ISBT 128 STANDARD

Labeling of Medical Products of Human Origin with INN and USAN Nonproprietary Names

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1   Introduction

1.1   Purpose

This document is intended to provide instructions for the labeling of medical products of human origin (MPHO) with INN and USAN nonproprietary names.

1.2   Scope

This Standard applies to MPHO that have an approved International Nonproprietary Name (INN) and/or a United States Adopted Name (USAN).

Specific Exclusions from Scope

The ISBT 128 Standard is not intended to replace or modify existing labeling information such as the trade name, nonproprietary name, and national identifiers (e.g., the national drug code [NDC] in the US).

ISBT 128 is intended to capture, in an electronically-readable format, essential product information for ensuring the unique identification of MPHO and to support traceability across international borders.

1.3   Intended Audience

The intended audience of this document is:
- Staff at processing and receiving facilities (managers, information technology, quality, validation, and laboratory)
- Software developers
- Label vendors
- Competent authority

1.4   Normative References

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

1.5   Other References

ICCBBA website (www.iccbba.org)

WHO International Nonproprietary Names
(http://www.who.int/medicines/services/inn/en/)

AMA United States Adopted Names Council
(https://www.ama-assn.org/about/united-states-adopted-names-council)

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)

Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

1.6   Background

Some medical products of human origin (MPHO), including some cellular and non-cellular therapy products, are required to have nonproprietary names. These are generic names assigned by national and/or international authorities. Nonproprietary names are public property; as opposed to trade (or proprietary) names, which are usually under patent protection.

Globally, the World Health Organization (WHO), through the INN Expert Group, will allocate International Nonproprietary Names (INN) to such MPHO. In the US, some MPHO are required to have a nonproprietary name, and this is often a United States Adopted Name (USAN) assigned by the United States Adopted Names Council (USANC). WHO and USANC have indicated their intent to ensure that where both an INN and USAN are assigned, the same name will be used. However, for an interim period, some products may carry different INN and USAN names.

The ISBT 128 Standard is a global terminology, coding, and labeling system. It is used worldwide to label MPHO and was developed to facilitate effective traceability from donor to patient. The WHO has recognized the ISBT 128 Standard as the sole global standard for identification and coding of MPHO. Terminology, coding, and labeling are actually three separate functions, and it is possible to use ISBT 128 coding and labeling with other terminology systems.

Nonproprietary names provide a nomenclature, but do not provide a coding and labeling system that supports electronic capture of information. Electronic capture of information is essential to ensure accurate records, support traceability, and to provide computer assistance in ensuring the correct product goes to the correct patient. The latter is especially important for cellular therapy products, which are often appropriate only for one specific patient.

This document describes how INN and USAN terminology may be used with the ISBT 128 coding and labeling system to create a complete system that supports electronic capture of information and computerized support for matching the right product to the right patient.

2   Terminology

ICCBBA will assign ISBT 128 Class Names to medical products of human origin (MPHO) with an INN and/or USAN nonproprietary name. The Class Name will be formed by the prefix INN or USAN followed by the nonproprietary name. See examples in Table 1.

Table 1 Examples of ISBT 128 Class Names for MPHO with an INN or USAN

Nonproprietary Names		ISBT 128 Category: MPHO with INN and/or USAN
Potential INN	USAN	ISBT 128 Class Name
azficel		INN:AZFICEL
	Carlecortemcel-L	USAN:CARLECORTEMCEL-L

If the INN and USAN are not the same for a single product, the ISBT 128 Class Name will include both nonproprietary names. See an example in Table 2.

Table 2 Example of an ISBT 128 Class Name for an MPHO with different INN and USAN

Nonproprietary Names		ISBT 128 Category: MPHO with INN and/or USAN
Potential INN	Potential USAN	ISBT 128 Class Name
sileucel	Sipuleucel-T	INN:SILEUCEL,USAN:SIPULEUCEL-T

If the INN and USAN names are the same for a single product, the ISBT 128 Class Name will include the INN nonproprietary name only. See an example in Table 3.

Table 3 Example of an ISBT 128 Class Name for an MPHO with the same INN and USAN

Nonproprietary Names		ISBT 128 Category: MPHO with INN and/or USAN
Potential INN	Potential USAN	ISBT 128 Class Name
cenplacel	cenplacel	INN:CENPLACEL

Each MPHO with an INN and/or USAN will be assigned an internationally standardized Product Description Code (PDC) starting with the alphabetic character H. See example in Table 4.

Table 4 Example of a PDC assigned to an MPHO with INN and USAN

Nonproprietary Names		ISBT 128 Category: MPHO with INN and/or USAN	
Potential INN	Potential USAN	ISBT 128 Class Name	ISBT 128 Product Description Code (PDC)
cenplacel	cenplacel	INN:CENPLACEL	H9991

If needed, product Attributes will be added to describe these products. In the example in Table 5, the Attribute "Refrigerated" has been added to the ISBT 128 Product Description.

Table 5 Example of an Attribute added to an MPHO with INN and USAN

Nonproprietary Names		ISBT 128 Category: MPHO with INN and/or USAN		
Potential INN	Potential USAN	ISBT 128 Class Name	ISBT 128 PDC	ISBT 128 Product Description
cenplacel	cenplacel	INN:CENPLACEL	H9992	INN:CENPLACEL│**Refrigerated**

3   Data Structures

The Donation Identification Number [Data Structure 001] and the Product Code [Data Structure 003] shall be used for labeling MPHO with nonproprietary names.

The Donation Identification Number [Data Structure 001] shall be used to encode the Donation Identification Number (DIN) and Flag Characters. The Check Character is required and shall be printed along with the DIN. Figure 1 illustrates the information encoded within Data Structure 001 and the Check Character.

Figure 1 Information encoded within Data Structure 001 and Check Character

Data Structure 001

A999917123456 01   **9**

Check Character

Facility Identification Number (FIN)

Year

Sequence Number

Flag Characters

Donation Identification Number (DIN)
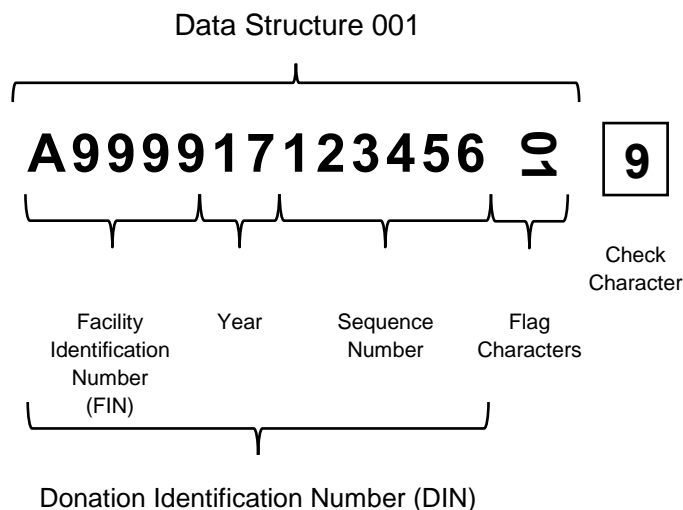
The Product Code [Data Structure 003] shall be used to encode the Product Description Code (PDC), Collection Type (e.g., allogeneic, autologous), and Division Code. Figure 2 illustrates the information encoded within Data Structure 003.

Figure 2 Information encoded within Data Structure 003

H99991A0

Product Description Code

Division Code

Collection Type Code
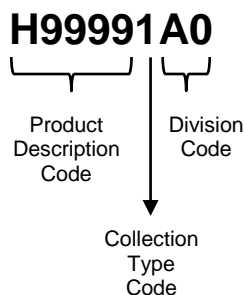
Other data structures found in the *ISBT 128 Standard Technical Specification* (ST-001)—such as the Collection Date and Time [Data Structure 007] and Expiration Date and Time [Data Structure 005]—may be used for encoding additional product characteristics.

4   Label Design

4.1   General Principles

The following general principles apply to label design:

- Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.

- Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

Facilities designing labels shall follow the technical specifications found in the *ISBT 128 Standard Technical Specification* (ST-001). This document contains the rules for the use of data structures and for printing labels with Code 128 (linear bar codes) and Data Matrix (2-D symbols). It also further describes other elements applicable to label design.

The *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) shall be used in conjunction with the ISBT 128 Product Description Code Database when selecting product description codes (PDC).

4.2   Minimum Labeling Requirements

Regardless of the size of the label, the minimum ISBT 128 information content on the label shall be:

- Electronically-readable Donation Identification Number (DIN). If a 2-D label is used, both the DIN and the Product Code shall be electronically-readable.

- The eye-readable Donation Identification Number, Flag Characters when required (rotated 90° clockwise), and the boxed Check Character.

- The eye-readable Product Code (Product Description Code, Collection Type Code, and Division Code). If this text does not appear in conjunction with a bar code (e.g., there is no linear bar code for the Product Code or a 2-D symbol is used), the word "Product" shall precede the Product Code.

4.3   Label Size and Shape

The label size and shape are user-defined. The size of the label may be limited by the size and packaging of the MPHO. Linear bar codes require more space than 2-D symbols; therefore, the label size should be considered when selecting the symbology. Facilities should ensure that the ISBT 128 label carries the minimum information required to ensure the unique identification of MPHO and to support traceability.

4.4   Delivery Mechanisms (Symbology)

Facilities may encode data structures using Code 128 or Data Matrix. Due to limited space on the label for MPHO with nonproprietary names, a 2-D symbol may be preferred to encode ISBT 128 information.

When multiple data structures are combined in a 2-D symbol, the Compound Message [Data Structure 023] shall be encoded along with the other data structures. Facilities implementing 2-D shall follow the technical specifications and guidance found in the *ISBT 128 Standard Technical Specification* (ST-001) and the *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).

When both ISBT 128 and non-ISBT 128 symbologies are present on a label, the text "ISBT 128" may be printed to identify the location of ISBT 128 information.

5 Label Examples

Figure 3 Label for an MPHO with a Nonproprietary Name
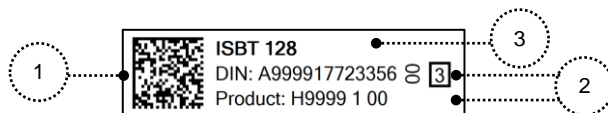
1. The 2-D symbol encodes the following information:

   =+04000=A99991772335600=<H9999100&*0170221120&>0170231120

   - =+04000 represents the Compound Message [Data Structure 023]

     =+ is the data identifier

     04 indicates that four data structures are encoded in the 2-D symbol

     000 indicates that the data structures are not encoded in a specific order in the string

   - =A99991772335600 represents the Donation Identification Number [Data Structure 001]

     =A is the data identifier

     A999917723356 is the DIN

     00 are the Flag Characters

   - =<H9999100 represents the Product Code [Data Structure 003]

     =< is the data identifier

     H9999 is the Product Description Code (PDC)

     1 is the Collection Type Code

     00 is the Division Code

   - &*0170221120 represents the Collection Date and Time [Data Structure 007]

     &* is the data identifier

     0170221120 represents the collection date 2017-01-22 and time 11:20 AM

   - &>0170231120 represents the Expiration Date and Time [Data Structure 005]

     &> is the data identifier

     0170231120 represents the expiration date 2017-01-23 and time 11:20 AM

2. The minimum text required on ISBT 128 labels:

   - The donation numbering comprises the DIN (A999917723356), Flag Characters (00), and Check Character (3)

   - The Product Code comprises the PDC (H9999), Collection Type Code (1), and Division Code (00)

3. The text "ISBT 128" printed to identify the location of ISBT 128 information

Figure 4 MPHO Labeled with INN/USAN Terminology, National Identifiers, and ISBT 128
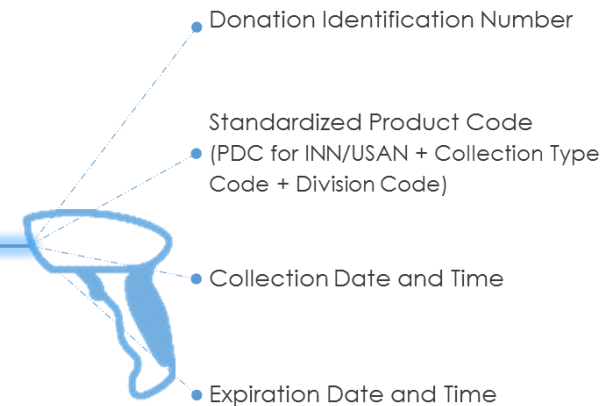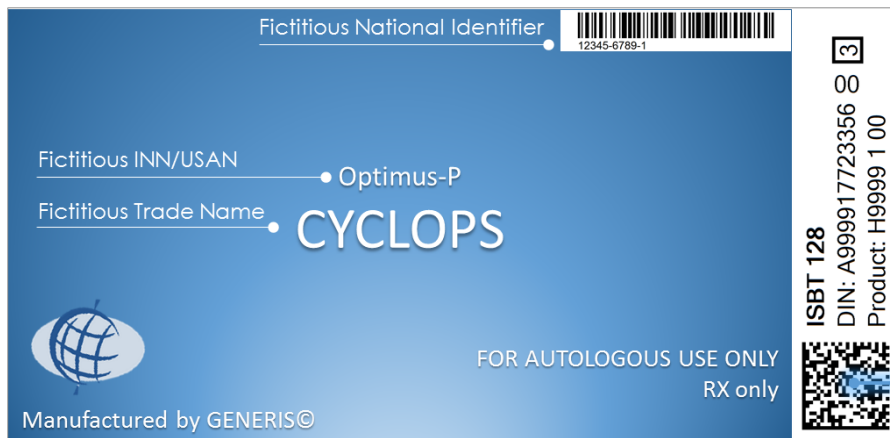
In this illustration, the 2-D symbol encodes four ISBT 128 data structures, and the text printed on the label identifies the Donation Identification Number (A999917723356), Product Description Code (H9999), Collection Type (1, Autologous), and Division Code (00).