SLOVENSKI STANDARD
kSIST-TS FprCEN ISO/TS 19844-1:2026

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Zdravstvena informatika - Identifikacija zdravil - 1. del: Izvajanje ISO 11238 (splošno) (ISO/DTS 19844-1:2026)

Health informatics - Identification of medicinal products (IDMP) - Part 1: Implementation of ISO 11238 (general) (ISO/DTS 19844-1:2026)

Medizinische Informatik - Identifikation von Arzneimitteln - Implementierungsleitfaden für ISO 11238 für Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen zu Stoffen - Teil 1: ISO 11238 Implementierungsleitfaden für Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen zu Stoffen (ISO/DTS 19844-1:2026)

Informatique de santé — Identification des médicaments — Lignes directrices pour·la·mise·en·oeuvre de l'ISO 11238 relative aux éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances — Partie 1: Titre manque (ISO/DTS 19844-1:2026)

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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FINAL DRAFT
Technical Specification

ISO/DTS 19844-1

Health informatics — Identification of medicinal products (IDMP) —

Part 1: Implementation of ISO 11238 (general)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO/TS 19844-1, together with ISO/TS 19844-2, ISO/TS 19844-3, ISO/TS 19844-4, ISO/TS 19844-5, ISO/TS 19844-6, ISO/TS 19844-7, ISO/TS 19844-8, ISO/TS 19844-9, ISO/TS 19844-10, ISO/TS 19844-11 and ISO/TS 19844-12, cancels and replaces ISO/TS 19844:2018, which has been technically revised.

The main changes compared to the previous edition are as follows:

— split of 19844 into a series of documents;

— addition of "minimum fields" and "definitional fields" per substance information.

A list of all parts in the ISO/TS 19844 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The objectives of the standards on the Identification of Medicinal Products (IDMP) are to support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products as well as pharmacovigilance and risk management.

Due to the lack of a common and harmonized approach to define substances, regulators and pharmaceutical industry are faced with the inability to:

— effectively exchange medicinal substance information in a structured and efficient way;

— ensure data consistency and evaluate/compare information across regions, which especially impairs pharmacovigilance and compliance activities;

— develop consistent terminology for use throughout the healthcare community.

The ISO standards on IDMP, developed in response to a worldwide demand for guidance on the implementation of internationally harmonized specifications for medicinal products, address the issues outlined above by developing harmonized standards that build on the regulatory and technical processes already established and to support the population and maintenance of existing systems/applications with fully reliable regulatory medicinal product information.

Harmonized standards will stimulate vendors to develop “off-the-shelf” tools (that are interoperable due to the standard itself). Harmonized standards will also help to maximize forward compatibility of data and minimize the complexities of backward compatibility.

The ISO standards on IDMP consist of ISO International Standards and their supporting technical specification. In addition to ISO 11238 [1], the other standards in this group are:

— ISO 11615 [2], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

— ISO 11616 [3], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*;

— ISO 11239 [4], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*;

— ISO 11240 [5], *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*.

This document provides requirements and recommendations for implementing ISO 11238 [1]. This document is intended to assist stakeholders (including pharmaceutical companies, regulatory authorities and non-commercial sponsors) in sharing information that allows substances to be defined unambiguously. It also provides guidance to help identify the correct Substance ID from a public data source that provides identified Substance and Specified Substance information. It is anticipated that an extensive list of substance identifiers, as well as the definitional elements upon which the ID was based, will be provided. This document is not intended to be a guide for a maintenance organization. The maintenance organization may also create alternative methods to submit information consistent with the ISO model.

For the purposes of this document, all conformance corresponds to the necessary requirements to uniquely and unambiguously identify a substance. In the context of ISO 11238 [1] and ISO/TS 19844 [6], conformance is expressed based on the following terminology: Mandatory, Conditional and Optional.

— Mandatory: refers to data elements that are required and shall therefore be implemented.

— Conditional: refers to data elements that are subject to business rules and can become required by:

  — data rules;

- process rules;
- regional rules.

— Optional: refers to data elements that are informative but not definitional.

The description on whether a data element is conditional by data, by process or by regional rule is out of scope of this document and will be defined within regional implementation guides. When there is no information in the conformance table row (see Table 1) (e.g. information on business rule is not provided), users need to refer to the regional implementation guide.

Regional implementation may also dictate that clauses tagged conditional or optional in the ISO standard are mandatory elements on regional requirements. Therefore, if a subclause is identified as 'optional' but is implemented in a specific region, conformance on data elements described within that subclause is applicable.

A systematic approach is being followed to describe classes and elements. Table 1 is an example table for class and elements description.

Table 1 — Example table for class and element description

User guidance	
Example(s)	
Conformance	
Data type	
Values allowed	
Business rule(s)	

Health informatics — Identification of medicinal products (IDMP) —

Part 1: Implementation of ISO 11238 (general)

1 Scope

This document provides requirements and recommendations for the implementation of ISO 11238 [1]. This document defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production.

ISO 11238 [1] provides the conceptual framework for defining Substances and Specified Substances and for assigning unique identifiers in the context of the ISO standards on IDMP. ISO 11238 [1] describes general concepts for defining and distinguishing substances and a high-level model for the structuring of information for substances. This document provides detailed explanations of each type or grouping of substance information, an element-by-element description for the implementation of ISO 11238 [1], and examples for a variety of Substances and Specified Substances.

This document covers:

— the data elements necessary for describing Substances and Specified Substances Groups 1 to 4;

— the data elements necessary for the unique definition of Substances and Specified Substances Groups 1;

— the logical use of data elements as defined in ISO 11238 [1].

This document does not cover:

— business processes for data management;

— implementation of a specific data information system (e.g. a relational database schema);

— normative messaging standards for substances;

— the maintenance of controlled vocabularies;

— the specific global identifier system to be used;

— nomenclature standards for substances.

This document does not cover Substances and Specified Substances Groups 1 to 4 business rules for:

— determining necessary data elements;

— distinguishing and defining material types according to ISO 11238 [1];

— triggering the assignment of identifiers.

Due to their inherent complexity, the specific case of Advanceed Therapies will be addresses in future versions of this document. An overview of Advanceed Therapies is available in Annex A.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

4 Symbols and abbreviated terms

NOTE Only general abbreviations are listed. They are used either within ISO 11238 [1] or ISO/TS 19844 [6] since these documents are regarded as inseparable.

CAS Chemical Abstracts Service number[1)]

INN International Nonproprietary Name [also consider as rINN (recommended International Nonproprietary Name) or pINN (proposed International Nonproprietary Name)][2)]

JAN Japanese Accepted Name[3)]

USAN United States Adopted Name[4)]

5 Substance

5.1 General

All medicinal products consist of substances; these substances can be active ingredients, excipients, or packaging materials. The substances shall be described in accordance with ISO 11238. There are two fundamental levels of information described in ISO 11238 [1], a “Substance level" and a “Specified Substance level”. Both levels are included in the more generic concept of an ingredient. At the Substance level, substances are defined based on inherent attributes rather than use or method of manufacture. At the Specified Substance level, four separate groups of elements provide additional information.

In order to define or distinguish material either at a Substance or Specified Substance level, a number of attributes should be taken into consideration:

— For chemicals, the molecular structure is captured at the Substance level.

— For proteins, the amino acid sequence, sites and type of glycosylation, and the presence of modifications and position of disulfide bonds are captured at the Substance level.

1) https://www.cas.org/about-us

2) http://www.who.int/medicines/services/inn/en/

3) https://moldb.nihs.go.jp/jan/En

4) https://www.ama-assn.org/about/united-states-adopted-names-council

— For nucleic acids, the sequence, type of sugar and linkage and modifications are captured at the Substance level.

— For other polymers, the monomers used to synthesize the polymer, the structural repeat units, the molecular weight and/or a property related to molecular weight (e.g. viscosity), the source of naturally derived polymers and any modifications that irreversibly alter the molecular structure are captured at the Substance level.

— For structurally diverse material, taxonomic, anatomical and fractionation information, properties related to the underlying molecular structure of the material, and modifications that alter the underlying molecular structure are captured at the Substance level.

— A Mixture consists of a simple combination of Single Substances that are either isolated together or are the result of the same synthetic process. This applies also to a homologous group of structurally diverse single substances used to prepare an allergen extract. The biological source of the mixture is also captured where relevant at the substance level. Proportions are not captured at the substance level. It should be noted that a mixture description should only include the substances that are generally or consistently present in the material. This excludes impurities and degradants.

Other attributes will be specific to the Specified Substance levels:

— constituent substances in a multi-substance material;

— proportions of constituent substances in a multi-substance material;

— physical state;

— grade or purity of material.

There are four groups of elements that are used to further define and specify Substances. Specified Substances are always composed of at least one substance.

Specified Substance Group 1 (SSG1) is typically used to define:

— multi-substance materials consisting of multiple substances, which are not defined as mixture;

— defining information regarding homeopathic, plasma derived, vaccines substances, herbal and allergenic extracts;

— physical state, including polymorphic forms;

— detailed glycosylation information.

Specified Substance Group 2 (SSG2) is typically used to define:

— manufacturer, manufacturing process and critical process version number. In some cases extended manufacturing information are used to provide information regarding herbal and allergenic extracts when multiple extraction methods with different solvent compositions are used or a stepwise manufacturing process is in place describing an extraction method followed by a general modification process of the extract, e.g. modified allergen extract, modified vaccines by multiple modification processes.

Specified Substance Group 3 (SSG3) is typically used to define:

— grade or level of purity (Pharmacopoeial Specifications) and in-house specification used to cover a set of specifications of all approved manufacturers for the substance.

Specified Substance Group 4 is typically used to define:

— detailed specification information including analytical information to be used in tests;

— detailed manufacturing information.

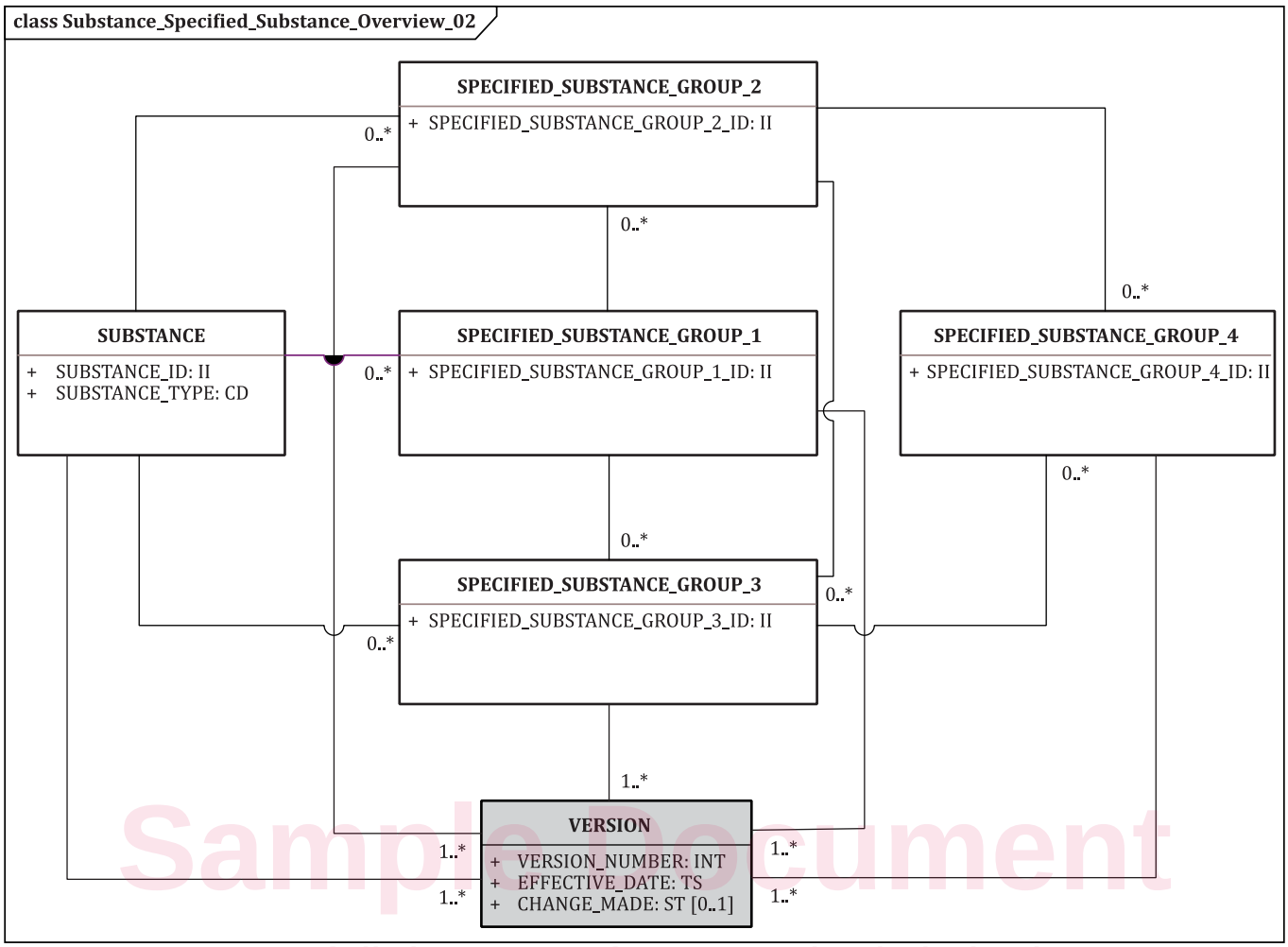

Figure 1 — High-level Substance-Specified Substance information model

EXAMPLE In Figure 1, the Substance class is parent of the classes Specified Substance Group 1 (SSG1), Specified Substance Group 2 (SSG2) and Specified Substance Group 3 (SSG3). Similarly, SSG1 is a parent of SSG2 and SSG3. For Triamcinolone acetonide, Figure 2 shows the relationships of Substance and Specified Substance Groups.

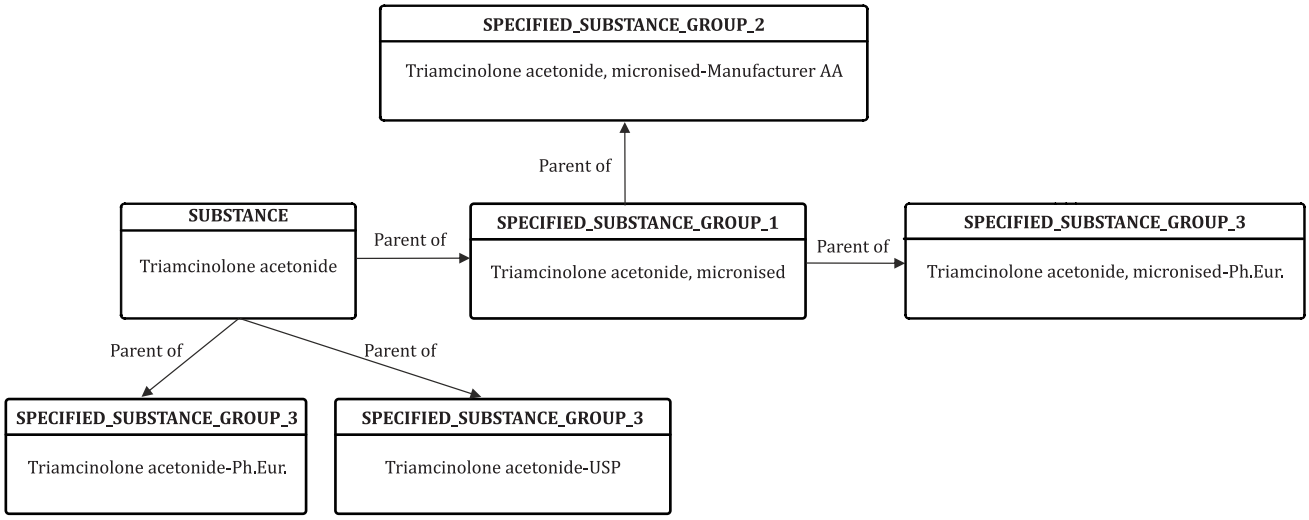

Figure 2 — Parent Substance and Specified Substances Groups relationships of Triamcinolone acetonide