



**Change to read:**

## **^<661.1> PLASTIC MATERIALS OF CONSTRUCTION**

(This chapter will become official on December 1, 2025. Early adoption of the requirements in this chapter and its companion chapter [Plastic Packaging Systems for Pharmaceutical Use <661.2>](#) are permitted by USP. When early adoption is not used, [Plastic Packaging Systems and Their Materials of Construction <661>](#) will apply. If <661.1> or <661.2> are referenced elsewhere in the *USP-NF* prior to December 1, 2025, the standards in <661> will apply if early adoption of <661.1> or <661.2> has not occurred.)

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### **INTRODUCTION**

The use of well-characterized materials to construct packaging systems is a primary means of ensuring that the packaging system is suited for its intended use. Materials are characterized so that their properties and characteristics can be matched to the performance requirements of the packaging system, thus facilitating the intentional selection of appropriate materials. For the purposes of this chapter, a plastic material of construction is considered to be well characterized for its intended use if the following characteristics have been adequately established: its identity, biological reactivity, general physicochemical properties, and composition (i.e., additives likely to be present). Extractable elements may also be relevant to the selection of a packaging system's materials of construction and therefore a relevant aspect of material characterization. Materials of construction can vary widely in terms of their intentionally and unintentionally added elements and their potential use. Because of this, it is challenging to provide universally effective and efficient tests methodologies, lists of target elements and reporting requirements. It is the material user's responsibility to evaluate the need for extractable elements testing and, if such testing is necessary, to establish and justify the means by which testing is accomplished, taking into account extraction conditions, target elements, and reporting requirements.

### **SCOPE**

The purpose of this chapter is to provide test methods for determining the suitability of plastic materials of construction used in packaging systems for drug products. Individual plastic materials of construction are considered to be well characterized if they meet the requirements in this chapter or are used in a packaging system that meets the requirements in [Plastic Packaging Systems for Pharmaceutical Use <661.2>](#). The testing and qualification of plastic packaging systems and components for pharmaceutical use are covered in <661.2>.

This chapter contains tests, methods, and acceptance criteria for the following materials: cyclic olefins; polyamide 6; polycarbonate; polyethylene; polyethylene terephthalate; polyethylene terephthalate G;

























































































