



**SLOVENSKI STANDARD**  
**SIST EN 50581:2012**  
**01-december-2012**

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**Tehnična dokumentacija za ocenjevanje električnih in elektronskih izdelkov glede na omejitve nevarnih snovi**

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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**iTeh STANDARD PREVIEW**

Documentation technique pour l'évaluation des produits électriques et électroniques par rapport à la restriction des substances dangereuses

[SIST EN 50581:2012](https://standards.iteh.ai/catalog/standards/sist/5892027a-a343-4131-9d63-5afced51443b/sist-en-50581-2012)

**Ta slovenski standard je istoveten z: EN 50581:2012**

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**ICS:**

01.110	Tehnična dokumentacija za izdelke	Technical product documentation
29.020	Elektrotehnika na splošno	Electrical engineering in general
31.020	Elektronske komponente na splošno	Electronic components in general

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**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN 50581**

September 2012

ICS 29.020; 31.020

English version

## **Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances**

Documentation technique pour l'évaluation des produits électriques et électroniques par rapport à la restriction des substances dangereuses

Technische Dokumentation zur Beurteilung von Elektro- und Elektronikgeräten hinsichtlich der Beschränkung gefährlicher Stoffe

### **iTeh STANDARD PREVIEW**

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This European Standard was approved by CENELEC on 2012-07-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## **CENELEC**

European Committee for Electrotechnical Standardization  
Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**Management Centre: Avenue Marnix 17, B - 1000 Brussels**

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## Foreword

This document (EN 50581:2012) has been prepared by CLC/TC 111X "Environment".

The following dates are fixed:

- latest date by which this document has to (dop) 2013-07-16  
be implemented at national level by  
publication of an identical national standard  
or by endorsement
- latest date by which the national standards (dow) 2015-07-16  
conflicting with this document have to  
be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 2011/65/EU.

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

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## Introduction

Certain substances contained in electrical and electronic products are restricted by legislation and/or customer specifications. Manufacturers of final products therefore need to be able to demonstrate that their products meet the applicable substance restrictions.

For those restrictions that apply at the "homogeneous material" level, it is impractical for manufacturers of complex products to undertake their own testing of all materials contained in the final assembled product. Instead, manufacturers work with their suppliers to manage compliance and compile technical documentation as evidence of compliance. This approach is well recognised by both industry and enforcement authorities.

The aim of this European Standard is to specify the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions. In this way, this European Standard supports Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

This European Standard can also find an application in demonstrating conformity to other substance regulations worldwide.

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## 1 Scope

This European Standard specifies the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions.

The documentation of the manufacturer's management system is outside the scope of this European Standard.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 62321:2009, *Electrotechnical products — Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) (IEC 62321:2008)*

NOTE EN 62321 will be replaced by a series of standards designated EN 62321-x.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 3.1

#### restricted substance

substance which is limited in its use in a product, part or material

### 3.2

#### manufacturer

natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

[SOURCE: Regulation (EC) N° 765/2008 or Decision N° 768/2008/EC]

Note 1 to entry: In certain circumstances, an importer or distributor is considered a manufacturer for the purposes of Directive 2011/65/EU.

### 3.3

#### supplier

organisation that provides the manufacturer with materials, parts and/or sub-assemblies

## 4 Technical documentation

### 4.1 Overview

The manufacturer shall compile technical documentation to demonstrate that electrical and electronic products comply with substance restrictions (see 4.2 and 4.3).

### 4.2 Content of the technical documentation

The technical documentation shall include at least the following elements:

- a general description of the product;

NOTE 1 Directive 2011/65/EU specifies 11 product categories. The product category is one of the factors that determines which exemptions apply.

- documents for materials, parts, and/or sub-assemblies (see 4.3);
- information showing the relationship between the technical documents identified in 4.3 and the corresponding materials, parts and/or sub-assemblies in the product;

- list of harmonized standards and/or other technical specifications that have been used to establish the technical documents identified in 4.3, or to which such documents refer.

NOTE 2 Annex A describes the relationship between Article 7(b) of Directive 2011/65/EU, Module A of Decision 768/2008/EC, this European Standard, and the technical documentation.

### 4.3 Information on materials, parts, and/or sub-assemblies

#### 4.3.1 Tasks to be undertaken by the manufacturer

The manufacturer shall undertake the following four tasks:

- determine the information needed (see 4.3.2);
- collect the information (see 4.3.3);
- evaluate the information with regard to its quality and trustworthiness and decide whether to include it in the technical documentation (see 4.3.4);
- ensure that the technical documentation remains valid (see 4.3.5).

Figure 1 (informative) shows the process to create the technical documentation:

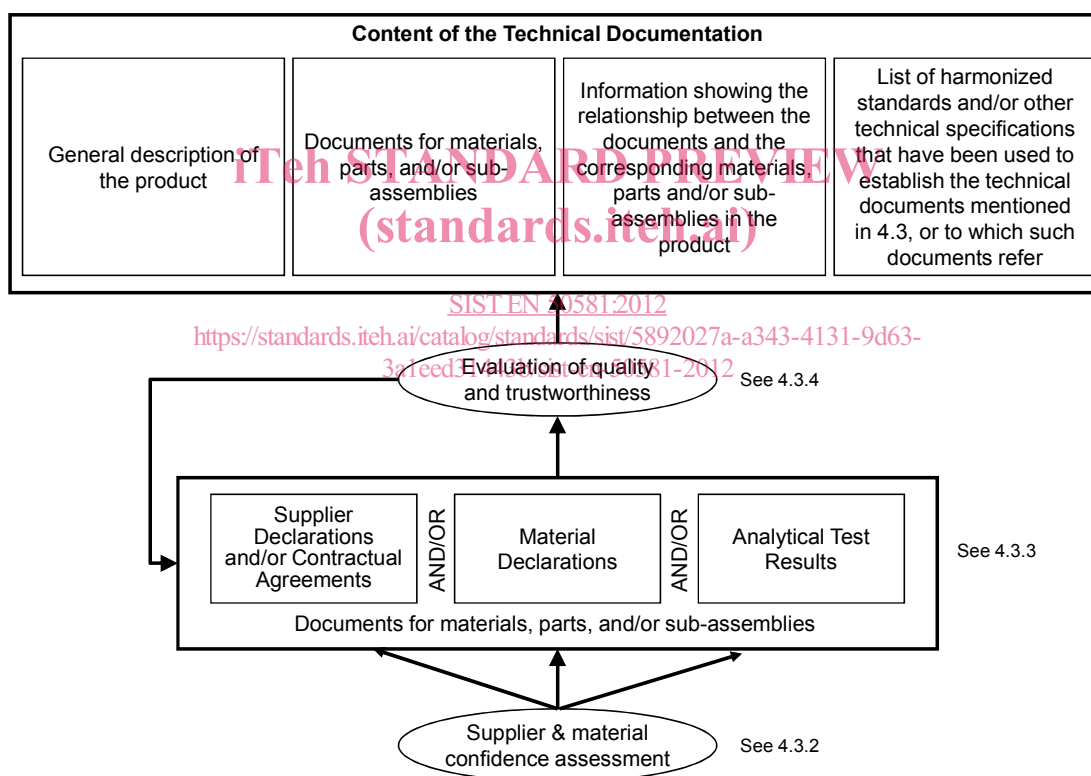


Figure 1 — Schematic representation of process to create the technical documentation

#### 4.3.2 Determine the information needed

The types of technical documents (see 4.3.3) that are required for materials, parts and/or sub-assemblies shall be based on the manufacturer's assessment of:

- a) the probability of restricted substances being present, in materials, parts or sub-assemblies, and
- b) the trustworthiness of the supplier.

Materials that are added during the production process (such as solder, paint, adhesives) shall also be considered as part of the assessment.



When undertaking the assessment described in point a), the manufacturer may apply technical judgement, as some substances are unlikely to be contained in certain materials (e.g. organic substances in metals). Such technical judgement could be based on technical information available via the electrical/electronic industry, or a literature investigation of the materials/parts used in electrical/electronic products.

NOTE 1 Additional information that can be used when undertaking the assessment described in points (a) and (b) includes:

- material types typically used in the part or sub-assembly;
- historical likelihood of restricted substances being present in each material type;
- historical experience with the supplier organization;
- results of previous supplier inspections or audits.

NOTE 2 The assessment and its associated procedures can form part of a quality management system or equivalent.

#### 4.3.3 Collecting information

As a result of the manufacturer's assessment, the following documents on materials, parts, and/or sub-assemblies shall be collected:

a) Supplier declarations and/or contractual agreements, such as:

- Supplier declarations, confirming that the restricted substance content of the material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied;
- Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.

Such declarations or agreements shall cover a specific material, part and/or sub-assembly, or a specific range of materials, parts and/or sub-assemblies.

and/or <https://standards.iteh.ai/catalog/standards/sist/5892027a-a343-4131-9d63-3a1eed31443b/sist-en-50581-2012>

b) Material Declarations:

- Material declarations providing information on specific substance content and identifying any exemptions that have been applied.

NOTE 1 The use of standards for such declarations helps ensure consistent and cost-effective flow of information throughout the supply chain. EN 62474 "Material declaration for products of and for the electrotechnical industry" describes the procedure, content, and form relating to material declaration. Other specifications for material declarations are also used in industry today.

and/or

c) Analytical test results:

- Analytical test results using the methods described or referenced in EN 62321.

NOTE 2 EN 62321 will be replaced by a series of standards designated EN 62321-x.

#### 4.3.4 Evaluation of information

The manufacturer shall establish procedures that shall be used to evaluate the documents described in 4.3.3 in order to determine their quality and trustworthiness.

NOTE 1 IEC/TR 62476 provides a framework for the use of internationally accepted standards, tools and practices to evaluate electrical and electronic products with respect to restricted substances.

The manufacturer shall evaluate, in accordance with these procedures, the source and content of each document received in order to determine whether or not the material, part, or sub-assembly meets the specified substance restrictions.

NOTE 2 The substance restrictions specified in Directive 2011/65/EU apply at the homogeneous material level.