

# Low Migration Portfolio



Avery Dennison now offers low-migration adhesives that are pretested to meet regulatory requirements in the North American and European markets. By choosing pretested, low-migration adhesives in combination with low-migration base materials, inks and varnishes for plastic containers, pharmaceutical companies can minimize the time and money they spend on migration certification, and in some cases can bypass it altogether. Other benefits include faster product approval and time to market, and the peace of mind of knowing that their medicinal products are safe for patients.

## Portfolio Characteristics

- ▶ High initial tack and very good adhesion to glass, PE, PP
- ▶ Excellent mandrel performance on glass, PE and PP containers
- ▶ Complies with the European food directives and legislations, FDA 175.105 and the German recommendations XIV as published by BfR. BfR (Bundesinstitut für Risikobewertung) is the German Federal Institute for Risk Assessment.
- ▶ The adhesives can be used in direct contact with dry, nonfatty foodstuffs.
- ▶ Dramatically reduce the risk of contamination with our industry proven low-migration adhesives

\* only applies to the following adhesives: S2000NP, S2045NP, S717P, S692NP

## Product information

Product Code	Product Description	Size (mm × mtrs)	Location	Lead Time
ALV434	FASSON® LW/PERMANENT(S692NP)/BG40	1500 X 1000	Pune	3 Days
AE947	FASSON® PE TOP WHITE/ S692NP/BG40 WH IMP	1500 X 1000	Pune	7 Days
AE948	FASSON® PP TOP WHITE/ S692NP/BG40 WH IMP	1500 X 1000	Pune	7 Days
AE949	FASSON® PP TOP CLEAR / S692NP/BG40 WH IMP	1500 X 1000	Pune	7 Days
SW4115	FASSON® SILVER MET.PAPER / S692NP/BG40 WH IMP	1500 X 1000	Pune	7 Days
BW8005	FASSON 85U TRANSPARENTPE TC /S692NP/BG40 WH IMP			

## The need for low migration

As per the European Union's 2005 guidelines around plastic packaging materials, & U.S. FDA guidelines for pharmaceutical industry: Container Closure Systems for Packaging Human Drugs and Biologics.” the “packaging components should be constructed of materials that will not leach harmful or undesirable amounts of substances to which a patient will be exposed when being treated with a drug product.” The chief way that regulatory agencies in the U.S. and Europe are encouraging pharmaceutical companies to address migration issues is by requiring that they use low-migration label materials.

The term low migration is used because some amount of migration will always occur in plastic packaging. However, if the migration or interaction happens within the accepted window determined by regulatory authorities, the packaging components are deemed safe for use. There are two certifications that pharmaceutical companies can obtain to certify low-migration label materials.

Certifications can be secured through the independent, globally accepted testing agency, under ISEGA (As per EU guidelines ) & 21 CFR 175.105,(US Regulation) guidelines Typically, ISEGA certification can take up to two years to complete before the label is cleared for companies to use in production, making it a long and costly process for businesses that want to get their products to market quickly and efficiently. At the same time, this certification is necessary for pharmaceutical companies if they want to sell products with plastic containers to the European or the U.S. markets.



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