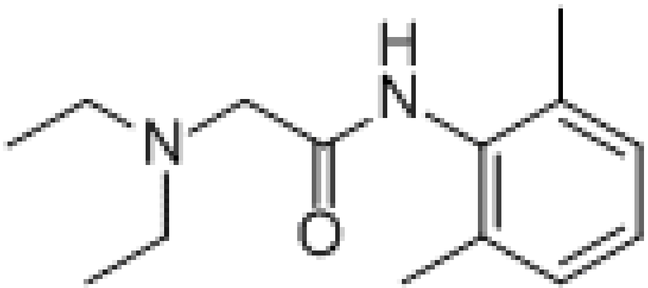




TOPAS® COC shows low adsorption for OTC medications, similar to PAN

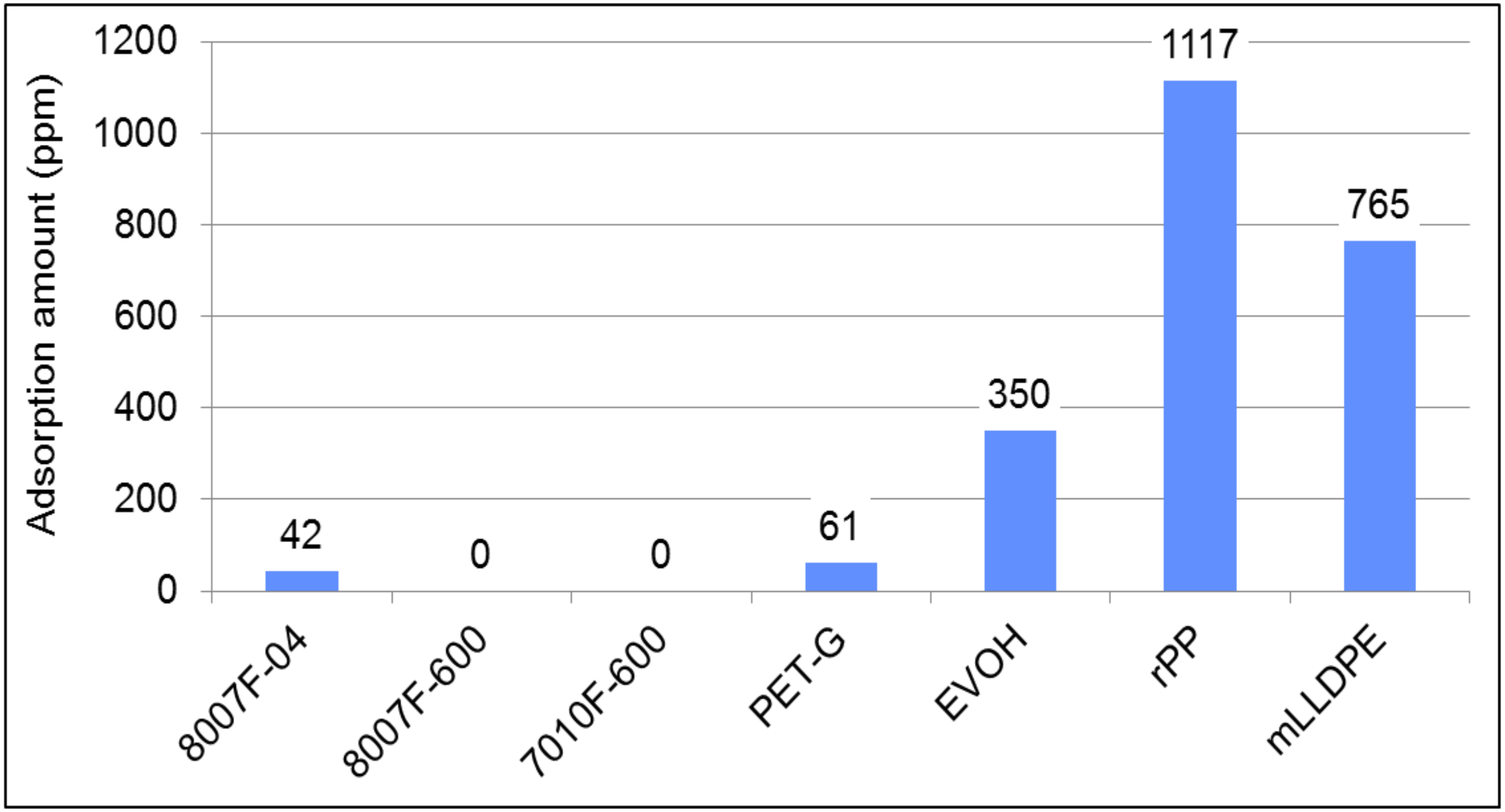
Case Study 5: Lidocaine

- **Film samples**
  - **8007F-04 (matte surface), 8007F-600 (cast), 7010F-600 (cast), PET-G, EVOH, rPP, mLLDPE**
  - **Sample size : 40mm×40mm×30μm**
- **Adsorption materials**
  - **Lidocaine**



- **Experimental method:**
  - **Hang films inside desiccator**
  - **Place 1.0 gram lidocaine in petri dish at the bottom of the desiccator**
  - **Stored it at 23℃ for 98 days**
  - **Determined adsorption amount using total nitrogen analysis**
  - **Instrument: Mitsubishi Chemical Analytech TS-100ND**
  - **Testing performed by Polyplastics, Japan**

Case Study 5: Adsorption Results



All grades of TOPAS® COC shows little or no adsorption for lidocaine, superior to PET-G and EVOH

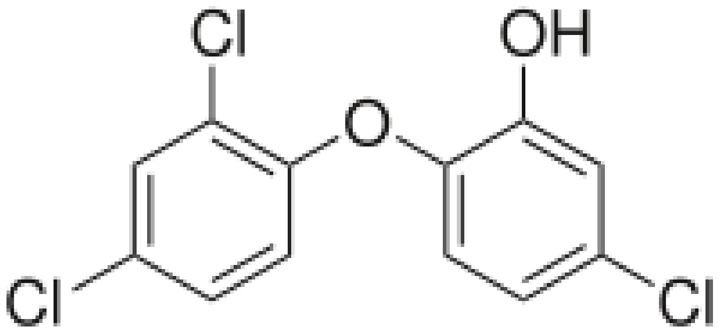
Case Study 6: Triclosan

- Adsorption Materials:
  - Triclosan: 56 day exposure
    - 0.2 g triclosan placed bottom of desiccator
- Experimental Method:
  - Hang test films (40 mm x 40 mm x 30 micron) under lid; store desiccator at room temperature
    - TOPAS COC: 8007F-600 & 7010F-600
    - PAN: INEOS Barex
    - m-LLDPE: Dow ELITE 5100
    - r-PP: Japan Polyethylene Novatec FX4E
    - PET-G: Eastman Eastar GN001
    - EVOH: Kuraray EVAL E105B
  - Testing performed by Polyplastics, Japan

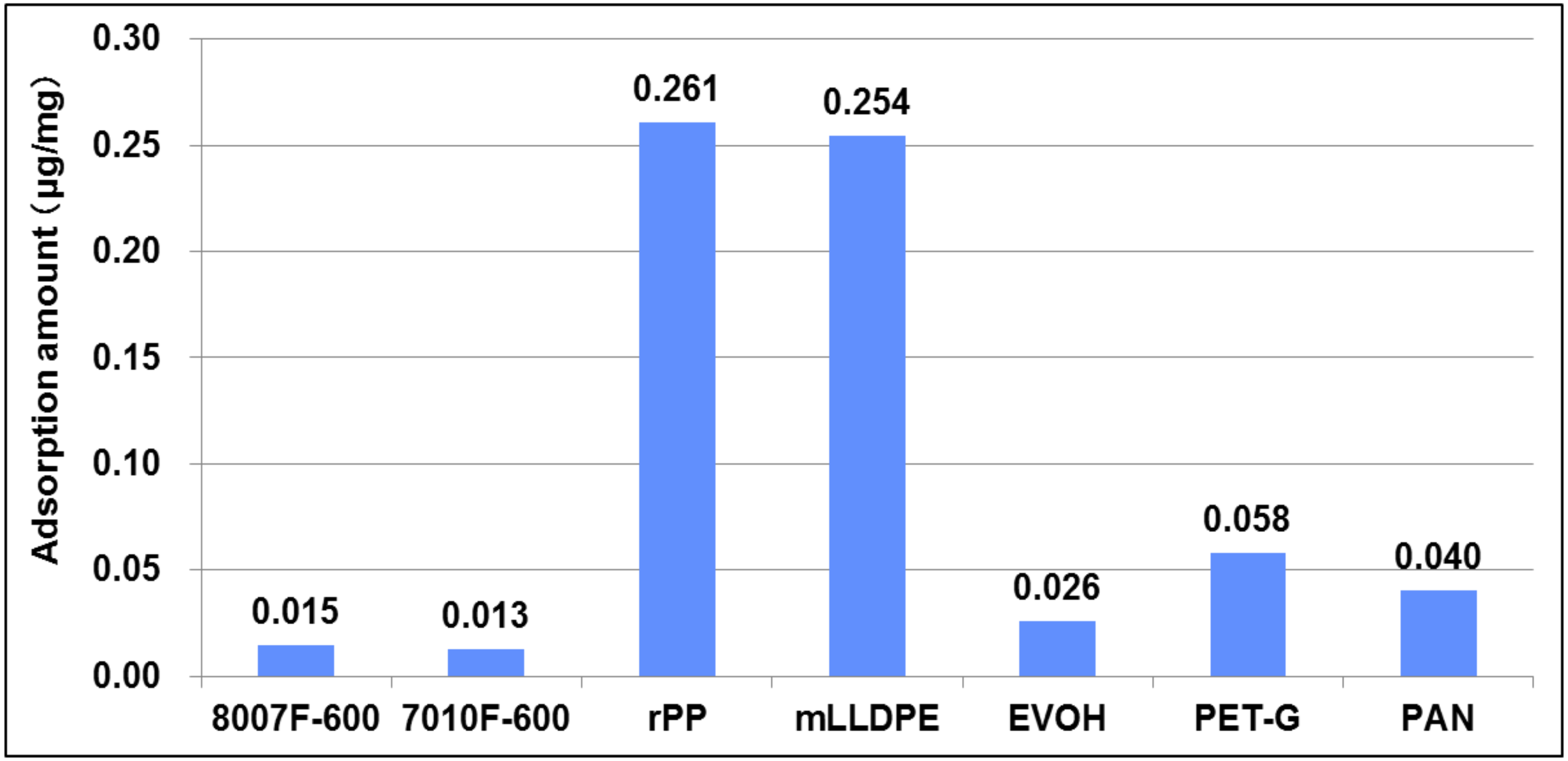
Case Study 6: Triclosan

Analysis:

- **Sample films were ashed; generated chlorine gas was ionized**
- **Chlorine ion content was determined with Ion Chromatography**
  - **Thermo-Fisher Scientific: DIONEX™ ICS-1600**
- **Chlorine ion content was converted to Triclosan weight**



Case Study 6: Adsorption Results



With the exception of rPP and mLLDPE, the adsorption data is below the minimum quantitative limit (0.13 µg/mg)

Case Study 7 & 8: Acetone & High SPF Sunblock

Test films:

- TOPAS COC: 8007F-04, 8007F-600, 7010F-600, 6013F-04, 6013M-07
- PET-G: Eastman Eastar GN001
- EVOH: Kuraray EVAL E105B
- r-PP: Japan Polyethylene Novatec FX4E
- m-LLDPE: Dow ELITE 5100
- PAN: INEOS Barex

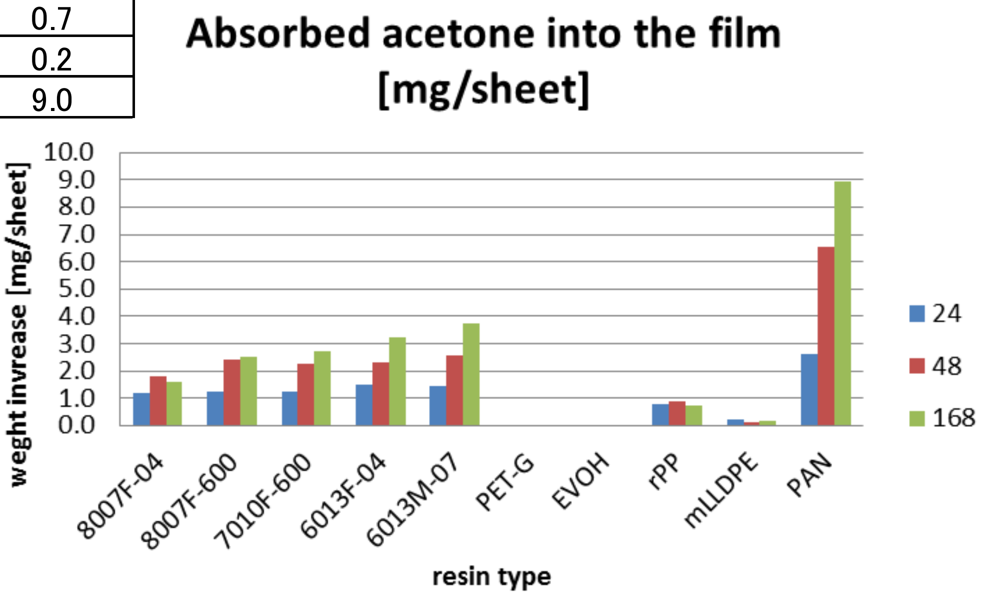
Analysis:

- Acetone:
  - Wipe 3 films sufficiently to achieve stable weight
  - Weigh all films together, calculate average
- High SPF Sunscreen:
  - Wash films in kitchen detergent
  - Wipe 3 films to remove moisture from surface
  - Weigh all films together, calculate average

Case Study 7: Acetone Adsorption Results

sample/hour	0	24	48	168
8007F−04	0	1.2	1.8	1.6
8007F−600	0	1.2	2.4	2.5
7010F−600	0	1.2	2.3	2.7
6013F−04	0	1.5	2.3	3.2
6013M−07	0	1.5	2.6	3.8
PET−G	0			
EVOH	0	−1.1	−1.3	−0.6
rPP	0	0.8	0.9	0.7
mLLDPE	0	0.2	0.1	0.2
PAN	0	2.6	6.6	9.0

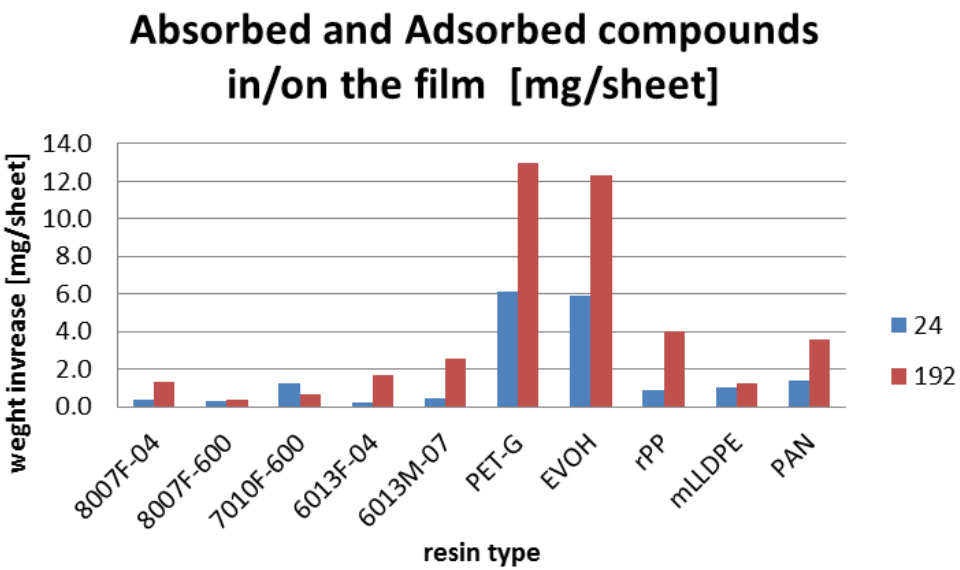
- **TOPAS COC offers low adsorption similar to polyolefins**
- **Dependence on Tg of COC**
- **PET-G and EVOH dissolves; PAN films swell and curl.**



Case Study 8: Sunblock Results

sample/hour	0	24	192
8007F−04	0	0.4	1.3
8007F−600	0	0.3	0.4
7010F−600	0	1.2	0.7
6013F−04	0	0.3	1.7
6013M−07	0	0.4	2.5
PET−G	0	6.1	13.0
EVOH	0	5.9	12.3
rPP	0	0.9	4.0
mLLDPE	0	1.0	1.2
PAN	0	1.4	3.6

- **Test results reflect quantity of sunblock chemical mixture swollen and adsorbed.**
- **Oily components can remain on the surface after washing.**
- **TOPAS COC shows lowest absorption and adsorption.**



Case Study 9: Eugenol

Adsorption Material:

- Eugenol: 0.1 g in Petri dish placed bottom of desiccator

Experimental Method:

- Hang test films (40 mm x 40 mm x 30 micron) under lid; stored in desiccator
- Exposure: 17 days at 23ºC

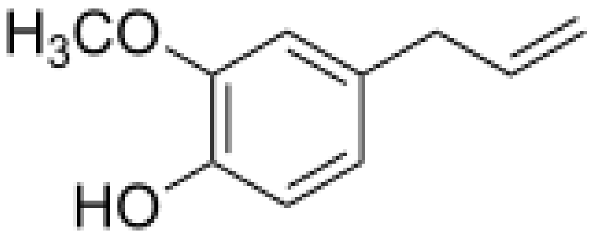
Test Materials:

- TOPAS COC: 8007F-04, 8007F-600, 7010F-600 & 6013F-04
- PETG: Eastman Eastar GN001
- EVOH: Kuraray EVAL E105B
- rPP: Japan Polyethylene Novatec FX4E
- m-LLDPE: Dow Elite 5100

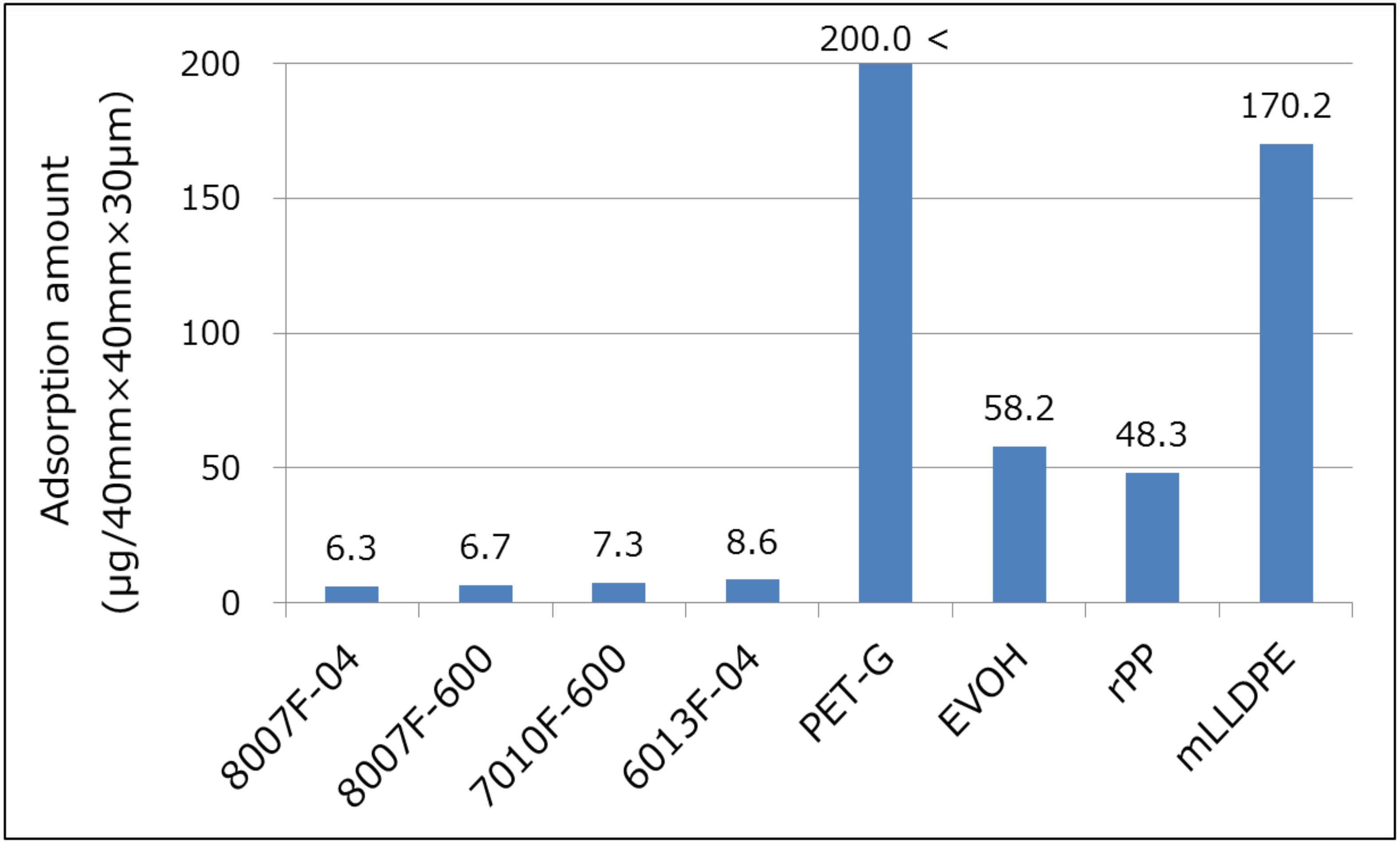
Case Study 9: Eugenol

Analysis:

- **Headspace gas chromatography with flame-ionization detection**
- **Testing performed by Polyplastics, Japan**



Case Study 9: Adsorption Results

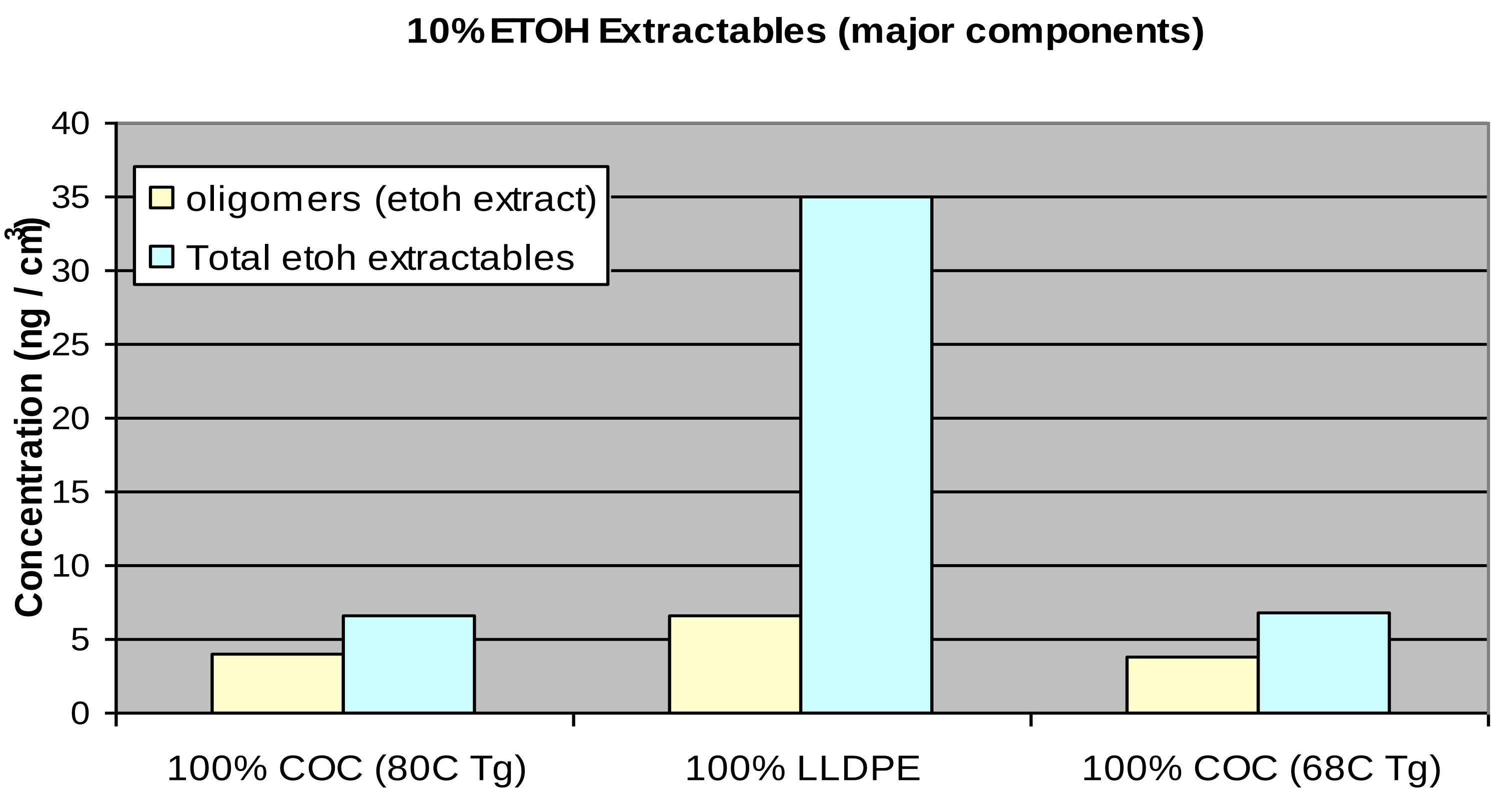


Adsorption of Eugenol is very low for COC, significantly better performance than EVOH, PETG and other polyolefins

Conclusions & Benefits

- TOPAS COC is preferred alternative to Barex (PAN) to package many medicinal chemistries & compounds, including nicotine.
- TOPAS COC adsorption is much less than in PETG after exposure to many medicinal chemistries & compounds.
- TOPAS COC adsorption is much less than in PETG & EVOH after exposure to nicotine.
- Adsorption of nicotine in COC blended films increase linearly as LLDPE or COC elastomer content increases.
- TOPAS COC is high purity, with broad global medical & food contact regulatory compliance.
- TOPAS COC has excellent heat sealing behavior.
- Unlike Barex (PAN), TOPAS COC can be safely melt processed by all common thermoplastic methods including mono & multi-layer film, sheet and extrusion coating, injection molding, and blow molding.
- TOPAS COC is available globally – Today!

TOPAS® COC - Reduced Extractables



Elevated temperature (60°C for 24 hours) extraction shows that COC has significantly lower extractables than LLDPE including about 50% lower oligomer levels which can produce off tastes in food.

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Properties molded parts, sheets and films can be influenced by a wide variety of factors including, but not limited to, material selection, additives, part design, processing conditions and environmental exposure. Any determination of the suitability of a particular material and part design for any use contemplated by the user is the sole responsibility of the user. The user must verify that the material, as subsequently processed, meets the requirements of the particular product or use. The user is encouraged to test prototypes or samples of the product under the harshest conditions to be encountered to determine the suitability of the materials.

Material data and values included in this publication are either based on testing of laboratory test specimens and represent data that fall within the normal range of properties for natural material or were extracted from various published sources. All are believed to be representative. These values alone do not represent a sufficient basis for any part design and are not intended for use in establishing maximum, minimum, or ranges of values for specification purposes. Colorants or other additives may cause significant variations in data values.

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