

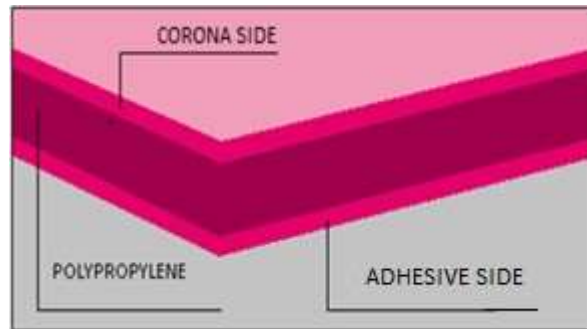
TECHNICAL DATA SHEET

060S

Art. 024340 THERMOSEAL BOPP ANTIBACTERIAL GLOSS

Profile:

- Biaxially oriented polypropylene gloss film with antibacterial treatment which reduces after 24hours the 99% of bacteria that comes into contact with the film. This is a thermal laminating film with an adhesive on one side for hot lamination. The film has the same gloss and transparency as the standard film.



Applications:

- Hospital communication materials and packaging, Children's books, Restaurant menus, Packaging for personal care products etc.
- This film is regulated for direct food contact with foodstuffs only on the film side, not the adhesive side.

PHYSICAL PROPERTIES ± 3%	TEST METHOD	UNIT	VALUE
Thickness	Internal	micron (µm)	24
Grammage	Internal	g/m ²	21,74
Yield	Internal	m ² /kg	46,00
Coefficient of friction film/film	ASTM D 1894	-	0,25
Surface tension Polypropylene side	ASTM D 2578	Dyne/cm	≥ 36
Surface tension adhesive side	ASTM D 2578	Dyne/cm	≥ 40
MECHANICAL PROPERTIES ± 3%	TEST METHOD	UNIT	VALUE
Lamination strength	Internal	N25/mm	≥ 7,5
THERMAL PROPERTIES ± 3%	TEST METHOD	UNIT	VALUE
Lamination temperature	Internal	°C	95-115

Storage Recommendations: The film can be sensitive to high humidity, store at standard storage temperature conditions of approx. 20°C, max 40% humidity, away from direct sunlight.

Disclaimer: The information given is to the best knowledge of the manufacturers specifications. These values are test results, which are indicative only and are provided merely as guidelines.

The aforementioned data is given most conscientiously but without any obligation. Any processing details are provided merely for guidance, it is the user's responsibility to check the suitability of the product for the intended application.

Warranty: This product has a warranty of 180 days as from the date on the invoice; claims after 180 days from the date on the invoice cannot be accepted. Please always keep the full label details of the film roll for warranty purposes, without full label details we cannot promise that we can handle or accept a claim.

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TK ANTIBACTERIA GLOSS (BOPP)

Declarations: This film complies with regulation EN 71-3 The European standard on the Safety of Toys (EN71) Part 3. The producer declares that the total quantity of heavy metals and substances of Lead, Cadmium, Chrome, Mercury, Arsenic, Barium and Selenium is lower than 100 ppm and are not added intentionally. As the presence of these substances are not expected, however the producer does not check its absence.

ANTIBACTERIAL DECLARATION

ISO 22196

Subject: Concerning the TK ANTIBACTERIAL GLOSS (Bopp antibacterial film)

On the basis of information provided by the Producer, Ultralen declares the following.

According to the study supplied by IMSL - INDUSTRIAL MICROBIOLOGICAL SERVICES LTD (independent testing and consultancy service specialized in the microbiology of industrial processes and products), which determines the Antibacterial Activity of Polypropylene Film Treated with Antimicrobial Agents against Escherichia coli and Staphylococcus aureus, using ISO 22196, it is declared that the above mentioned Antibacterial films containing in their composition a tested antimicrobial additive and in the percentage recommended by the raw material supplier, achieve the antimicrobial effect.

This certificate delivered by the raw material supplier was tested using a PP base film containing the additive in similar percentages, so the antibacterial properties of our films can be confirmed with an efficiency more than 99,0 % (reduction Antibacterial activity) based on ISO 22196.

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TK ANTIBACTERIA GLOSS (BOPP)
STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

USE NOTE: The Adhesive side of this film is not suitable for direct contact with foodstuffs.

The producer declares that this Antibacterial listed bi-oriented polypropylene film, when leaving the factory, have a composition that complies with the following requirements for direct food contact applications:

1. EUROPEAN UNION: Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011 (including its amendments up to Regulation (EU) 2020/1245) and Resolution AP (89) 1. Monomers and additives are listed in the Annex I of the Regulation (EU) No. 10/2011. Migration tests, carried out following the Regulation (EU) No. 10/2011 (simulants A, B, D2 at the condition of 10 days at 40°C), confirm an Overall migration results below to 10 mg/dm² (as reported here below):

Simulant A (mg/dm ²)	Simulant B (mg/dm ²)	Simulant D2 (mg/dm ²)
<1	<1	<2

The above listed film can contain some substances for which a specific migration limit (SML) is established. Specific migration has been evaluated in compliance with Regulation (EU) No. 10/2011 in a theoretical (assuming that 1 Kg of food is packaged with 6 dm² of film) or, if necessary, in experimental way (simulants A, B and D2 for 10 days at 60°C). Herewith are reported the analysis' results.

SML Substances	Simulant A (mg/Kg)	Simulant B (mg/Kg)	Simulant D2 (mg/Kg)
FCM Nr: 19 Ref Nr: 39090 + FCM Nr: 20 REF Nr: 39120 SML(T): 1.2 mg/Kg	<0.5	<0.5	<0.5
FCM Nr: 779 CAS Nr: 182121-12-6 Ref Nr: 39815 SML: 0.05 mg/Kg	<0.02	<0.02	<0.02
Silver CAS Nr: 7440-22-4 SML: 0.05	-	<0.001 (1)	-

(1) This simulant is the most critical for silver

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TK ANTIBACTERIA GLOSS (BOPP)

In order to verify the compliance of annex II of Regulation (EU) 10/2011, a specific migration analysis has been carried out concerning the metals (simulant B for 10 days at 60°C). Herewith are the reported the analysis' results.

Metals	Simulant B (mg/Kg)	Metals	Simulant B (mg/Kg)
Aluminium	<0.1	Iron	<1
Antimony	<0.01	Lanthanum	<0.01
Arsenic	<0.002	Lead	<0.005
Barium	<0.1	Lithium	<0.1
Cadmium	<0.002	Manganese	<0.1
Chrome	<0.01	Mercury	<0.002
Cobalt	<0.01	Nickel	<0.01
Copper	<1	Terbium	<0.002
Europium	<0.01	Zinc	<1
Gadolinium	<0.01		

The above listed film can contain some other substances for which a specific migration limit (SML) is established. For these substances, the SML will not be exceeded (assuming that 1 Kg of food is packaged with 6 dm² of film):

FCM Nr:132	CAS Nr: 75-38-7	Ref Nr: 26140	SML	:5	mg/kg
FCM Nr:156	CAS Nr: 80-62-6	Ref Nr: 21130	SML	:6	mg/kg (expressed as
FCM Nr:185	CAS Nr: 97-90-5	Ref Nr: 20440	SML	:0.05	methacrylic acid) mg/kg
FCM Nr: 231	CAS Nr: 108-05-4	Ref Nr: 10120	SML	:12	mg/kg
FCM Nr: 246	CAS Nr: 109-99-9	Ref Nr: 25150	SML	:0.6	mg/kg
FCM Nr: 264	CAS Nr: 111-66-0	Ref Nr: 22660	SML	:15	mg/kg
FCM Nr: 282	CAS Nr: 116-15-4	Ref Nr: 18430	SML	:0.01	mg/kg
FCM Nr: 292	CAS Nr: 122-20-3	Ref Nr: 94560	SML	:5	mg/kg
FCM Nr: 310	CAS Nr: 126-30-7	Ref Nr: 16390	SML	:0.05	mg/kg
FCM Nr: 315	CAS Nr: 128-37-0	Ref Nr: 46640	SML	:3	mg/kg
FCM Nr: 325	CAS Nr: 141-32-2	Ref Nr: 10780	SML	:6	mg/kg (expressed as acrylic acid)
FCM Nr: 334	CAS Nr: 151-56-4	Ref Nr: 17005	SML	:0.01	mg/kg
FCM Nr: 356	CAS Nr: 592-41-6	Ref Nr: 18820	SML	:3	mg/kg
FCM Nr: 402	CAS Nr: 1314-13-2	Ref Nr: 96240	SML	:25	mg/kg (expressed as zinc)
FCM Nr: 433	CAS Nr: 2082-79-3	Ref Nr: 68320	SML	:6	mg/kg
FCM Nr: 475	CAS Nr: 4098-71-9	Ref Nr: 19110	SML	:1	mg/kg (expressed as
FCM Nr: 484	CAS Nr: 4767-03-7	Ref Nr: 13395	SML	:0.05	isocyanate) mg/kg
FCM Nr: 661	CAS Nr: 27676-62-6	Ref Nr: 95360	SML	:5.0	mg/Kg
FCM Nr: 688	CAS Nr: 38613-77-3	Ref Nr: 92560	SML	:18	mg/Kg
FCM Nr: 760	CAS Nr: 119345-01-6	Ref Nr: 83595	SML	:18	mg/Kg
FCM Nr: 765	CAS Nr: 134701-20-5	Ref Nr: 49485	SML	:1	mg/Kg
FCM Nr: 974	CAS Nr: 939402-02-5	Ref Nr:74050	SML	:10	mg/kg

In accordance with Regulation (EC), No.2023/2006 This Antibacterial film is manufactured in compliance with general rules on good manufacturing practice (GMP).

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2. **DUAL USE ADDITIVES:** The following dual use additives subject to restriction in food as defined in Regulation (EU) No. 10/2011 are present in the above mentioned film:

•	Calcium carbonates	E170
•	Alpha Tocopherol	E307
•	Butylated hydroxytoluene	E321
•	Citric Acid	E330
•	Sodium, potassium and calcium salts of fatty acids	E470a
•	Magnesium salts of fatty acids	E470b
•	Mono and diglycerides of fatty acid	E471
•	Silicon dioxide	E551
•	Magnesium silicates	E553b
•	Fatty acids	E570
•	Dimethyl polysiloxane	E900

Their migration is lower than the overall migration reported at point 1

2. PHTHALATES: Phthalates are not intentionally added in the above-mentioned film. However, traces of phthalates may be present as impurities from the catalytic system used to manufacture some of the base polyolefin resins used for BOPP production; maximum residuals are no more than 15 ppm.

3. USA: The above listed films are suitable for use in food contact applications with the following restrictions based on the composition of the film and the U.S. FDA regulation applicable:

Base film: The raw materials used in the composition of the BOPET film are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 177.1520 (c) 1.1a, 3.1a, 3.2a and other applicable regulations in 21 CFR referenced therein.

Adhesive: The raw materials used in the composition of the olefin copolymer (adhesive) and coatings are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 175.320 and other applicable regulations in 21 CFR referenced therein.

Adhesion promoter: The raw materials used in the composition of the adhesion promoter are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 175.105 and other applicable regulations in 21 CFR referenced therein.

4. EPA: According to the producers suppliers, the antimicrobial agent is registered with the EPA and can be used in accordance with applications listed on EPA label. These treated films can be

sold throughout USA in line with the treated article exemption, Pesticide Registration Notice (PR) 2000-1. It is extremely important, and customer responsibility, that any claim is checked to ensure it is not outside those allowed within scope of the PR notice. Any penalty due to claims made that are outside scope are responsibility of the customer.

Responsibility: Customers must check that their use of the film is safe and technically suitable for their applications. The final item producer is responsible for the evaluation of global/specific migration at the real time/ temperature conditions.