

### **Master Data Exchange Quick Reference**

#### **United States**

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## tracelink | Help

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# REQUIRED FIELDS

## **US Product Master Data**

The following tables list the **required** fields in Product Master Data for compliance regulations.

#### **Product Information Fields**

Field	Description	Values
Data Status	Whether the product data is active within TraceLink. <b>CSV Element Header:</b> DataStatus 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> </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Withdrawn - The company removed this product from the market.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>Men the product has an Export From Country of India, the only Item Status options are Released, Items no longer stocked, and Withdrawn.</li> </ul>

#### **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 <i>Master Data Exchange Online Help.</i>
	At least one Item Code required for all countries.	
	CSV Element Header: ItemCodeType	
Item Code Value	The value of the <b>Item Code Type</b> . The value must be unique within the <b>Item Code Type</b> , and special characters (e.g, ., /. \) are removed from this value. <b>CSV Element Header:</b> 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. <b>CSV Element Header:</b> ItemCodePrimary	n/a
	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.	n/a
	A Required for all countries.	
	CSV Element Header: CountryMarket	
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.	<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</li> </ul>

Field Name	Description	Values
	CSV Element Header: CountryMarketProductOrigin	<ul> <li>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> <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>

#### **Item Information Fields**

Field	Description	Values
Language Code	Language for the item information.	n/a
	<ul><li>Must include:</li><li>English for US.</li></ul>	
	A 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
	A Required for all countries.	
	<b>CSV Element Header:</b> ItemInfoProductDescription	
Product Name	The name of the product.	n/a
	⚠ Required for all countries.	
	CSV Element Header: ItemInfoDrugName	
Manufacturer	The name of the manufacturer or re-packager as it appears on the product label.	n/a
	$\triangle$ Required for all countries.	
	CSV Element Header: ItemInfoManufacturer	
Strength	The strength of the product (e.g. 100 mg).	n/a
	<ul> <li>Required if:</li> <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> </ul>	
	CSV Element Header: ItemInfoStrength	
Dosage Form	<ul> <li>The form the product is dispensed in (e.g. tablet or pill).</li> <li>▲ Required if:</li> <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> </ul>	n/a

Field	Description	Values
	CSV Element Header: ItemInfoDosageForm	
Package Size / Spec	The number of individual doses in the pack.	n/a
	A Required if:	
	• US [United States] is a Target Market, the Language Code is	
	English, and the <b>Product Type</b> is not Medical Device, OTC Drug, Nutritional Product, or Derivative Product.	
	CSV Element Header: ItemInfoPackageSize	

#### **Packaging Information Fields**

<sup>(i)</sup> Only serialized functions require **Packaging Information** fields, not lot-level.

Field	Description	Values
	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>
	A Required if any other <b>Packaging Information</b> fields are entered.	<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</li> </ul>
	CSV Element Header: PackagingCodeType	to a single country (must be 14 digits).
Packaging Code	The unique value for the <b>Packaging Code Type</b> . See <b>Packaging Code Type</b> above for the field requirements.	n/a
	If the Packaging Code Type is CN-ResCode, fill out Rescode instead of Packaging Code.	

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Field	Description	Values
	Required if a Packaging Code Type is selected. CSV Element Header: PackagingCode	
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. ▲ Required if a Packaging Code Type is selected. CSV Element Header: PackagingUOM	<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> <li>Inner Pack/Bundle – A grouping of eaches.</li> <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</li> </ul>
GS1 Company Prefix	Prefix included in the packaging code, assigned by the GS1 organization.	available for CN-ResCodes).  • None – Available only for CN-Rescodes.  n/a
	<b>A</b> Required if the <b>Packaging Code Type</b> is GTIN-14.	
Data Status	CSV Element Header: PackagingGS1CompanyPrefix Whether the packaging information data is active or inactive within TraceLink.	<ul> <li>Active – The data can be used in messages and UI functions, and TraceLink pulls the data when necessary.</li> </ul>
	▲ Required if a <b>Packaging Code Type</b> is selected. <b>CSV Element Header:</b> PackagingDataStatus	<ul> <li>Inactive – The data cannot be pulled for other functions within TraceLink.</li> </ul>