

# Standard Operating Procedure

## Title: Classification of Defects for Incoming Packaging Components

Department	Warehouse	Document no	WAR-110		
Title	Classification of Defects for Incoming Packaging Components				
Prepared by:		Date:		Supersedes:	
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### 1.0 DOCUMENT OWNER

Warehouse / Quality Manager

### 2.0 PURPOSE

Define the classification of defects found during the inspection of incoming packaging components.

### 3.0 SCOPE

This SOP explains the Acceptable Quality Limit (AQL) levels and categories of defects for all incoming packaging components received and tested at a GMP site.

It also determines the responsibility levels for the acceptance or rejection when an Out of Specification (OOS) result occurs.

### 4.0 RESPONSIBILITY

It is the responsibility of the Incoming Goods Inspectors to identify and evaluate the extent of a defect when inspecting a packaging component.

It is the responsibility of the Quality Assurance Manager to accept or reject the defective packaging component that falls outside its AQL level.

### 5.0 PROCEDURE

All deliveries of packaging components undergo thorough sampling and inspection against artwork and the Packaging Material Specification (PMS).

When a defect is found during the inspection:

**5.1 Determine the type of problem, defects or failure** for any characteristics of the component whether it's related to the delivery, appearance, dimension, printing, assembly, weight or material.

**5.2 Refer** to the Tables of Defects (**Appendix A**) and find the listed defect that corresponds to the type of problem determined.

**5.3** If the defect is listed in:

**5.3.1 Appendix 1** – It is a **Critical** defect: a defect that would result in hazardous or unsafe conditions for individual using, maintaining or depending upon the product. **(AQL of 0.0%)**.

**5.3.2 Appendix 2** – It is a **Major** defect: a defect that is likely to result in failure or that would materially reduce the usability of the product for its intended purpose. **(AQL of 0.4%)**.

**5.3.3 Appendix 3** – It is a **Minor** defect: a defect that is not likely to materially reduce the usability of the product for its intended purpose. **(AQL of 1.5%)**.

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**Léo Pomar**



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