

Standard Operating Procedure

Title: Classification of Defects for Incoming Packaging Components

Department	Quality Management	Document no	QMS-150
Title: Classification of Defects for Incoming Packaging Components			
Prepared by:		Date:	
Checked by:		Date:	
Approved by:		Date:	

1.0 DOCUMENT OWNER

Technical/Quality Manager

2.0 PURPOSE

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

This SOP is linked to [QMS-145 Classification of Defects in Manufacturing Operation](#).

3.0 SCOPE

This SOP explains the 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 \(OOS\)](#) 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) as per [WAR-090 Sampling Inspection](#) and Release of Packaging Materials.

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 (**Appendices 1, 2 and 3**) 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%**).

Copyright©www.gmpsop.com. All rights reserved.

Unauthorized copying, publishing, transmission and distribution of any part of the content by electronic means are strictly prohibited. Page 1 of 5

Standard Operating Procedure

Title: Classification of Defects for Incoming Packaging Components

5.6.2 If this **defect** or non-conformance is determined to be **Minor**, the component will be **approved to proceed** for use in production.

In both cases, no deviation will be raised.

5.7 Where only part of a delivery is to be rejected the lot will be sub-lotted.

5.8 Write in the *History Supplier Folder* that the batch is approved but, in the comment section, write that a part of the lot. (i.e. knives number...) has been rejected under the created sub lot.

5.9 The next delivery from **the same supplier** will have to follow a tighter inspection plan.

6.0 TYPE OF PACKAGING DEFECTS & THEIR AQL:

6.1 Critical Defects (AQL: 0~0.25%)

A defect that would result in hazardous or unsafe conditions for individual using, maintaining or depending upon the product.

Following is list of Critical Defects typically found in incoming packaging lots:

Delivery:

- Delivery damaged or contaminated and the component can't be used
- Bag/Sack is cut, crooked or ragged and the component can't be used
- Splice tap on safety seal

Appearance:

- Internal or External surface foreign matter, rust or corrosion, which can interact with products.

Printing:

- Missing or unreadable printing which may be detrimental for the consumer
- Incorrect printing

6.2 Major Defects (AQL: 0.4~0.65%)

A defect that is likely to result in failure or that would materially reduce the usability of the product for its intended purpose.

Following is list of Major Defects typically found in incoming packaging lots:

Delivery:

- Seals not present
- Missing polyethylene liner bag
- Missing, illegible or incorrect pallet markings.
- Missing plastic protection bag
- Wrong delivery quantity
- Not labelled with site order no / code no / component description

Appearance:

- Pin hole, pitting, scuffing, streak, nicks, embedded foreign matter, splits.

Copyright©www.gmpsop.com. All rights reserved.

Unauthorized copying, publishing, transmission and distribution of any part of the content by electronic means are strictly prohibited. Page 3 of 5