

SCIP Notification Format

# Preparing a SCIP dossier

Oct 2021

# ABC

Version	Changes	
1.0	1 <sup>st</sup> version	July 2020
2.0	Correction of chapter numbers Additional explanation on the mangament of mandatoriness in IUCLID format (Section 2.4) Referencing features updates Update of the link to SCIP information requirements to the Requirements for SCIP Notifications.	Oct 2021

## Legal notice

This document aims to assist users in complying with their obligations under Article 9(1)(i) of the Waste Framework Directive 2008/98/EC (WFD). However, users are reminded that the text of the WFD is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

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## 1. Introduction

The SCIP is the database for submitted information on **S**ubstances of **C**oncern **I**n articles, as such or in complex objects (**P**roducts) established under the Waste Framework Directive (WFD). Article 9(1)(i) of the WFD requires that any supplier of an article has to provide the information on that article containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) to ECHA as from 5 January 2021.

This document provides a technical background and offers a practical guide to duty holders on how to prepare a SCIP dossier.

### 1.1 Information required for SCIP notification

The information that needs to be included in a SCIP notification is explained in detail in the [Requirements for SCIP Notification](#) document and in the data model document.

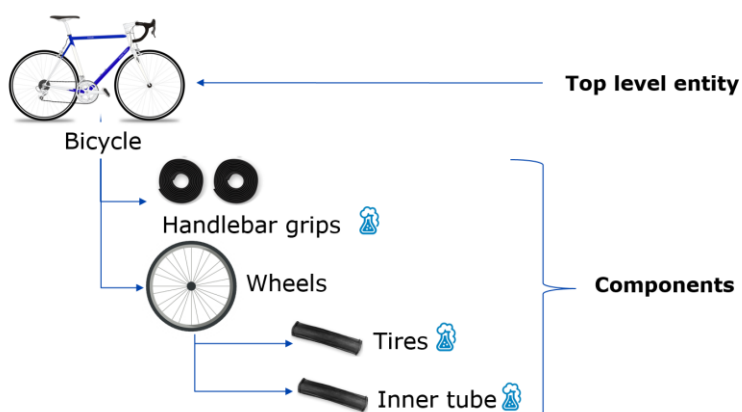
This information consists on elements that allow:

1. the identification of the (concerned) article as such or in a complex object;
2. the identification of the Candidate List substance present in the concerned article;
3. the safe use of the article.

Conceptually, the article, as used in this document is a generalisation of articles as such and complex objects, i.e. an article is either an article as such (e.g. handlebar grip, one-piece plastic spoon, O-ring), or a complex object (e.g. bicycle, sofa, vehicle's engine, electronic equipment). Each complex object incorporates two or more components, each of which is either an article as such or another complex object (complex object component) (e.g. the handlebar grip and the wheel are component articles of a bicycle). However, for a SCIP notification purposes only components of the complex object that incorporate articles as such with Candidate List substances (in a concentration above 0.1% w/w), or articles as such with such substances that are components of that complex object are relevant.

The '**Hierarchy**' in a complex object consists in the relationship between the complex object and its components, sub-components and articles as such (complex object components) containing a Candidate List substance (🧪) to be built in a SCIP notification according to the SCIP data model. An example is shown below:

**Figure 1: Illustration of the 'hierarchy' for a bicycle (complex object)**



The SCIP notification of an article as such is built from a dataset that include in the concern elements section the information related with the Candidate List substance present in the article.

The SCIP notification of a complex object is built in a main dataset that incorporates one or more link components datasets of either an article as such or another complex object (complex object component) that includes the information related with the Candidate List substance present in each component of the complex object.

The **SCIP format**<sup>1</sup> is XML-based compatible with IUCLID. It structures the information to be submitted to ECHA.

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<sup>1</sup> The SCIP format is maintained by ECHA and made publicly available free of charge. For additional information, visit the following ECHA webpage: <https://echa.europa.eu/scip-format>

## 2. IUCLID format

### 2.1 Background

The SCIP format is part of IUCLID since October 2019. It is structured and organised in line with the SCIP Data Model<sup>2</sup> and according to the defined Requirements for SCIP Notifications<sup>3</sup>.

### 2.2 Structure of information

In IUCLID, the information is organised in *IUCLID Documents* that gather all relevant data fields for a specific type of information. These documents are grouped in so-called '*definitions providers*' in order to indicate whether they are meant to be reused (all documents part of the 'IUCLID CORE' or the 'OECD definitions provider') or if they are specific to a single legislation/context (e.g. 'EU SCIP').

All the data is entered and stored in logical 'datasets' containing documents. When all the data have been prepared and encoded, all the datasets should then be assembled together in a final compressed file called 'dossier' (.i6z extension file). A dossier containing all the required information can then be submitted to ECHA applications (e.g. the ECHA Submission portal).

In order to ensure the data referential integrity and maintain the correct relationship between the various documents contained in the final dossier, a numeric identifier called a Universal Unique Identifier (UUID) must be generated and associated to each and every document contained in the dossier, acting as an unequivocal identifier. Additionally, the dossier itself must be identified with a separate UUID (also known as Snapshot UUID) each time it is created in order to be submitted.

The term entity in this document refers to a set of data that form an object with common characteristics. Entities are the entry point documents for a set of documents (datasets). Article is an example of root entity.

The latest version of IUCLID can be downloaded free of charge from the IUCLID website at the following address: <https://iuclid6.echa.europa.eu/home>. For more details about the installation and use of IUCLID 6 go to the website's [Support tab](#). The online preparation of a SCIP notification in IUCLID Cloud is available in the ECHA Cloud services (<https://ecs.echa.europa.eu/cloud/home.html>). The Cloud services are maintained, backed-up, updated by ECHA and the data is securely stored in the Cloud.

### 2.3 Data types

The SCIP format supports the following data types listed and explained in this paragraph.

#### **Text**

It enables the user to enter free text (with no formatting). For *single-line*, *multi-line text*, *text area* and *text template* components, a user is allowed to enter only plain text including letters, numbers and symbols in the selected character set (UTF-8). For *rich text area* the user is allowed

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<sup>2</sup> The SCIP Data Model is available on the following ECHA webpage: <https://echa.europa.eu/scip-format> .

<sup>3</sup> The Requirements for SCIP Notifications document is available on following ECHA webpage: <https://echa.europa.eu/scip-database>.

to specify formatting options such as font family, size and color, bullets and other text attributes.

### **Single-line text (255 chars)**

It is referred in all IUCLID documents simply as Text (255 Char). Its default maximum length is 255 characters with no line breaks. If the text field contents should be limited to fewer characters, this will be clearly defined.

### **Multi-line text (2,000 chars)**

It is a text field allowing default maximum length of 2,000 characters.

### **Text area (32,768 chars)**

It is a text field allowing a maximum of 32,768 characters. It has the same functionality as the *multi-line text*, differing only in its capacity.

### **Picklist (single)**

Picklists contain a collection of pre-defined values from which the user can provide only a single value. Only the corresponding identifiers must be provided in the format and not the actual label or description of the value. The list of all picklists and picklist elements identifiers is available as an annex.

### **List multi.(multi-select list)**

This data-type provides a list of items from which the user can select either one or more values. The list of all picklists and picklist elements identifiers is available as an annex.

### **Check box**

A check box is a simple boolean flag stored as text field that can accept the following values: <true> or <false>. The absence of this field is considered the same as a <false> value for the checkbox.

### **Numeric**

This data-type allows entering numeric values only.

### **Decimal**

This data-type allows entering decimal values only. Decimals must separated with a dot ".".

### **Attachment**

This data-type allows encoding a file attachment (e.g. Pictures, Disassembling instructions).

## **2.4 Mandatory fields**

In the IUCLID format a field is defined mandatory either directly in the XSD format or by using dynamic content or Validation assistant rules.

In the SCIP context a field can be classified as Mandatory, Required or Optional. ECHA recommend to refer to section 2 of the [Requirements for SCIP Notification](#) document, to learn more about this classification.

## 3. SCIP Dataset, Table of content (TOC) and Dossier

### 3.1 SCIP Dataset

A dataset is a central core of information, containing information for a specific article, its components and concern elements. It is thus the repository of technical and scientific data related to the article in question.

In order to assist the users with the data entry, the documents are logically organised in datasets using a specific table of content (TOC). This also allows re-using the individual datasets in different notifications if needed.

The SCIP format currently supports a single TOC including the main/root article as the starting point for creating a SCIP notification. Under each article,

- additional articles can be associated as complex object components, or
- Reference Substances can be associated as concern elements / substances no longer present



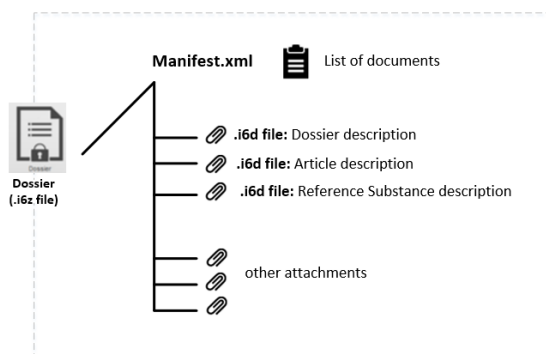
The format allows to associate both complex object components and concern element information to a main/root article, but this double association to a main/root article is considered incorrect. An article as such dossier must be associated only to concern element information and a complex object main /root article must have associated other components and not a reference substance directly.

### 3.2 Dossier

The dossier should be considered as a snapshot/instance of the underlying datasets (article information) taken at a specific time with the aim to be submitted to the ECHA Submission portal. It is a single file having the i6z extension. Once submitted, the dossier cannot be re-submitted. On the other hand, the raw data continuously evolves, also as a basis to create new dossiers out of it and send update SCIP notifications to fulfil legal obligations.

The dossier must contain all the relevant information in XML files (file extension “.i6d”) representing and corresponding to the various documents. The dossier must also contain a manifest file (“manifest.xml”) containing a table of contents with all the data files (including file attachments e.g. Pictures and Disassembling instructions) and documents that are available in the dossier. For more information on the i6z IUCLID files, please refer to '[Developers' guide to the IUCLID i6z format](#)'.

Figure 2 : Dossier file and Manifest





### 3.3 Dossier Header

A single Dossier header document must be provided in a dossier. The Dossier header contains administrative and technical information that are required in order to process correctly the information received.



Once the dossier has been submitted to ECHA, it cannot be modified and sent again as it is. If changes are required, a new Dossier must be created, assigning a new (snapshot) UUID to the new dossier, re-using the existing documents if needed.

#### DOSSIER.SCIP – Field definition

Field	Description
<b>Dossier name (given by user)</b>	<b>PlatformMetadata/name</b>  Optional – Text (255 char.)  Given by the user. Report the most appropriate name to manage the dossier. For example internal incremental reference numbers and/or codes can be used in order to keep track and better organize the information submitted.
<b>Dossier submission remark</b>	<b>DOSSIER.SCIP/remarks</b>  Optional - Text (32,768 char.)  Given by the user. Report additional notes and interal remarks to manage the dossier.

## 4. SCIP Article Dataset

The article dataset comprises the following fields, the definition of each field is included on annex I: Glossary.

### Identifiers

Field	Description	
<b>Article name</b>	Text (2,000 char.)	This is a <b>mandatory</b> field
<b>Other names type</b>	Type List (picklist)	This is an <b>optional</b> field
<b>Other name value</b>	Text (255 char.)	This is an <b>optional</b> field

Field	Description	
<b>Primary article identifier type</b>	Type List (picklist)	This is a <b>mandatory</b> field
<b>Primary article identifier value</b>	Text (255 char.)	This is a <b>mandatory</b> field



The Primary article identifier type and value and the Legal entity that submit the SCIP notification will form a composite key to identify each article in the SCIP database.



Additionally, upon submission, each notified article will be assigned a SCIP number which can be used in the context of referencing (explained later).

Field	Description	
<b>Other article identifier type</b>	Type List (picklist)	This is an <b>optional</b> field.
<b>Other article identifier value</b>	Text (255 char.)	This is an <b>optional</b> field.

### Categorisation



Field	Description	
<b>Article Category</b>	Type List (picklist)	This is a <b>mandatory</b> field
<b>Production in European Union</b>	Type List (picklist)	This is a <b>required</b> field


## Characteristics

Field	Description	
<b>Picture Image upload</b>	Files attachments	This is an optional field.
<b>Height Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Length Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Width Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Diameter Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Density Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Weight Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Volume Numeric</b>	Measurement units Pick list	This is an optional field.
<b>Colour</b>	Colours Pick List	This is an optional field.

Field	Description	
<b>Other characteristic type</b>	Text (255 char.)	This is an optional field.
<b>Other characteristic value</b>	Text (255 char.)	This is an optional field.

## Safe use instruction(s)

Field	Description	
<b>Safe use instruction</b>	Text field (2,000 char)	
<b>No need to provide safe use information beyond the identification of the Candidate List substance</b>	Check box	

 At least one of these fields either 'safe use instruction' or 'No need to provide safe use information beyond the identification of the Candidate List substance' check box are required.



Field	Description	
<b>Disassembling instructions</b>	PDF, Doc	This is an optional field.
<b>Instructions Language</b>	Language List (pick list)	This is an optional field.


## Complex object component(s)

Field	Description	
<b>Article Link to (single) article</b>	Article link	This is <b>mandatory</b> for a complex object .
<b>Number of units</b>	Integer	This is an <b>optional</b> field. Only applicable in complex object dossiers.

## Concern elements

Provide a set of concern elements for each Candidate List substance present in the article: Identification of the substance, concentration range of the substance in the article and the material/mixture category where the substance is present. The concern elements are only reported for an article as such.

Field	Description	
<b>Candidate list substance</b>	Link to Candidate List Substance (reference substance)	This is a <b>mandatory field</b> for an article as such.
A Reference substance is a single document used (in IUCLID) in the SCIP format to define the identity of a Candidate List Substance.		
<b>Concentration range</b>	Concentration range (picklist)	This is a <b>required field</b> for an article as such.
<b>Material category</b>	Material category (picklist)	 *
<b>Additional material characteristics</b>	List multi.(multi-select list)	This is an <b>optional</b> field for an article as such.
<b>Mixture category (EUPCS)</b>	List multi.(multi-select list)	 *

 \*At least one of these fields either 'material category' or 'mixture category' are mandatory for an article as such.

Field	Description	Field
<b>Candidate list substance no longer present</b>	Link to Candidate List Substance	This is an optional field.

This section allows to declare that an already notified article, used to contain a Candidate List substance, no longer contains this substance. This could happen due to different reasons, for instance due to substitution of the substance by a safer alternative. Use this section to report that the article no longer contains a Candidate List substance that used to be present in the article.

## 5. SCIP Article dossiers

### 3.3 SCIP dossier

Technically, the requested information in a SCIP dossier comprises the following documents:

#### Article as such dossier:

- Identifiers
- Categorisation
- Characteristics
- Safe use instructions
- Concern element information

#### Article as such example (illustration purpose only)



Handlebar grip

#### Identifiers:

**Name:** Black Mountain bicycle Handlebar grips

Other names: Brand: EUB & Model: Black mountain

**Primary article identifier type & value** EAN: 332288995

Other article identifiers: Catalogue number 29-78-78S

**Article category:** 8714999000 - Other; parts (Vehicles, aircraft, vessels and associated transport equipment > Vehicles other than railway or tramway rolling stock, and parts and accessories thereof > Parts and accessories of vehicles of headings|8711|to 8713 > Other > Other; parts) (CN/Taric code)

Characteristics: Black, 30mm length, Picture.

#### Safe use instructions:

Instruction 1 ...

Instruction 2 ...

(...)

#### Concern element

**Candidate list substance:** 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich, EC 276-158-1, CAS 71888-89-6

**Concentration range:**  $\geq 1.0$  % w/w and  $< 10.0$  % w/w

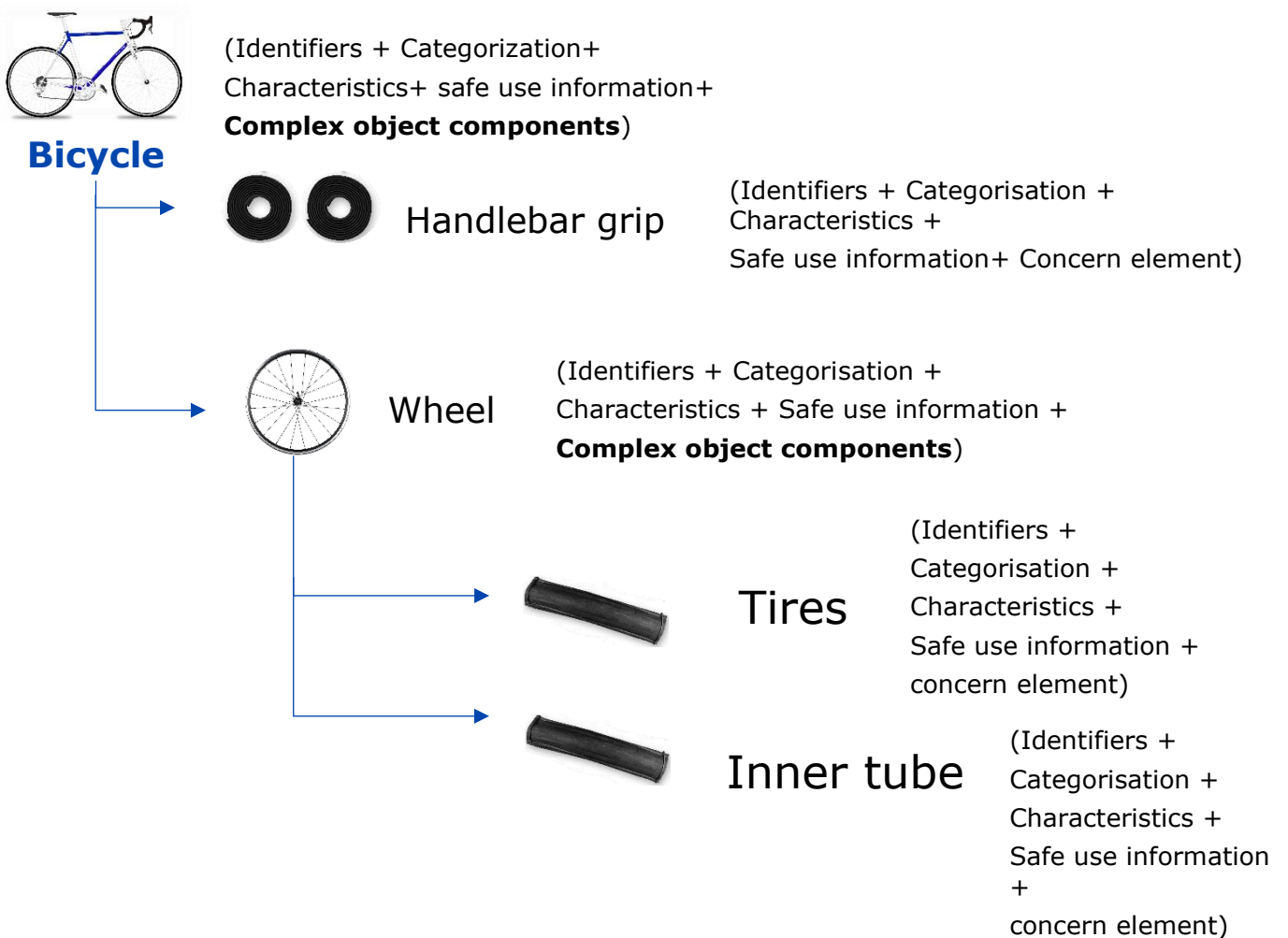
**Material category:** plastic (and polymers)> polyvinylchloride (pvc), soft

**Additional material characteristics:** thermoplastic

**Complex object dossier:**

- Complex object (Top level entity)
    - o Identifiers
    - o Categorisation
    - o Characteristics
    - o Safe use instructions
    - o Complex object component:
      - Dataset for a complex object **component:**
- }
  - Identifiers
  - Categorisation
  - Characteristics
  - Safe use information
  - **Complex object components** or **Concern element**

**Example for a complex object**



### 3.4 Specific considerations when using tools to refer to data already submitted to SCIP in a SCIP dossier

ECHA has developed technical solutions that can be used on a voluntary basis to make it possible for suppliers of articles (e.g. distributors, 'assemblers') to refer to data already submitted under SCIP by other duty holders. These tools facilitate the submission of SCIP notifications to ECHA, while keeping consistency in the information submitted, by avoiding multiple reporting of same data and thereby limiting duty holders' administrative burden. The two tools that can be used to refer to information already successfully submitted to the SCIP Database are:

1. The simplified SCIP notification (SSN)
2. The 'referencing' in a SCIP notification dossier.



#### Referring to data already submitted

**There are 2 main tools / features for this**

- o Simplified SCIP notification (SSN)
- o 'Referencing' in a SCIP notification dossier



More details on these tools are available in the document ["Tools to refer to SCIP data already submitted to ECHA"](#).

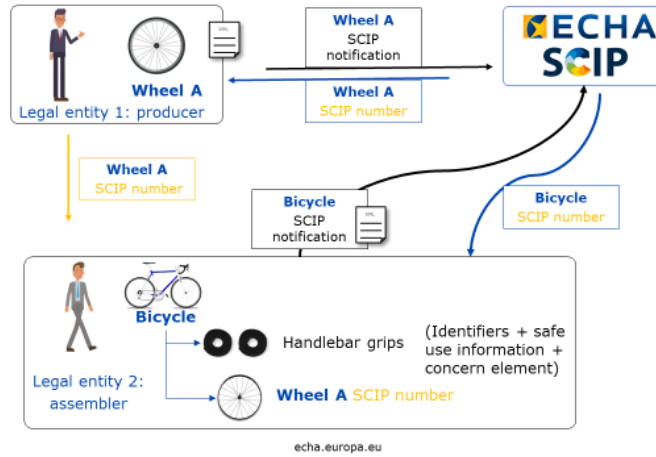
The submission of a **simplified SCIP notification (SSN)** for a specific article does not require the preparation of a SCIP dossier.

The 'referencing' in a SCIP notification dossier has as main target users assemblers or complex object producers that received information from their suppliers for the components of the complex objects they are assembling and placing on the market.





**How referencing works**

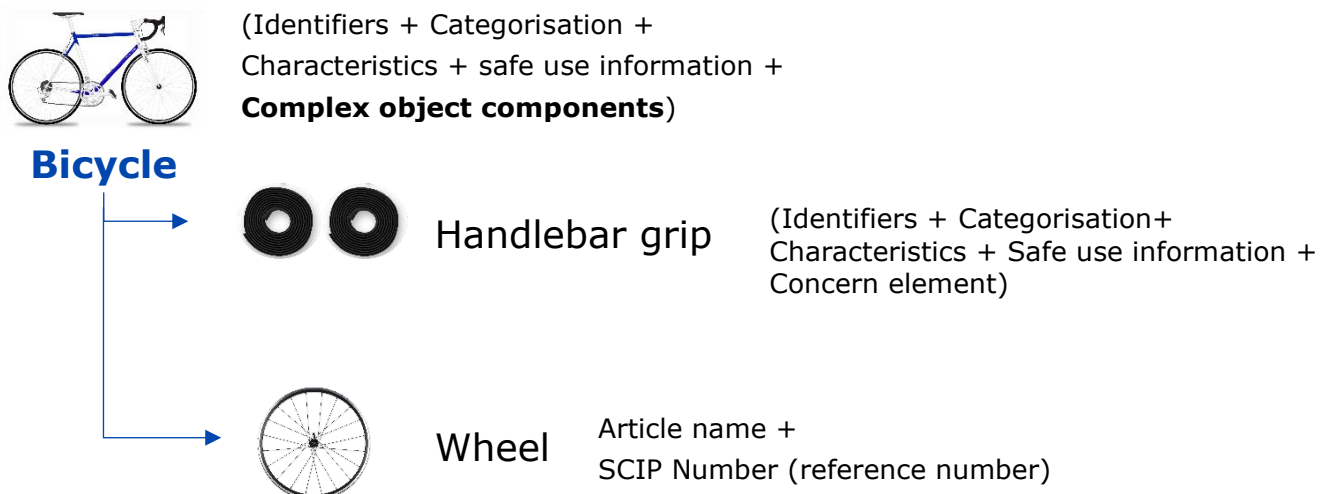


This feature can be used when preparing a IUCLID dataset for the creation of a SCIP dossier of a complex object and allow to introduce the information for a component of that complex object by reporting a SCIP number (in the complex object component section) which refers to information already submitted to the SCIP database.

A SCIP dossier that use 'Referencing' comprises the following documents:

- Complex object (Top level entity):
  - o Identifiers
  - o Categorisation
  - o Characteristics
  - o Safe use instruction(s)
  - o Complex object component:
    - *Complex object component information (Reference):*
      - o Article name
      - o Primary article identifier type: 'SCIP number'
      - o Primary article identifier value: SCIP number (UUID) provided by the supplier of the referenced article or for the article you want to refer to.

Example:



## Appendix 1. SCIP Glossary

SCIP Glossary is included in the SCIP Data model document available at <https://echa.europa.eu/scip-format>.

## Appendix 2. Picklists


Picklists and picklist items are available as SCIP format annex available at <https://echa.europa.eu/scip-format>.

Lists Id	Lists Name
PG6-60741	Other names - Type
PG6-60746	Primary Article Identifier Type / Other Article Identifier - Type
PG6-60742	Production in European Union
PG6-60759	Characteristics – Height / Length / Width / Diameter
PG6-60760	Characteristics - Density
PG6-60761	Characteristics - Weight
PG6-60762	Characteristics - Volume
PG6-60569	Characteristics - Colour
PG6-60564	Disassembling instructions - Language
PG6-60757	Concentration range
PG6-60768	Article Category
PG6-60753	Material Category
PG6-60766	Additional material characteristics
PG6-60567	Mixture Category (EU PCS)

## Appendix 3. Icons, abbreviations and terminology

This manual uses various icons and specific abbreviations throughout. The icons are displayed to highlight useful or important information. The following icons are used:

 Very important note

 Useful information, guidance, assistance

Term or Abbreviation	Explanation
(IUCLID) Document	A document is the generic designation of a set of information that can be entered in the PCN Format. A document is also the standard set of data that exists in a substance dataset and compose the nodes of the table of contents. Documents are discriminated between <i>records</i> and <i>summaries</i> , which in turn are separated in <i>fixed records</i> , <i>flexible records</i> , <i>endpoint study records</i> , <i>flexible summaries</i> and <i>endpoint summaries</i> respectively.
Block	A block or repeatable block is a set of fields grouped because of common business behaviour or database dependency. They are grouped and commonly identified in order to be reused throughout the application. When a block is repeatable it means that all the fields in the same group can be provided multiple times (in the same set).
Dataset	A dataset (or data set) is a collection of related sets of information (e.g. an Article dataset) that is composed of other datasets (Articles or Reference Substances).
Dossier	A dossier or IUCLID dossier represents the collection of all the scientific and administrative information at any given time (snapshot).
ECHA	European Chemicals Agency
(ECHA) Submission portal	Online tool provided free of charge by ECHA that supports both industry and authority users in fulfilling their obligations related to the notification of hazardous mixtures as required under Article 45 of the CLP Regulation.
EuPCS	European Product Categorisation System
IUCLID	International Uniform Chemical Information Database, is a software application system for managing data on intrinsic and hazard properties of chemical substances and mixtures for accurate reporting to the regulatory authorities.
Legal entity	A legal entity may represent anything between a complex business structure and a simple organized business (e.g. corporation, company, organization) or a single natural person capable and having the right to engage into contracts or commercial transactions.

Term or Abbreviation	Explanation
OECD	Organisation for Economic Co-operation and Development. The OECD is an intergovernmental economic organisation with 35 member countries, founded in 1961 to stimulate economic progress and world trade.
Reference substance	<p>A Reference substance is a single document used (in IUCLID) to define the identity of a Substance, in such a way that the definition may be re-used in more than one location. This provides consistency and avoids duplication of work. A Reference substance contains both the chemical identifiers and the structural information.</p> <p>In the SCIP context, ECHA has prepared and recommends the use of the Candidate List reference substance package including all Candidate list entries in IUCLID Reference Substance format (<a href="https://echa.europa.eu/scip-format">https://echa.europa.eu/scip-format</a>).</p>
Submission	A submission is an event resulting from the transmission of a Dossier prepared and submitted electronically.
TOC	Table of content for a specific dataset
UUID	A universally unique identifier (UUID) is a 128-bit number used to identify data and information in computer systems.
w/w %	Weight by weight percent concentration.
XML	eXtensible Markup Language

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