

WHITE PAPER

ESSENTIAL CONSIDERATIONS WHEN CHANGING POLYETHYLENE RESINS IN REGULATED PACKAGING APPLICATIONS

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Find out about the
testing requirements
following any changes to
PE packaging materials.
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Does your company use plastic packing materials in its manufacturing supply line? Do you know which resin is used to manufacture your polyethylene packaging? Does it matter? It may do, especially if the packaging supplier alters the packaging by changing the resin used in its production.

When a change in PE grade is made the packaging supplier may need to undertake appropriate re-testing. This may include compulsory regulatory compliance testing.

In this paper, we list a program of regulatory and industry testing requirements following changes in packaging for the blow moulding and injection moulding sectors. The tests are applicable to a range of applications, including food contact materials, dangerous goods, mobile garbage bins, therapeutic goods and pharmaceuticals.

THE SAFE PACKAGING OF PRODUCTS, MATERIALS AND REAGENTS IS VITAL IN ALL MAJOR INDUSTRY SECTORS. IT IS ESPECIALLY IMPORTANT FOR PRODUCTS INTENDED FOR HUMAN USE OR PRODUCTS THAT PRESENT A RISK TO HEALTH OR THE ENVIRONMENT. EXAMPLES INCLUDE FOODS, PHARMACEUTICALS, CHEMICALS AND HAZARDOUS GOODS. EACH OF THESE INDUSTRIES MUST ADHERE TO STRICT PACKAGING REGULATIONS DESIGNED TO KEEP THE PUBLIC SAFE.

Polyethylene (PE) is used in many different forms of packaging that are produced by blow moulding and injection moulding processes, including rigid bottles, drums and injection moulded caps. Depending on the end use of the packaging material, the packaging manufacturer will conduct a series of tests on the material in its primary and final form to verify its suitability for the task. Such assessments may include mandatory compliance testing as set out in regulations relating to the package type.

If a manufacturer changes the resin-supplier, grade of PE resin or mix of resins used to make the packaging, it is important that adequate testing is undertaken to ensure the material remains fit-for-purpose – and meets any regulatory or industry requirements.

IS THERE A PROGRAM OF REGULATORY TESTING FOR PACKAGING MATERIALS IN YOUR INDUSTRY?

Companies that out-source the packaging of their products to third party packaging companies or buy in containers for filling in-house should be aware of the regulatory environment relating to packaging within their industry. In this paper (on page 2), we provide an overview of the testing requirements of a selection of industries.

DANGEROUS GOODS

Any products classified as “dangerous goods” that are transported by road or rail must comply with The Australian Code for the Transport of Dangerous Goods by Road & Rail, commonly known as the Australian Dangerous Goods Code (DG Code) [1]. All members of the supply chain – from manufactures and packaging companies to transport companies and drivers, are obliged to adhere to the requirements specified in the document.

In the case of containers used for the storage of chemicals and hazardous substances, it is essential that material testing is conducted in accordance with the requirements set out in the DG Code.



THE CONSEQUENCES OF FAILURE OF CONTAINERS CAN HAVE A DRAMATIC EFFECT UPON BRAND REPUTATION AND PROFITABILITY

Test requirements for plastic containers include low temperature impact, pressure and elevated temperature stacking testing – all designed to ensure the basic suitability of the container for its intended use. It is mandatory that each material and design combination is tested. End-users of any plastic containers used to store hazardous goods can request a copy of the compliance test report from the packaging supplier.

THE IMPORTANCE OF STORAGE TESTING

While mandatory compliance to the DG Code is important, it is not a guarantee of the suitability of a container for the storage of a specific chemical. To verify suitability, medium-term storage testing in a controlled and safe environment should be conducted as a matter of good-practice.

When changing the PE grade used for a DG container it is important to evaluate containers produced from the two materials in parallel. The results will show whether the change in material provides better, similar or worse performance. To accelerate comparative testing, elevated temperature testing should be considered where it is safe to do so. Testing at 40°C for two months will provide an indication as to how a container/material combination will perform over the summer months in Australia.

Household cleaning products

It is not only bottles and drums used for the storage of dangerous goods that should undergo storage testing to determine suitability of a PE grade/container type/chemical combination. Containers such as bottles used for the storage of household and industrial chemicals should also undergo such testing. This is recommended when moving away from a PE grade with a proven record of good performance. The consequences of failure of containers can have a dramatic effect upon brand reputation and profitability.

PHYSICAL CHARACTERISTICS OF PE RESINS

Wall-thickness distribution

Blow moulded bottles made from PE resins made by different suppliers will typically not process in the same way, resulting in varying wall-thickness distribution profiles. This can affect the top load strength of the bottle, and its resistance to cracking. The positioning of the ends of the base “pinch offs” will almost certainly change. The pinch offs are the points where the tube that the bottles are made from are sealed together. When sealed, the ends of the tube form small “lumps” on the inside of the bottles. The position of these lumps has a large bearing on the crack resistance of the bottles. It is imperative, therefore, to conduct side-by-side storage test comparisons for the different resins.

If a bottle supplier changes supplier of PE, brand owners should check if appropriate comparative testing has been conducted. A full report that details comparative testing, including elevated temperature storage testing should be available on request.

CAPS AND CLOSURES

The caps and closures used for containers also need to be thoroughly evaluated when a change in PE grade used in their production is made. Each resin grade, particularly from different PE suppliers, will perform differently with respect to dimensions, release torque, tamper evidence and impact strength. These properties need to be assessed against the specifications of every cap and closure when a change in PE grade is made.

Dimensional stability

Different PE grades will also perform differently with respect to dimensional stability over time. Problems may occur if the dimensions of a cap or closure change prior to use. Performance evaluations should be conducted on caps and closures versus storage time/environmental conditions. The consequences of cap or closure failures can be just as significant as failure of the bottle or drum.

UV stability

For goods that are designed for long term performance outdoors, a range of tests can be required. For instance, for mobile garbage bins manufactured from HDPE, performance requirements and test methods are specified in Australian standard AS 4123. To ensure the bins are stable against UV light, the physical properties are assessed after 8000 hours exposure in accelerated weathering conditions. Weatherometer testing is conducted in accordance with the AS4123 standard.

REGULATORY AND INDUSTRY TESTING REQUIREMENTS FOLLOWING CHANGES IN PACKAGING FOR THE BLOW MOULDING AND INJECTION MOULDING SECTORS

The PE resin and/or the final packaging may need to demonstrate strict compliance with:

- Applicable U.S. Food and Drug Administration (FDA) regulations e.g. 21 CFR 177.1520(c) 3.1a
- European Union (EU) directives/regulations for consumer safety such as Commission Regulation (EU) No 10/2011, 1935/2004 and 2023/2006
- Applicable US Pharmacopoeia (USP) requirements
- Applicable European Pharmacopoeia requirements
- Australian Standard AS4123 Mobile Waste Containers
- The Australian Code for the Transport of Dangerous Goods by Road & Rail

FOOD AND PHARMACEUTICAL PRODUCTS

The materials used to package food and pharmaceuticals are subject to stringent regulations. To prevent cross-contamination of unwanted substances from containers, contact materials and container closure systems to the product, packaging must be thoroughly tested for a wide range of chemicals and impurities.

For food packaging in Australia this means compliance to the requirements of the Food and Drug Administration of the USA or European Union regulations. Pharmaceutical packaging is required to meet the requirements of the US or European Pharmacopeia.

CONCLUSIONS AND OBSERVATIONS

An awareness of the possible impact on packaging performance of changing the PE resin grade or resin supplier enables brand owners to ask the right questions.

- What PE resin is used in my brand's packaging materials?
- How long has the same resin been used?
- What tests have been run on the materials?
- How often are the tests repeated?
- Does our brand packaging meet all necessary regulations and standards?
- If a manufacturer changes the resin-supplier, grade of PE resin or mix of resins used to make the packaging, what re-testing is necessary?
- If a change of PE grade has been made have comparative tests been conducted?

REFERENCE

1. The Australian Dangerous Goods Code Edition 7.4, Department of Infrastructure, Regional Development and Cities, accessed April 2018, https://infrastructure.gov.au/transport/australia/dangerous/dg_code_7e.aspx

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