#### USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

# Guidance on Collection of Product, Item, and Trade Item Master Data Hierarchies Leveraging GS1 Global Standards

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# **Table of Contents**

| Introduction                                     | 3                            |
|--|------------------------------|
| Purpose  | 3                            |
| Background                                       | 4                            |
| What is master data?                             | 4                            |
| GS1 Global Standards                             | 4                            |
| Data Hierarchies                                 | 6                            |
| Product and trade item hierarchy                 | 6                            |
| Trade item packaging hierarchy                   | 7                            |
| Navigation                                       | 9                            |
| Recommended Data Collection and Entry Procedures | 10                           |
| Adding a new product                             | Error! Bookmark not defined. |
| Adding a new item                                | 12                           |
| Adding a new trade item                          | 14                           |

#### Introduction

#### **Purpose**

This template for collecting product, item, and trade item master data hierarchies leveraging GS1 global standards is intended to guide the development of standardized master product lists in support of pharmaceutical traceability. This template is not intended to be prescriptive, but rather to serve as a guide for structuring the collection of standardized master data, including the use of the GTIN where applicable. Implementers should view this template as a starting point to be tailored to their specific needs and country contexts. The data attribute fields included are illustrative and can be removed, altered, or expanded upon as needed, including adding country-specific attributes as relevant (e.g., insurance codes, reimbursement codes, program attributes).

To support understanding of the template structure, an example is included and populated across all data levels. This example builds out the data hierarchy for atazanavir/ritonavir 300/100 mg tablet, including two manufacturer-specific instances of the product and various packaging levels for each.

Once implementers have established a standardized master product list, ongoing efforts in master data management are critical. For additional information on master data management, please refer to GHSC-PSM's Product Master Data Management (PMDM) Reference Guide and Toolkit found here: <a href="https://www.ghsupplychain.org/PMDMReferenceGuide">https://www.ghsupplychain.org/PMDMReferenceGuide</a>.

## **Background**

#### What is master data?

Three main types of data are managed in the supply chain: master data, transaction data, and event data. (See Table I). The focus of this template is limited to collecting product master data, which is the critical enabler for successfully leveraging the other types of data for supply chain decision-making.

Table 1. Descriptions of Supply Chain Data Types

| SUPPLY CHAIN INFORMATION DATA TYPES   |  |  |
|---------------------------------------|--|--|
|                                       | DEFINITION   | EXAMPLES OR DESCRIPTION  |
| O                                     | ITEM: product identifiers and associated descriptive attributes  | ITEM: Manufacturer, brand name,<br>item description, unit of measure, net<br>content, shelf life |
| MASTER DATA                           | LOCATION: facility (legal entity) identifiers and associated descriptive attributes  | LOCATION: Address, contact information, role   |
| ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐  ☐ | Information about production, planning ordering, delivering, paying, and other transaction-related processes that occur through the supply chain | Order quantity, units sold, stock on hand, forecasted units, price                               |
| <b>©</b><br>EVENT DATA                | Information about the physical move-<br>ment and status of products as they move<br>through the supply chain                                     | Commissioning, shipping, receiving, decommissioning  |

Product master data core information is about "what" is being traded in the supply chain. The "what" is identifying information about a given trade item, such as name, brand, description, size, and unique identification number. These kinds of data underpin commerce and are used daily among trading partners to execute transactions in the supply chain and also by a broader value chain of health-sector stakeholders, such as regulators. Supply chain transactions rely heavily on master and reference data; inaccurate data create inefficiencies in the procure-to-pay process and every other downstream supply chain function, and inhibit the ability to ensure that the six rights of logistics are achieved: the right goods, in the right quantities, in the right condition are delivered to the right place, at the right time, at the right cost.

#### **GSI** Global Standards

GS1 is an international standards organization that develops and maintains a comprehensive system of data standards for health supply chains, including identifying locations, legal entities, trade items, and

logistic units; capturing data through specific data carriers, such as barcodes; and sharing data through standards for master, transaction, and event data exchange, as summarized in Figure 1.

Figure 1. Summary of the GS1 System of Standards for Identify, Capture, and Share



The GS1 standard used in this template is the Global Trade Item Number. The GTIN is the GS1 identification key used to identify trade items—any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain. The GTIN is included as the secondary unique global identifier for trade items that pairs the physical product with the master data about that product in a product information management (PIM) system through use of a data carrier (e.g., through scanning a barcode).

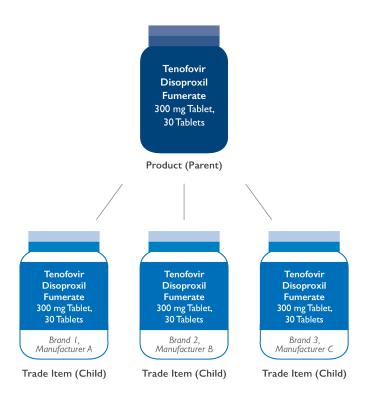
#### **Data Hierarchies**

#### Product and trade item hierarchy

The terms "product" and "trade item" are often used interchangeably, but in practice, the two concepts have differentiating characteristics that are important to understand for effectively managing commodities in the health supply chain.

In general, a product refers to a general concept of a commodity, whereas the trade item refers to a commercialized instance of that commodity by a specific manufacturer. Products have a set of defining characteristics, often defined by a local entity that may include active ingredients, dosage, and dosage form. Trade items are instances of products with unique characteristics, such as manufacturer, brand name, shelf life, and net content. Trade items will be assigned GTINs unique to each packaging level—products will not. An entity's product master data should be able to support and manage both concepts as well as the hierarchy or relationship between the two, sometimes referred to as a parent-child relationship. An example of this concept is provided in Figure 2.

Figure 2. Relationship Analysis: GTIN Parent-Child Relationship



In public health supply chains, the planning and requisitioning functions are generally executed using the generic concept of a product, while procurement, order fulfillment, and all subsequent processes are executed with the specific instance of a trade item.

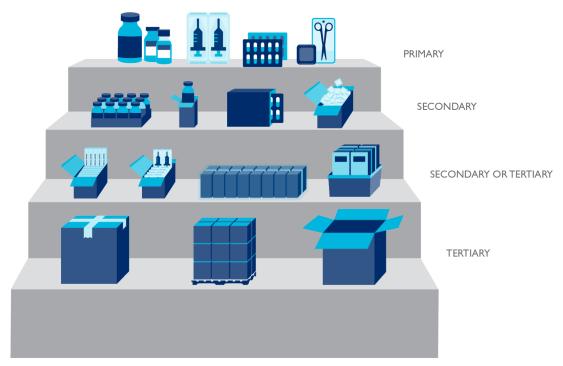
In this template, an intermediary level of "item" is also introduced. For this data structure, the item level refers to the manufacturer-specific instance of a product that is not yet specified by packaging level. In this way, "trade items" are each associated with one item, which is then associated with one "product." Inclusion of this intermediary item level allows for more efficient maintenance of the manufacturer-specific item data that are consistent across packaging levels (i.e., these data will be input only once and maintained at the item level rather than repeated for each trade item in the packaging hierarchy).

These product hierarchies are managed through including a reference attribute at the item and tradeitem levels of the hierarchy. At the trade item level, for each trade item entered into the template, the "ITEM\_KEY" of the associated item should be provided in the "ITEM\_KEY" attribute field. At the item level, for each item entered into the template, the "PRODUCT\_KEY" of the associated product should be provided in the "PRODUCT\_KEY" attribute field. In this way, the relationship among the product, item, and trade item is identified and the hierarchy is established.

#### Trade item packaging hierarchy

Any level of packaging that can be priced, ordered, or invoiced throughout the supply chain is considered a trade item. An "each" is often packed in an "inner pack" with multiple inner packs packed into a "case." Each level of packaging can be considered a trade item; therefore, each is also to be assigned a Global Trade Item Number (GTIN). The definition of trade item packaging configurations and the relationship among those different levels is called the trade item packaging hierarchy. (See Figure 3.) Part of the process for aligning master data to manage trade items at different packaging levels as they move through the supply chain (e.g., receive items into a warehouse at the case level, pack them at an inner pack level) is managing each trade item uniquely but establishing the parent-child relationships between those trade items in the product master data. The barcode on the physical package containing the GTIN is what links the physical item with the master data about that item in the system.

Figure 3. Example of the Trade item Packaging Hierarchy for Health Care Products



Trade item master data should be managed in a way that links the primary, secondary, and tertiary GTINs of each trade item and its variants. This creates a hierarchical, parent-child relationship between a containing object (i.e., parent) and one or more objects (i.e., children) that are contained.

In this template, these parent-child relationships are managed by including a "CHILD\_TRADE\_ITEM\_SKU" attribute at the trade item level. For each trade item entered into the template, the "TRADE\_ITEM\_SKU" of the associated child (i.e., the next-lowest packaging level contained within the given trade item) should be provided in the "CHILD\_TRADE\_ITEM\_SKU" attribute field.

# **N**avigation

| Tab             | Description  |
|-----------------|--|
| PRODUCT         | Provides an overview of the attributes included in the "PRODUCT_DATA" tab, including a brief attribute description, acceptable data types, and whether the attribute is considered a nullable field. The attributes included here are considered unique at the product level.  |
| ITEM            | Provides an overview of the attributes included in the "ITEM_DATA" tab, including a brief attribute description, acceptable data types, and whether the attribute is considered a nullable field. The attributes included here are considered unique at the item level.  |
| TRADE_ITEM      | Provides an overview of the attributes included in the "TRADE_ITEM_DATA" tab, including a brief attribute description, acceptable data types, and whether the attribute is considered a nullable field. The attributes included here are considered unique at the trade item level.  |
| PRODUCT_DATA    | Holds the master data for the product level of the data hierarchy.   |
| ITEM_DATA       | Holds the master data for the item level of the data hierarchy. At this level, data lines are manufacturer-specific but packaging levels are not specified. Each data line is associated with exactly one product from the "PRODUCT_DATA" tab.   |
| TRADE_ITEM_DATA | Holds the master data for the trade item level of the data hierarchy. This includes a buildout of the packaging level hierarchies and volumetric information. Each data line is associated with exactly one item from the "ITEM_DATA" tab.   |
| Code Lists      | Provides a code list of the accepted entries for given attribute fields in the "PRODUCT_DATA," "ITEM_DATA," "TRADE_ITEM_DATA" tabs. To ensure consistent input and avoid errors due to manual entry, code lists are used in applicable attribute fields. Rather than keying in free texts in these fields, the code lists provided in this tab constrain the accepted entry. Users may define their own code lists as needed but in doing so, referencing a definitive source (e.g., European Pharmaceutical Market Research Association, U.S. Food and Drug Administration (FDA), International Organization for Standardization), where available, is recommended. |

# **Recommended Data Collection and Entry Procedures**

#### Adding a new product

- I. Ensure the product being added is not already listed in the file. If the product has an alternate name(s) (e.g., epinephrine is also known as adrenaline), check against these names to avoid duplication.
- 2. Sort the "PRODUCT\_KEY" field by "Ascending." The new product will be added in the first available row beneath the most recently entered product. The "PRODUCT\_KEY" for the new product should be generated according to existing system protocols.
- 3. Populate the product description by entering the appropriate data into the "GENERIC\_NAME," "STRENGTH," and "PRODUCT\_FORM" fields, as applicable. This will automatically generate the "PRODUCT DESCRIPTION" field. **Do not** populate the "PRODUCT DESCRIPTION" field directly.
  - Rules for populating the "GENERIC NAME" field:
    - For pharmaceuticals, use the INN names per product alphabetically and delimited with a forward slash, "/." If it is a nonhomogenous, combination product, use a plus sign, "+," to separate each component (e.g., amodiaquine + sulfadoxine/pyrimethamine).
    - For non-pharmaceuticals, use a standardized description that can be procured from multiple vendors using applicable standards.
  - Rules for populating the "STRENGTH" field:
    - For pharmaceuticals, input the ingredient strength expressed with units (e.g., 300 mg). If there are multiple ingredients, input the strengths in the order the respective ingredients were entered in the "GENERIC\_NAME" field. Delimit multiple strengths using a forward slash, "/" (e.g., 600/300 mg). For non-homogenous, combination products, use a plus sign, "+," to separate the components' respective strengths (e.g., 76.5 mg + 250/12.5 mg).
  - Rules for populating the "PRODUCT\_FORM" field:
    - For pharmaceuticals, use a standardized description that can be procured from multiple vendors using applicable standards (e.g., Film-coated Tablet, Suppository, Powder for Oral Solution).
- 4. Populate the remaining fields, as possible, with available data. For more information on the included fields, see Table 2 below.

Table 2. Product Data Attributes

| Attribute Name          | Input   |
|-------------------------|---|
| PRODUCT KEY             | See 1.2.  |
| PRODUCT DESCRIPTION     | See 1.3.  |
| GENERIC NAME            | See 1.3.  |
| STRENGTH                | See 1.3.  |
| PRODUCT FORM            | See 1.3.  |
| ACTIVE INGREDIENT       | The active ingredient is the ingredient (s) in a  |
|                         | pharmaceutical that is biologically active and responsible for its effects.   |
| DOSAGE_FORM             | The dosage form for a pharmaceutical describes the physical form of the product. For pharmaceuticals, use the code list provided in the file to populate this field. For non-pharmaceuticals, this field may be left blank.   |
| ROUTE_OF_ADMINISTRATION | The route of administration describes the method(s) by which a product is administered. In pharmacology and toxicology, a route of administration is the path by which a drug, fluid, or other substance is brought into contact with the body. Use the code list provided in the file to populate this field. For non-pharmaceuticals, this field may be left blank. |
| UNSPSC_CODE             | The United Nations Standard Products and Services Code (UNSPSC) is a four-level taxonomy of products and services for use in eCommerce.   |
| GPC_CODE                | The Global Product Classification (GPC) Code, a mandatory field in the GDSN, specifies a product's category according to the GS1 GPC standard.  |
| ATC_CODE                | The Anatomical Therapeutic Chemical (ATC) Code refers to a product's ATC/Defined Daily Dose pharmaceutical classification structure number.   |
| GMDN_CODE               | The Global Medical Device Nomenclature (GMDN) Code field is used to store a product's GMDN classification structure number.   |
| DONOR_PRO_CLASS_CODE    | The donor product classification code is a donor classification hierarchy attribute based on UNSPSC but modified to include a Level 5 code.   |
| HS_CODE                 | The HS code refers to the Harmonized Commodity Description and Coding System, an international standardized system of names and numbers for classifying commodities.  |
| HEALTH_INS_STATUS       | This field should be used to indicate the reimbursement status of the product with a given country's National Health Insurance organization, if applicable.   |
| PRODUCT_ID_CODE         | This field should be used to indicate the product code (e.g., Health Commodity Code) assigned by a given country's Ministry of Health or Regulatory Authority, if applicable.   |

#### Adding a new item

- I. Ensure the item being added is not already listed in the file. If the item has an alternate name(s) (e.g., epinephrine is also known as adrenaline), check against these names to avoid duplication.
- 2. Sort the "ITEM\_KEY" field by "Ascending." The new item will be added in the first available row beneath the most recently entered item. Generate the "ITEM\_KEY" for the new item according to existing system protocols.
- 3. Populate the "PRODUCT\_KEY" with the product key for the item's associated product. For example, for "Abacavir 60 mg Dispersible Tablet, Bottle, 60 Tablet [Cipla]," the associated product is "Abacavir 60 mg Dispersible Tablet." This can be found by searching for the item's associated product in the "Product\_Data" table and referencing the "PRODUCT\_KEY." If an item's associated product has not yet been added to the "Product\_Data" table, do so before proceeding with adding the new item.
- 4. Populate the item description by entering the appropriate data into the "PACKAGING," "CONTENT," "PACK\_MEASURE," "PACK\_COUNT," "UNIT\_MEASURE," "UNIT\_COUNT," "UNIT\_SIZE," and "MANU\_SHORT" fields, as applicable. This will automatically generate the "ITEM\_DESCRIPTION" field. **Do not** populate the "ITEM\_DESCRIPTION" field directly.

Following are the rules for populating each field:

- "PACKAGING" field:
  - o For pharmaceuticals, input the packaging as applicable (e.g., Bottle, Blister).
- "CONTENT" field:
  - The "CONTENT" field is automatically generated through population of the "PACK\_MEASURE" and "PACK\_COUNT" fields. Do not populate the "CONTENT" field directly.
- "PACK MEASURE" field:
  - The "PACK\_MEASURE" field is used to generate the "CONTENT" field. Enter the
    measure by which the item pack is divisible (e.g., tablets for bulk jars, "10 Tablet"
    for blister sheets of 10 tablets, "10 mL Bottle" for packs of multiple bottles).
- "PACK COUNT" field:
  - Enter the number of "PACK\_MEASURE" that is contained in one unit of the item (e.g., 60 for a jar of 60 tablets, 10 for a pack of 10 blister sheets, 5 for a pack of five bottles).
- "UNIT MEASURE" field:
  - Enter the counting unit for the base units in the item. This should be at the lowest level and may be different from "PACK\_MEASURE" (e.g., Tablet for both bulk jars and blisters, Bottle for single bottle or multiple bottles).

#### • "UNIT\_COUNT" field:

Enter the number of "UNIT\_MEASURE" contained in the item as an integer (e.g., 50 for 50 tablets, 100 for 10 blister sheets of 10 tablets, 1 for single bottles).

#### • "UNIT SIZE" field:

 Enter the size of the single unit for a "UNIT\_MEASURE." In most cases, this should be 1 (e.g., "1" for a single tablet or capsule, "125 mL" in a single bottle, "200 mg" for the contents of a Sachet).

#### • "MANU\_SHORT" field:

- o Input the short name for the item's manufacturer (e.g., "Fisher" for Fisher Scientific Company LLC) for use in the item description. If applicable, reference existing items from the same manufacturer to ensure standardization in the abbreviation.
- 5. Populate the remaining fields, as possible, with available data. For additional information on the included fields, see Table 3 below.

Table 3. Item Data Attributes

| Attribute Name       | Input   |
|----------------------|---|
| ITEM_KEY             | See 2.2   |
| PRODUCT_KEY          | See 2.3   |
| ITEM_DESCRIPTION     | See 2.4   |
| PACKAGING            | See 2.4   |
| CONTENT              | See 2.4   |
| PACK_MEASURE         | See 2.4   |
| PACK_COUNT           | See 2.4   |
| UNIT_MEASURE         | See 2.4   |
| UNIT_COUNT           | See 2.4   |
| UNIT_SIZE            | See 2.4   |
| MANU_SHORT           | See 2.4   |
| BRAND_NAME           | The brand name of an item refers to its           |
|                      | proprietary name, the item name, or number        |
|                      | used by the enterprise that manufactures the item |
|                      | (e.g., Implanon Nxt for Etonogestrel 68 mg/Rod    |
|                      | manufactured by MSD).                             |
| BRAND_OWNER_NAME     | The brand owner name refers to the name of the    |
|                      | brand owner of the trade item.                    |
| BRAND_OWNER_LOCATION | The brand owner location refers to the            |
|                      | address associated with the organization that     |
|                      | owns the brand.                                   |
| BRAND_OWNER_GLN      | The brand owner Global Location Number            |
|                      | (GLN) refers to the GLN used to identify the      |
|                      | organization that owns the brand.                 |
| MANUFACTURER_NAME    | The manufacturer name refers to the legal name    |
|                      | of the item manufacturer.                         |

| MANUFACTURER_LOCATION    | The manufacturer location refers to the address    |
|--------------------------|--|
|                          | associated with the manufacturing site.            |
| MANUFACTURER_GLN         | The manufacturer GLN refers to the GLN used        |
|                          | to identify the organization that manufactures the |
|                          | trade item.  |
| MANUFACTURER_PART_NUMBER | The manufacturer part number refers to a           |
|                          | unique part number assigned to the trade item      |
|                          | by the manufacturer.                               |
| COUNTRY_OF_ORIGIN        | For the country of origin, input the two-letter    |
|                          | International Organization for Standardization     |
|                          | country code associated with the country where     |
|                          | the trade item is manufactured. Use the code list  |
|                          | provided in the file to populate this field.       |
| SHELF_LIFE_DAYS          | Input the period of days, guaranteed by the        |
|                          | manufacturer, between production of the trade      |
|                          | item and its expiration date.                      |
| STORAGE_INSTRUCTIONS     | Express in text the consumer storage instructions  |
|                          | for a product, which are normally held on the      |
|                          | label or accompanying the product. This            |
|                          | information may or may not be labelled on the      |
|                          | pack. Instructions may refer to a suggested        |
|                          | storage temperature, a specific storage            |
|                          | requirement, etc.                                  |
| MAX_TEMPERATURE          | Input the maximum temperature the item can         |
|                          | safely be exposed to, without units.               |
| MAX_TEMP_UOM             | Input the unit of measure (UOM) for the            |
|                          | maximum temperature measurement (e.g., "F" if      |
|                          | the maximum temperature was given in               |
|                          | Fahrenheit).                                       |
| MIN_TEMPERATURE          | Input the minimum temperature the item can         |
|                          | safely be exposed to, without units.               |
| MIN_TEMP_UOM             | Input the unit of measure for the minimum          |
|                          | temperature measurement (e.g., "F" if the          |
|                          | maximum temperature was given in Fahrenheit).      |
| registration_no          | The registration number refers to the market       |
|                          | authorization number of the item provided by a     |
|                          | given country's Regulatory Authority.              |
| REGISTRATION_NO_EXPIRY   | Input the date on which the item's given FDA       |
|                          | registration number expires.                       |

## Adding a new trade item

I. Ensure the item packaging level being added is not already listed in the file. If the item has an alternate name(s) (e.g., epinephrine is also known as adrenaline), check against these names to avoid duplication.

- 2. Sort the "TRADE\_ITEM \_SKU" field by "Ascending." The new item packaging level will be added in the first available row beneath the most recently entered item. Generate the "TRADE\_ITEM \_SKU" for the new trade item according to existing system protocol.
- 3. Populate the "ITEM\_KEY" with the item key for the item packaging level's associated item (e.g., for "Efavirenz 600 mg Tablet, Bottle, 30 Tablet, Pallet [Strides]," the associated product is "Efavirenz 600 mg Tablet, Bottle, 30 Tablet [Strides]"). This can be found by searching for the item packaging level's associated item in the "Item\_Data" table and referencing the "ITEM\_KEY." If an item packaging level's associated item has not yet been added to the "Item\_Data" table, do so before proceeding with adding the new item packaging level.
- 4. If applicable, populate the "CHILD\_TRADE\_ITEM \_SKU" field with the "TRADE\_ITEM \_SKU" for the item packaging level's child item, the item packaging level one level below that which is being entered. For example, for "Efavirenz 600 mg Tablet, Bottle, 30 Tablet, Pallet [Mylan]," the child is "Efavirenz 600 mg Tablet, Bottle, 30 Tablet, Case [Mylan]".
- 5. Populate the TRADE\_ITEM\_DESCRIPTION field manually by using the associated item's item description and adding in the specific packaging level before the manufacturer's short name. For example, for the case level of the item "Efavirenz 600 mg Tablet, Bottle, 30 Tablet [Mylan]," the item UOM description is "Efavirenz 600 mg Tablet, Bottle, 30 Tablet, Case [Mylan]."
- 6. Populate the remaining fields, as possible, with available data. For additional information on the included fields, please reference Table 4 below.

Table 4. Item Data Attributes

| Attribute Name             | Input  |
|----------------------------|--|
| TRADE_ITEM _SKU            | See 3.2  |
| ITEM_KEY                   | See 3.3  |
| CHILD_TRADE_ITEM _SKU      | See 3.4  |
| TRADE_ITEM_DESCRIPTION     | See 3.5  |
| GTIN                       | The GTIN refers to the Global Trade Item Number, the standard 14-digit number used to identify all trade items in the GDSN.                                  |
| TRADE_ITEM_UNIT_DESCRIPTOR | The trade item unit description describes the hierarchical packaging level of the trade item. Use the code list provided in the file to populate this field. |
| DEPTH                      | Input the length/depth of the item, without units.   |
| DEPTH_UOM                  | Input the unit of measure for the length/depth measurement. Use the code list provided in the file to populate this field.                                   |
| HEIGHT                     | Input the measurement of the vertical dimension from the lowest extremity of   |

|                  | the trade item to the highest extremity, without units.   |
|------------------|---|
| HEIGHT_UOM       | Input the unit of measure for the height measurement. Use the code list provided in the file to populate this field.  |
| VOLUME           | Input, without units, the measurement of the dimensions of an imaginary cube that can be drawn around the trade item as defined in the formula of H x W x D.  |
| VOLUME_UOM       | Input the unit of measure for the volume measurement. Use the code list provided in the file to populate this field.  |
| WIDTH            | Input, without units, the measurement of the extent of the trade item from side to side. The width measurement should be taken from left to right.  |
| WIDTH_UOM        | Input the unit of measure for the width measure. Use the code list provided in the file to populate this field.   |
| GROSS_WEIGHT     | Input the gross weight of the item, without units. The gross weight measurement includes all packaging materials of the trade item. At the pallet level, the gross weight measurement includes the weight of the pallet itself. |
| GROSS_WEIGHT_UOM | Input the unit of measure for the gross weight measurement. Use the code list provided in the file to populate this field.  |
| IS_ORDER_UOM     | Identify using a "Y" or "N" value whether this unit level is the level at which ordering is managed for a given trade item.   |
| IS_STOCK_UOM     | Identify using a "Y" or "N" value whether this unit level is the level at which stock keeping is managed for a given trade item.  |
| IS_DISPENSE_UOM  | Identify using a "Y" or "N" value whether this unit level is the level at which dispensing is managed for a given trade item.   |
| IS_BASE_UNIT     | Identify using a "Y" or "N" value whether this unit level is the base level for a given trade item hierarchy.   |
| BASE_UNIT_MULT   | Identify the number of base units included at this packaging level. For example, a case of 20 bottles, for an item where a bottle is the base unit, would have a base unit multiplier of 20.                                    |

| NET_CONTENT     | Identify the amount/number of NET_CONTENT_UOM contained in a package at the given packaging level.      |
|-----------------|---|
| NET_CONTENT_UOM | Identify the unit of measure for the NET_CONTENT. Valid values are found in Code List and also in GDSN. |