Pharma labelling solutions

Build a healthier business with dedicated pharma labelling solutions







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Choosing the right material for your pharmaceutical label

A solution for any and every application

Sterilisation

Glossary of Terms



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This brochure, together with our product overviews, give you comprehensive details of key Avery Dennison products designed for pharmaceutical labelling applications.

Avery Dennison - your local access to global expertise

Avery Dennison is a global leader in the development and supply of pressure-sensitive adhesives, self-adhesive materials for consumer and industrial products. We provide customers with local access to worldwide resources and expertise.

This brochure, and our separately available product overviews, presents information on dedicated pharma segment adhesives, facestocks and liners - all designed to meet the stringent demands of the pharmaceutical industry. Our goal is to help drugs manufacturers, printers and converters to choose the best possible materials for challenging pharma labelling applications.

Our Commitment. Your Advantage

For more than 80 years, Avery Dennison has been innovating and advancing the labelling industry. The Avery Dennison ADvantage Technical Excellence Team exists to meet new challenges, and to make innovation possible for customers all over the world.

Our pharma team of dedicated compliance and R&D experts specializes in helping you meet pharmaceutical industry challenges. We are here to provide detailed advice on all aspects of pharma applications, and to address highly specific application needs. Comprehensive technical sales support makes product qualification and implementation as simple as possible.

Technology that performs

Legislative requirements governing pharmaceutical packaging are becoming more demanding, and new applications pose novel technical challenges. Avery Dennison innovations keep you up to date, with products that have been extensively tested in laboratories and in the field. We work closely with value chain during product qualification to ensure the right technology is used for a particular application.

Complete Compliance

Avery Dennison's Pharma and Complete Compliance Team ensures that converters and pharmaceutical companies have the detailed information and the transparency needed to address complex regulations and fulfill regulatory requirements.

The regulatory environment is closely monitored and carefully reviewed by our technical and compliance specialists. All of our products comply with REACH regulations and EU Directive 94/62/EC. In addition, our dedicated pharma portfolio includes products that are compliant with both European food regulation 1935/2004/ EC, including 10/2011/EU (also compliant with FDA regulations); and with Falsified Medicine Directive 2011/62/EU.

Avery Dennison products are tested by recognised third-party organisations to ensure complete transparency. We understand that users of our products also have their own compliance obligations, and we provide detailed support to them in order to help them to meet those obligations.



Change management and advanced notification

Whenever a change is made in a pharma product, its impact on performance must be communicated and assessed. For products that need to be re-tested, complete change management documentation have to be created for pharmaceutical manufacturers and third parties.

Avery Dennison offers advanced notification of product changes, and provides pharma customers with the business-friendly support needed to manage pharma materials over their entire production lifetime:

- Pharma adhesives, with 1-year prenotification of modification* Specific performance requirements -
- validated via application based testing – Change management control with complete change management documentation
- **Supporting documentation** e.g. Customer Product Specification, risk analyses and validation report related to proposed changes
- **Third-party certificates** e.g. Food Contact, FDA, tests against specific ISO norms, Toxicology
- Customised analytical tests on request
- Applies to specific pharma adhesives: S2000NP,
 S2045NP, S717P, S692NP,
 S788P, S799P



Choosing the right material for your pharmaceutical label

Pharmaceutical labelling includes a wide variety of applications and many different real-world conditions. Challenges include extremely low temperatures (cryogenic), exposure to sterilization treatments, and the small diameter of containers such vials or syringes (which are also made from plastics that are difficult to label) as labels applied on high-speed dispensing lines.

In order to address all of these challenges, a number of key criteria must be met. The selection of labelling materials is critical, and is governed by all of the following:

- Variations in labelling and storage conditions
- The physical characteristics of the application substrate
- Required levels of resistance to solvents, moisture, UV rays, etc.
- Performance requirements at different temperatures
- Mandrel performance on small-diameter containers
- Certification and specification

Once all of these factors have been determined, further criteria must be addressed relating to product characteristics, label dispensing, and the substrate to which the label is to be applied. Only then can an application be tested with confidence that results will be as required.



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Small diameter labelling

Typical pharmaceutical containers have volumes as low as 1-150 ml. and diameters down to 10 mm. This presents a major potential issue with label 'lift'. Plastic surfaces with tight curvature (mandrel) place enormous demands on a label adhesive - and changes designed to raise productivity can complicate matters further. The Avery Dennison range of specialist materials includes labels for syringes, vials, test tubes and other applications. These materials provide outstanding tight mandrel performance without edge lift, and also ensure a low risk of adhesive migration into package contents.







Security

Security is an increasingly important topic for pharmaceutical packaging and labelling. Security failures have the potential to put patients' health and lives in danger and cause large financial losses for a medicine manufacturer. The European Commission approved The "EU Directive on Falsified Medicines" (Directive 2011/62/EU), which came into force in February 2019 in order to improve levels of security in pharma industry. Every prescription medication must now have a tamper evident feature incorporated into packaging. Many layers of protection technology are available, ranging from simple but effective destructible labels and VOID effect labels through to high-end custom taggants. Avery Dennison offers low-level anti-counterfeit technology, visible to the consumer, and also high-level security features using a covert or forensic technology - allowing brand owners to protect any medicine, no matter what its value or intended use.

Cold Chain

Low temperature labelling

Many medications and vaccines are stored in chilled conditions. Blood and plasma bags are stored and transported in temperatures around -30°C. Human tissue samples require storage and transport temperatures as low as -196°C.

Our comprehensive low temperature portfolio is designed for bottles, test-tubes, vials and other containers used in hospitals, clinics and research labs. It enables many printing technologies, across different applications from blood bags through to cryogenic and laboratory packaging. Labels comply with FDA and European food regulations, and have been certified by ISEGA testing institute according to DIN ISO 3826 for "Plastic Collapsible Containers for Human Blood and Blood Components".



TT Sensor Plus[™] 2 technology

Producers and purchasers of temperature-sensitive products need to ensure the quality of their products, and to identify any supply chain issues that may lead to compromised products. The half credit-card sized Avery Dennison TT Sensor Plus 2 data logger uses the NFC technology to transfer temperature logging data wirelessly to mobile devices. It is a complete solution, with multiple services such as an application for smartphones, a cloud environment, an application programming interface and individual calibration capabilities.

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Intelligent labels

Hospitals, pharmacies, and other healthcare providers are looking for ways to better manage costs, increase efficiencies, and ensure the wellbeing of their patients. RFID technology can help itemize and sort stock, to ensure quality and prevent waste. Benefits go beyond return on investment - with the potential to save lives by supporting clinicians with vital information. Our RFIDenabled solutions boost efficiency by improving accuracy substantially - 99%+ is realistically achievable. They also help to manage costs across the supply chain, and to prevent pharmaceutical brand counterfeiting.

Intelligent labels can also track asset movements and locations, and keep high-demand items available at all times - something that is critical for the pharmaceutical business, and especially complex for those with a global supply chain. Avery Dennison creates cost-effective RFID inlays and technologies that provide end-toend inventory and item tracking solutions for increased accuracy, visibility, and security, starting at the point of manufacture.

ThermaVIP+™ technology

For drugs that need to be transported at cold temperatures, it is important to use a packaging solution that not only keeps contents cold during shipment, but which is also efficient and cost effective. A vacuum insulated panel (VIP) is a form of thermal insulation consisting of a gas-tight enclosure surrounding a rigid core, from which the air has been evacuated. VIPs are used widely in many sectors including pharmaceutical and medical. For temperature controlled packaging, where temperature is critical, VIPs are the undisputed top-of-the-line insulation solution. Durable ThermaVIP+ makes them a robust yet competitivelypriced option.





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A solution for any and every application

Avery Dennison self-adhesive labelling materials are manufactured using coating technology - a process which involves the lamination of four key elements: facestock, adhesive, release coat and liner. The right combination of layers ensures a pharma-compliant product with the performance and properties needed to meet specific application demands.

Facestocks

The facestock material, made of paper or film, is printed and die-cut to form the label itself. Many different performance characteristics include resistance and appearance - as illustrated in Table 1 (paper facestocks) and 2 (film facestocks).

Identifying the right paper stock depends on a mix of design, functionality, performance and more. Search our products to determine which paper is right for your needs. Options include:

- Supercalendered, white uncoated wood-free paper
- Machine coated, woodfree, semi-gloss white paper
- Cast coated high gloss finished, wood-free white paper
- Double-coated light-weight wood-free paper semi-gloss appearance, semi-conformable with stated luminescence level

Table 1 Paper facestocks Paper Type	Face Appearance	Flexibility	Opacity	Gloss	Print Quality	Smudge Resistance	
Uncoated paper Vellum)	Matt	••	••		•	•••	
Double Coated LW)	Semi-gloss	•••	••	••	•••	••	
Coated paper MC)	Semi-gloss	••	••	••	••	••	
Cast Coated paper HGW)	Gloss	•	•••	•••	•••	••	

Filmic facestocks are attractive for converters and end users because of their transparency, durability, conversion speed and efficiency. There are several important considerations when choosing the right filmic label as shown in table 2. The options for filmic labels include:

- Blown extruded PE film which is flexible and conformable
- Biaxially-oriented PP film which is rigid and low in flexibility and conformability
- Semi-conformable films machine direction oriented (MDO) product with good performance
- PET rigid highly transparent film with good heat resistance and durability

Avery Dennison self-adhesive labelstocks can be printed via conventional technologies including letterpress, UV and conventional flexo, gravure and screen process.

Label liner

The liner is an essential part of the label construction, serving to carry the self-adhesive material all the way through the manufacturing process until application of the label onto the substrate. In general, liners are divided in three main groups:

- Glassine a smooth and glossy paper manufactured by supercalendering. Designed for medium to high speed conversion. Good caliper consistency allows accurate kiss die cutting. The paper's translucent properties are well suited to automatic label applicators. Particularly suitable for products in reels.
- Filmic made from polyester or polypropylene. Filmic liners provide optimum smoothness to the adhesive layer and feature very high strength. Suitable for applications where highest clarity of the applied label is required (i.e. the 'no label' look). The film's high strength and uniform caliper permit very high speed conversion and dispensing.
- Kraft a paper liner made from chemical pulp produced in the kraft process and bleached. The liner is combined with face materials suitable for label applications using variable information such as address, instruction and inventory labels, labels for office use and those requiring manual application.



Table 2 **Film facestocks**

Film Type	Face Appearance	Conformability	Diecutting	Dispensing	Print Registrati	Transparency	Opacity (White
Conformable PE	Gloss	•••	••	••	••	••	••
Semi-conformable Primax, Fasclear	Semi-matt	••	••	•••	•••	•	•••
Rigid BOPP	Gloss	•	•••	•••	•••	•••	•••
Rigid PET	Gloss	•	•••	•••	•••	•••	•••

VI printing

In pharmaceutical, healthcare and laboratory applications, late-stage serialisation and variable information print play a crucial role. Most medications must include unique serial codes, and all samples, specimens, test tubes need to be identifiable.

Please consult the table to compare the VI print techniques combined with different facestocks:

Thermal transfer printing is especially convenient for end users who need to customise every label on demand using a compact and convenient printer, for example in laboratories or small offices.

Industrial thermal (solvent) inkjet performs well on a variety of film and paper facestocks - a reasonably priced technique that offers a durable print resistant to moisture, UV light and a good print quality.

Laser engraving printers are commonly installed on packing lines to print additional information such as LOT number or QR code on the package or pre-printed label. The benefits of laser engraving include high accuracy (and repeatable print) as well as a high print speed.

UV Inkjet offers sharp contrast, which can be important when a large amount of text has to be fitted onto a small label. Another benefit is the smudge resistance that can be critical for pharmaceutical labels. This platform does not enable, however, the use of paper facestocks.

Table 3 VI printable facestocks Papers	Thermal Transfer (TT)*	Industrial Thermal (Solvent) Inkjet*	Laser Engraving	UV Inkjet
Uncoated Calendered	•••	•••	•••	
Double Coated (LW)	••	••	••	
Coated calendered	••	••	••	
Cast Coated	••	••	••	
Films				
PE Non topcoated	••	••		
PE Topcoated	•••	•••		•••
Semi-conformable Primax, Fasclear	•••	•••		••
Rigid BOPP Topcoated	•••	•••	••	•••
Rigid PET PT**	••	••	••	••
Rigid PET Topcoated	•••	•••	••	•••

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* Please always consider the ribbon supplier's guidance

** For Water-based Inkjet printing, a special top coat is needed.



Digital printing

In recent years digital printing has become more popular, and the technology offers many advantages for pharmaceutical printing. Digital machines have a shorter setup time and allow short print runs at lower cost. Digital print also allows every printed label to be customised and serialised at the same time, while maintaining the highest quality print. The three main digital printing technologies include UV Inkjet, Water-Based Inkjet and Dry Toner. The latter is especially suited for pharmaceutical label print requiring fine details. Table 3 shows possible facestock combinations with specific digital technologies.

This table serves as a reference only. Testing is required before using a specific facestock.



Table 4 Digital printable facestocks Papers	Dry Toner	UV Inkjet	Waterbased inkjet
Uncoated Calendered	~		
Double Coated (LW)	✓	✓	
Coated Calendered	✓	✓	✓
Cast Coated	✓	✓	
Films			
PE Non topcoated			
PE Topcoated	~	✓	~
Semi-conformable Primax, Fasclear	✓	✓	
Rigid BOPP Topcoated	✓	~	~
Rigid PET PT	✓	✓	~
Rigid PET Topcoated	✓	~	~





Adhesives

The choice of adhesives has a critical impact on specific application properties, and on how well a label performs in the environment where the packaging or container will be used. Different adhesive options are suitable for specific surfaces. Labelling materials are available using solvent, emulsion or hot melt adhesive technologies.

Table 5 provides an overview of pharmaceutical performance requirements based on adhesive technologies, whilst Table 6 outlines the characteristics and abilities of some key Avery Dennison adhesives.

A number of key criteria must be addressed (see below) to ensure that the material selected meets pharma and individual end user requirements. All of our materials are tested according to the methods specified by FINAT, the European association for the self-adhesive label industry.

Initial tack

The tack value of a pressure sensitive material is the force required to separate a label from the substrate at a specified speed (FINAT). Strong initial tack is very important in the case of medication packaging where the plastic bottles, vials or syringes are being packed/filled and labeled on a high speed production lines (>300 per minute - with application time per package of less than 0.0045 of a second).

Adhesion

Peel adhesion is defined as the force required to remove a pressure-sensitive coated material from its substrate (FINAT). High adhesion is crucial for pharmaceutical labels. A label with a low adhesion level could fall off the product or attach to another, causing traceability problems and misidentification of products, lab samples etc.

Mandrel

Mandrel adhesion is defined as the edge lifting (expressed in mm) of a pressuresensitive adhesive-coated material from a standard cylindrical rod / tubes of small diameter (FINAT). Small, round containers are common in pharma - from medicine bottles through test tubes to syringes - making mandrel performance critically important.

Migration

Pharmaceutical labels are often a subject of migration risk assessment. Migration can be described as the movement of one or more constituents from one material to another, which may result in contamination of one or both constituents. Pharmaceutical companies and their suppliers have to conduct tests based on the EMA 'Guideline on Plastic Immediate Packaging Materials', including extraction, interaction and migration studies for all new packaging materials. Also the FDA (Food and Drug Administration) issued their guidelines on Assay Migration Studies for In Vitro Diagnostic Devices. Avery Dennison has developed several pharmaceutical labelling adhesives that follow those guidelines.

Table 5Adhesive performancePerformance Requirement	Acrylic Emulsion	Acrylic Solvent	Hot Melt Rubber	Solvent Rubber	
	HDPE/LDPE	•	•	•••	•••
Initial tack/Adhesion	PP	•	•	•••	•••
Initial tack/Adhesion	Glass	••	•••	•••	•••
	PET	••	•••	•••	•••
Small Diameter* (Mandrel)	<15 mm	••	•••	•	•••
	Autoclave	••	•••		••
Sterilisation Resistance	ETO	••	•••		••
	Radiation	••	•••		••
Chemical Resistance		••	•••	•	•
Heat Resistance		•••	•••	•	••
Humidity Resistance		•	•••	•••	•••
Clarity	Clear-on-Clear	•••	•••	•	•
High-speed Converting/ Dispensing		•••	•••	••	••

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* Depend on face material and type of substrate (Glass, plastic)

Table 6Adhesives overview	Adhesion		Small Diam	ieter Glass*
Adhesive Small-diameter labelling	Glass	PE / PP	~10 mm	>15 mm
S2000NP	•••	••	••	•••
S692NP	••	•	•	••
S717P	••	••	••	•••
S2045NP	•••	•••		••
S697	•••	•	••	•••
S700	•••	••	••	•••
MP318N	•••	•	•••	•••
S692NP LUM	••	•	•	••
S4000 LUM	••	•	•	••
S697 LUM	•••	•	••	•••
S700 LUM	•••	••	••	•••
MP318 LUM	•••	•	•••	•••
Low temperature labelling				
C2020P	••	••		•
C2050P	•	•	•	•
S2060NP	•••	•••		••
AL171	•••	••	•	••
MI465	•••	••	•	••
S2196	•••	••	•	••
Security				
S788P	••	••		
S799P	•••	••		

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* Application specific testing recommended ** Depend on facestock selection

PE/	PP*	<u>د</u>	Sterilization*	*		Resitance to	,
~10 mm	>15 mm	Autoclave	ЕТО	Gamma	Chemical	Heat	Humidity
•	••	•	•	•	••	••	•
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Sterilisation

Sterilisation resistance

Label materials should be able to withstand the most commonly used sterilisation procedures including autoclaving, ETO and gamma radiation. The effects of procedures on the labels themselves ultimately depend on the choice of procedure and the sterilisation conditions, as summarised below:

- Autoclaving good results can be achieved with paper labels and acrylic adhesives under these conditions. PE cannot withstand such temperatures. Polypropylene and polyester are possible alternatives.
- Ethylene oxide gas (ETO) this method also produces good results with paper labels and acrylic adhesives. Film labels - particularly PE and PP - can be adversely affected.
- Gamma radiation good results are achievable using film and paper labels with acrylic adhesives. Rubber-based adhesives are generally not recommended, and PP labels can also be adversely affected.

The table below summarises the key advantages, disadvantages and general characteristics of these sterilisation techniques.

Table 7Sterilisation overview	Autoclave	ETO	Radiation
Sterilising Agent	Steam heat	Ethylene oxide gas	Gamma rays and electron beam
Major Advantages	Ease of operation	Least damaging to package	Speed of operation
Major Disadvantages	Extremes of temperature, vacuum and pressure	Operation time, toxic residues, and cost	High initial cost
Cost	Low	High	Medium to high
Temperature	90° C to 135° C	20° C to 60° C	Ambient room
Operation Time	6 minutes to 2 hours	6 to 24 hours	Minutes
Moisture	Higher than 70 % R.H.	25 % to 60 % R.H.	Not applicable
Vacuum Required	Yes	Yes	No
Pressure Required	Yes	Yes	No
Paper Face Materials	Good results with paper facestocks	Good results with paper facestocks	Good results with paper facestocks
Filmic Face Materials	Polyethylene - not recommended	Polyolefin labels can be damaged	Polypropelyne labels can be damaged
Adhesives	Rubber-based adhesives - not recommended	Rubber-based adhesives - not recommended	Rubber-based adhesives - not recommended

The materials portfolio comprises carefully selected combinations of facestock, adhesive and liner designed to offer the performance and properties to meet the most demanding application requirements in the pharmaceutical market. By following the product information guide, you can be confident of selecting materials that meet all of your labelling needs. Avery Dennison provides comprehensive sales and technical support at all stages of selection, testing and implementation to help with organisation of relevant certifications, tests, guidance and advice.

If you have any questions, please contact your Avery Dennison sales representative or visit our website label.averydennison.com.



Glossary of Terms

Adhesion, peel

The adhesion determined by the force required to remove adhesive-coated material which has been applied to a standard test plate under specified conditions from the plate, at a specified angle and speed (please refer to FINAT Test Method FTM 1 and FTM 2).

Adhesive, emulsion acrylic

Emulsion adhesives are acrylic polymer adhesives that are suspended in water. This type of adhesive is widely used throughout the pharmaceutical market.

Adhesive, hot melt rubber

An adhesive that does not use a carrier. The adhesive is liquefied for coating during the laminate manufacturing process by heating it to a high temperature. This type of adhesive is used in the pharmaceutical market primarily for labelling cartons and boxes.

Adhesive, low-migration

A pure polymer adhesive with no molecular weight additives such as resins. Here, the adhesive stays on the surface of the bottle and does not migrate through to contaminate the contents. The highest risk is on thin-wall low-density polyethylene (LDPE) and highdensity polyethylene (HDPE) containers which have low barrier properties.

Adhesive, solvent acrylic

An adhesive which uses a solvent as a carrier. This type of adhesive is normally used where high resistance to chemicals, heat or moisture is required.

Adhesive, solvent rubber

An adhesive which uses a solvent as a carrier. This type of adhesive has a high initial tack and is normally used for difficult and rough surfaces.

Basis weight

The weight, or mass of paper in grams per square meter (gsm).

BfR (Bundesinstitut für Risikobewertung)

The German Federal Bureau for Risk Assessment) provides international standards regarding substance risks which may arise from a wide range of materials and articles, primarily those that come into contact with foods.

Chemical resistance

Resistance to alcohol, organic solvents, petrochemical solvents, etc.

Die-cutting

Labels are printed on a web of paper or film laminate which is then die-cut to create the individual labels. The die-cutting process cuts through the facestock and adhesive but not through the liner.

FDA

The Food and Drug Administration (FDA) is an agency of the United States Department of Health and Human Services and is responsible for regulating and supervising the safety of a broad range of products, including pharmaceuticals and foods.

Gloss

The property of a surface which causes reflection of light.

Label, destructible; Label, tamperproof

A label that cannot be removed from a substrate without damaging it, thus rendering re-use impossible.

Laminate

A self-adhesive laminate is a construction made up of a facestock, adhesive and release coated liner. This laminate is printed and diecut to produce labels. It is also referred to as a PSA (pressure-sensitive adhesive) laminate.

Luminescent laminate

A laminate containing luminescent compounds that can be detected automatically when illuminated with UV light sources. The luminescent compounds can be applied as special inks, top coats, adhesives etc. Luminescence of an object is commonly measured against the Laetus scale.

Machine coated paper

A printing paper that has been coated to achieve a certain paper quality such as gloss finish, smoothness or reduced ink absorbency.

Matt finish

A finish that causes a diffuse reflection of light.

REACH

The regulation: "Registration, Evaluation and Authorization of Chemicals" in Europe (1907/2006/EC). This requires the registration of chemicals before placing on the market. See also SVHC.

Release

The force required to separate a pressuresensitive label from its liner. A relatively low force is referred to as 'easy', while a high force is termed 'tight'.

Release force, high speed; low speed

The force required to separate a pressuresensitive adhesive-coated material from its liner (or vice versa) at an angle of 180°C and at jaw separation rates between 10 and 300m per minute (see FINAT Test Method FTM 4).

Release coat

This is a silicone layer that prevents a label from sticking to its liner, and which permits consistent, controlled release.

Release liner

The bottom layer in a self-adhesive laminate. This can be paper or film and has a silicone coating on the upper surface from which the adhesive releases easily.

SVHC

REACH (see above) contains provisions for a list known as Annex XIV, Substances of Very High Concern (SVHC). For these substances, authorization must be sought for continued use, which requires a technical dossier, a socio-economic analysis, and proof that there is no suitable alternative for the application.

Temperature, application

The temperature at the point when the label is applied. Application temperature can impact how quickly a laminate bonds with the surface to which it is applied, and potentially how strong that bond is.

Temperature, service

The range within which the adhesive will function once the label has been applied and allowed to achieve maximum adhesion.

Shelf life

The duration of a product's validity or efficacy; the date by which a product must be used or applied.

Smudge resistance

The inks' resistance to smearing once applied to a material.

Substrate

A term normally used to describe the type of surface to which the label will be applied, eg plastic bottle, glass bottle, cardboard carton etc.

Sterilisation

A process that kills microorganisms that might be present. If this is to be performed after labelling, care must be taken in selecting the correct laminate.

Sterilisation resistance

The ability to maintain product properties during the sterilisation process.

Supercalendered paper

Paper that has been passed through a series of nips (between steel and hard polymer rolls) under high pressure and/or temperature to impart improved properties such as smoothness, gloss and increased density.

Surface coated paper

A paper with a white or coloured pigment coating on the printing surface.

Tamper-evident

A label that leaves visible evidence that it has been removed. Typically this takes the form of void material, that leaves a message on the substrate, or a fragile material that breaks during removal, making it extremely difficult to remove the entire label.



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For more information on technical performance and printing recommendations, please refer to the respective datasheets. Please note that the Avery Dennison product range and service offering can be subject to changes. For an accurate overview, please check our website label.averydennison.eu or contact your local Avery Dennison sales representative.

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