Global Standards Trade Item Labeling and Barcode Requirements

for pharmaceuticals, medical devices, sterile kits and laboratory reagents



HELPFUL TERMS

HRI: Human Readable Interpretation; the printed characters that accompany a barcode or other data carrier

GTIN: Global Trade Item Number, the GS1 key that uniquely identifies a product

Trade Item: Trade items are products and services that may be priced, ordered, or invoiced at any point in the supply chain

PRIMARY PACK

Primary packaging is the first level of packaging that is in direct contact with the item.

Data carrier required only when the item is supplied in cartonless packaging.

GS1 DataMatrix symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot
- (17) Expiration date
- (21) Serial number¹

HOMOGENOUS

TERTIARY PACK

Tertiary packaging refers to upper levels of the packaging hierarchy. Homogenous tertiary packaging may be:

- A pallet that contains (one or usually) several cases
- A case that contains (one or usually) several items in the items' primary or secondary packaging

GS1 DataMatrix or GS1-128 barcode symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot
- (17) Expiration date
- (21) Serial number¹



SECONDARY PACK

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item

- GS1 DataMatrix symbology encoded with and printed as HRI:
- (01) GTIN
- (10) Batch/lot
- (17) Expiration date
- (21) Serial number¹

MIXED OR PARTIAL

TERTIARY PACK

Tertiary packaging refers to upper levels of the packaging hierarchy. Mixed or partial tertiary packaging may be:

- Partial consisting of a homogenous pack of items that is not to be considered a trade item because it is less than full
- Mixed either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates



For more guidance on labeling mixed or partial tertiary packs, please see the "Global Standards Logistic Unit Labeling and Barcode Requirements."

¹mandatory for pharmaceuticals only



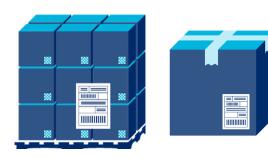




Global Standards Logistic Unit Labeling and Barcode Requirements

for pharmaceuticals, medical devices, sterile kits and laboratory reagents

EXAMPLES OF LOGISTIC UNITS



HELPFUL TERMS

HRI: Human Readable Interpretation; the printed characters that accompany a barcode or other data carrier

SSCC: Serial Shipping Container Code; a unique identification key used to identify logistic units

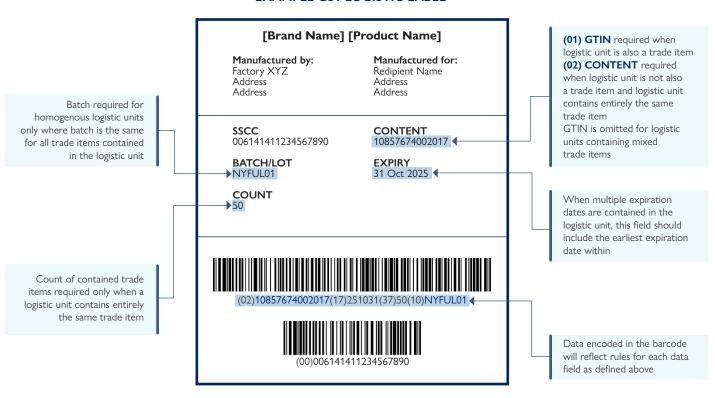
GTIN: Global Trade Item Number, the GS1 key that uniquely identifies a product **Count:** The total number of contained trade items identified by the GTIN

Logistic Unit: An item of any composition established for transport and/or storage that needs to be managed through the supply chain

Homogenous: A logistic unit containing one or more trade items with the same batch and/or expiration date

Heterogeneous: A logistic unit containing multiple different trade items and/or one trade item that varies by batch and/or expiration date

EXAMPLE GS1 LOGISTIC LABEL*



*Per the GS1 General Specifications Section 2.2.1, Individual logistics units, a GS1 DataMatrix symbol MAY be included in addition to the GS1-128 symbol



See the *Global Standards Technical Implementation Guideline* for Global Health Commodities for additional information on how to apply the logistic unit guidance in different scenarios.







SSCC

Global Standards Trade Item Labeling and Barcode Requirements

for long-lasting insecticide-treated nets (LLINs)





(21)1087FYW07₇

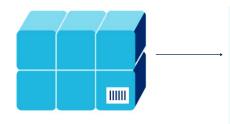
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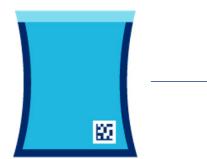


TERIARY PACK LOGISTICS UNIT (BALE)1

GS1-128 barcode symbology encoded with and printed as HRI:

(00) SSCC

- (02) GTIN of contained items
- (37) Count of contained items
- (10) Batch/lot number
- (11) Production date



PRIMARY PACK (BAG WITH LLIN)

GS1 DataMatrix symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot number
- (11) Production date



INDIVIDUAL LLIN

GS1 DataMatrix symbology encoded with and printed as HRI:

- (01) GTIN
- (10) Batch/lot number
- (11) Production date
- (21) Serial number¹

