

## **Master Data Exchange Quick Reference**

For Syncing US Products to Product Information Manager (Master Data Share)

Version 2025.1.0 | Revision 01



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# **Table of Contents**

Master Data Exchange Quick Reference	1
For Syncing US Products to Product Information Manager (Master Data Share)	1
Copyright	2
Table of Contents	3
Fields	4
Product Master Data	5
Product Information Fields	5
Item Code Fields	6
Target Markets Fields	6
Item Information Fields	8
Packaging Information Fields	10



### **Product Master Data**

The following tables list the fields in Product Master Data for syncing product information for all US Target Markets to Product Information Manager to support the US DSCSA Saleable Returns requirements. Some fields stated here as required do not display the red asterisk in the UI but are required for syncing to Product Information Manager.

#### **Product Information Fields**

Field	Description	Values
Data Status	Whether the product data is active within TraceLink.  CSV Element Header: DataStatus  A Required for all countries.	<ul> <li>Active – The data can be used in messages and UI functions, and TraceLink pulls the data when necessary.</li> <li>Inactive – The data cannot be pulled for other functions within TraceLink.</li> <li>Must be Active to sync the product entry to Product Information Manager.</li> </ul>
Item Status	The product's commercial status.  CSV Element Header: ItemStatus  Required for all countries.	<ul> <li>Released – The company approved the product for commercial release.</li> <li>Alternate items available – The company has alternate items that can take the place of this product.</li> <li>Phase out – The company phased out this product from production and sale.</li> <li>Items no longer stocked – The company does not currently stock this product.</li> <li>Withdrawn – The company removed this product from the market.</li> <li>When the product has an Export From Country of India, the only Item Status options are Released, Items no longer stocked, and Withdrawn.</li> </ul>

Field	Description	Values
		⚠ Must be Released to sync the product entry to Product Information Manager.

#### **Item Code Fields**

Field	Description	Values
Item Code Type	The unique item code that identifies this product. Products require an item code for every target market. Each item code type can only be used once for each product, except for Internal Material Number.	For more information, see Identifier and Item Code Types in the Master Data Exchange Online Help.
	⚠ At least one Item Code required for all countries.	<ul> <li>▲ Must include:</li> <li>At least one NDC-442, NDC-532, NDC-541, or NDC-542 if the Owner</li> </ul>
	CSV Element Header: ItemCodeType	needs to sync the product entry to Product Information Manager.
Item Code Value	The value of the Item Code Type. The value must be unique within the Item Code Type, and special characters (e.g, ., /. \) are removed from this value.  CSV Element Header: ItemCodeValue	For more information, see Identifier and Item Code Types in the <i>Master Data Exchange Online Help.</i>
Primary Item Code	The radio button indicates the primary item code used by this company. TraceLink uses the primary item code to identify the correct product when the user updates the product master data by importing a CSV file or with an asynchronous message.  CSV Element Header: ItemCodePrimary	n/a
	⚠ The first Item Code in the CSV must be the <b>Primary Item Code</b> .	

### **Target Markets Fields**

Field Name	Description	Values
Country Market Code	Two-letter ISO 3166-1alpha-2:1997 Country Code of the Target Market's country.  A Required for all countries.	⚠ Must include a target market that is also defined for syncing on the Product Information Manager Data Rules screen in Management to sync the product entry to Product Information Manager.
Product Type	Type of product. Traceability regulations differ depending on the product type (e.g. over-the-counter drugs do not fall under DSCSA regulations in the US). For informational purposes only, not compliance reporting.  CSV Element Header: CountryMarketProductType	<ul> <li>Bulk Pharmaceutical – A product that is the main active ingredient in one or more pharmaceutical formulas (e.g. antibiotics).</li> <li>Derivative Product – A product derived from another chemical compound.</li> <li>Food Supplement – A medicine available over the counter that is used for health and nutritional benefits.</li> <li>Medical Device – A device developed and used for a medical purpose.</li> <li>Nutritional Product – A specific class of over-the-counter product use for health and nutrition benefit.</li> <li>OTC Drug – A medicine available over the counter.</li> <li>Prescription Drug – A medicine available by prescription only.</li> </ul>
Traceability Required	Indicates whether the product legally needs to be traced through the pharmaceutical supply chain.  CSV Element Header: CountryMarketTraceabilityRequired	<ul> <li>Not Required – The product is exempt from tracking.</li> <li>Required – The product requires tracking.</li> </ul>
Product Origin	How the company acquires the product. Regulatory laws require different data for sales transactions depending on whether a company is the product originator, has purchased directly from the product originator, or has purchased from an intermediary.  CSV Element Header: CountryMarketProductOrigin	<ul> <li>Direct Purchase from Exclusive Distributor – The company purchased the product from the sole distributor of the product.</li> <li>Direct Purchase from Manufacturer – The company purchased the product from the manufacturer.</li> <li>Direct Purchase from Repackager – The company purchased the product from a repackager.</li> <li>Indirect Purchase – The company purchased the product from a wholesale distributor.</li> </ul>

Field Name	Description	Values
		<ul> <li>Originator (Exclusive Distributor) – The company, as a wholesale distributor, directly purchased the product from the manufacturer and serves as the sole distributor of the product. This option only applies if the Country Market Code is United States.</li> <li>Originator (Manufacturer) – The company manufactures the product.</li> </ul>
MAH ID	The company or location identifier of the MAH, which must exist in Company or Partner Master Data. Required if MAH is selected in the <b>Manufactured By</b> field.	For more information, see Identifier and Item Code Types in the <i>Master Data Exchange Online Help</i> .
	CSV Element Header: CountryMarketMAHId and CountryMarketMAHIDType	⚠ Must be a GLN and the identifier must exist in Company Master Data to sync the product entry to Product Information Manager.

### **Item Information Fields**

Field	Description	Values
Language Code	Language for the item information.	n/a
	<ul> <li>• English for US.</li> <li>Only one English item information can be defined if the product entry must be synced to Product Information Manager.</li> </ul>	
	⚠ Required for all countries.	
	CSV Element Header: ItemInfoLanguageCode	
Product Description	Typically includes the product name, dosage, form, and the number of doses.	n/a

Field	Description	Values
	Required for all countries.  CSV Element Header: ItemInfoProductDescription	
Product Name	The name of the product.  A Required for all countries.  CSV Element Header: ItemInfoDrugName	n/a
Generic Name	The chemical or non-proprietary name of the product.  CSV Element Header:  ItemInfoGenericName	n/a
Manufacturer	The name of the manufacturer or re-packager as it appears on the product label.  A Required for all countries.  CSV Element Header: ItemInfoManufacturer	n/a
Strength	The strength of the product (e.g. 100 mg).  CSV Element Header: ItemInfoStrength	n/a
Dosage Form	<ul> <li>The form the product is dispensed in (e.g. tablet or pill).</li> <li>⚠ Required if:         <ul> <li>US [United States] is a Target Market, the Language Code is English, and the Product Type is not Medical Device, OTC Drug, Nutritional Product, or Derivative Product.</li> <li>The Owner needs to sync the product entry to Product Information Manager.</li> </ul> </li> </ul>	n/a

Field	Description	Values
	CSV Element Header: ItemInfoDosageForm	
Package Size / Spec	The number of individual doses in the pack.  CSV Element Header: ItemInfoPackageSize	n/a

### **Packaging Information Fields**

① Only serialized functions require **Packaging Information** fields, not lot-level.

Field	Description	Values
Packaging Code Type	The serial numbers for the product are generated according to the packaging code type. If necessary, define a packaging code for each packaging unit of measure that needs to be tracked.	<ul> <li>CN-ResCode – This packaging code type is specific to China (must be 5 digits).</li> </ul>
	Required if any other <b>Packaging Information</b> fields are entered.  CSV Element Header: PackagingCodeType	<ul> <li>GTIN-14 – (Global Trade Item Number) This packaging code type is accepted in any country (must be 14 digits).</li> <li>NTIN – (National Trade Item Number) This packaging code type is specific to a single country (must be 14 digits).</li> </ul>
		<ul> <li>Must be:</li> <li>GTIN-14 to sync the product entry to Product Information Manager.</li> </ul>
	The unique value for the Packaging Code Type. See Packaging Code Type above for the field requirements.  If the Packaging Code Type is CN-ResCode, fill out Rescode instead of Packaging Code.	n/a
	Required if a Packaging Code Type is selected.  CSV Element Header: PackagingCode	

Field	Description	Values
Packaging UOM	(Packaging Unit of Measure) Determines the level of the packaging hierarchy for this packaging code. If multiple packaging codes are defined, serial numbers can be generated for each level of the packaging hierarchy.	<ul> <li>Primary – The level of packaging that physically touches the product, i.e. blister packs (not available for CN-ResCodes).</li> <li>Each – The smallest salable unit of the product.</li> </ul>
	Required if a Packaging Code Type is selected.	Inner Pack/Bundle – A grouping of eaches.
	CSV Element Header: PackagingUOM	<ul> <li>Case/Shipper – A grouping of inner packs/bundles or a grouping of eaches if the packaging hierarchy does not include inner packs/bundles.</li> <li>Pallet – The level of packaging with cases grouped together on a pallet (not available for CN-ResCodes).</li> <li>None – Available only for CN-Rescodes.</li> </ul>
		<ul> <li>Must be:</li> <li>Each if the Owner needs to sync the product entry to Product Information Manager. Only one Packaging Code for each Packaging UOM can be defined. If more than one packaging code is defined for the same packaging UOM, TraceLink does not sync the product entry to Product Information Manager. TraceLink also does not sync Primary packaging codes.</li> </ul>
Container Aggregation Quantity	Number of children contained in this level of shipment. E.g. for a Case, the <b>Container Aggregation Quantity</b> would list the number of Inner Packs contained in each Case. TraceLink only uses this field for compliance reporting purposes, not validation during aggregation.	⚠ Must be 0 for eaches if the Owner needs to sync the product entry to Product Information Manager. TraceLink also syncs other packaging UOMs that have a Container Aggregation Quantity set, as long as an each is defined with a Container Aggregation Quantity of 0.
	<ul> <li>Required if:</li> <li>The Packaging UOM is Each and the Owner needs to sync the product entry to Product Information Manager.</li> </ul>	
	<b>CSV Element Header:</b> PackagingContainerAggregationQty	

Field	Description	Values
GS1 Company Prefix	Prefix included in the packaging code, assigned by the GS1 organization, must be a numeric value 4 to 6 characters long.	⚠ Must be a numeric value 4 to 6 characters long to sync the product entry to Product Information Manager.
	⚠ Required if the Packaging Code Type is GTIN-14.	
	CSV Element Header: PackagingGS1CompanyPrefix	
Data Status	Whether the packaging information data is active or inactive within TraceLink.	Active – The data can be used in messages and UI functions, and TraceLink
	⚠ Required if a Packaging Code Type is selected.	<ul> <li>pulls the data when necessary.</li> <li>Inactive – The data cannot be pulled for other functions within TraceLink.</li> </ul>
	CSV Element Header: PackagingDataStatus	