SLOVENSKI STANDARD
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Izpostavljenost na delovnem mestu ï Merjenje dermalne izpostavljenosti koģe ï Naļ ela in metode

Workplace exposure - Measurement of dermal exposure - Principles and methods

Exposition am Arbeitsplatz - Messung der Hautbelastung - Grundsätze und Verfahren

Exposition sur les lieux de travail - Mesurage de l'exposition cutanée - Principes et méthodes

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13.100	Varnost pri delu. Industrijska higiena	Occupational safety. Industrial hygiene

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Workplace exposure - Measurement of dermal exposure - Principles and methods

Exposition sur les lieux de travail - Mesurage de l'exposition cutanée - Principes et méthodes

Exposition am Arbeitsplatz - Messung der Hautbelastung - Grundsätze und Verfahren

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Foreword

This Technical Specification (CEN/TS 15279:2006) has been prepared by Technical Committee CEN/TC 137 “Assessment of workplace exposure to chemical and biological agents”, the secretariat of which is held by DIN.

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Introduction

Dermal exposure assessment explores the dynamic interaction between environmental contaminants and the skin. In contrast to inhalation exposure assessment, the assessment of dermal exposure remained a nascent field of scientific research and applied occupational hygiene for most of the twentieth century, although multiple fatalities and occupational skin diseases due to dermal exposure have been described in literature.

During the last decade, dermal exposure has received more attention, and one of the important results was the development of a conceptual model for dermal exposure (see [1]). The model systematically describes the transport of contaminant mass from exposure sources to the surface of the skin. The model provides a structure for evaluating dermal exposure both qualitatively and quantitatively.

The purpose of evaluating dermal exposure can differ substantially, as exposure analysis (to give guidance to control), risk assessment, and evaluation of exposure control can all be objectives to undertake assessments. In order to give guidance and to harmonise measurements, requirements and test methods for measurement of dermal exposure are proposed.

1 Scope

This Technical Specification establishes principles and describes methods for the measurement of dermal exposure in workplaces. It gives guidance on the commonly used approaches to the measurement of dermal exposure, their advantages and limitations and how these might be assessed in specific circumstances for specific compounds.

This Technical Specification should enable users of dermal sampling methods to adopt a consistent approach to method validation and provide a framework for the assessment of method performance.

This Technical Specification describes the requirements against which sampling methods need to be assessed. It will then indicate methods for agreement with these requirements. Requirements include specification of the following:

NOTE Not all requirements are applicable to all methods.

— sampling efficiency;

— recovery efficiency;

— sample stability;

— maximum capacity;

— bias, precision, overall uncertainty;

— core information;

— contextual information.

2 Terms and definitions

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

NOTE The definitions are based on CEN/TR 15278.

2.1
agent
any chemical or biological entity on its own or admixed as it occurs in the natural state or as produced by any work activity, whether or not produced intentionally and whether or not placed on the market

NOTE Adapted from EN 1540.

2.2
bias
<air quality measuring methods> consistent deviation of the measured value from the value of the air quality characteristic itself or the accepted reference value

[ISO 6879:1995, 5.2.3.1]

2.3
dermal contact volume
volume containing the mass of the agent that contacts the exposure surface

NOTE 1 The dermal contact volume is given in litres (l).

NOTE 2 The dermal contact volume is equivalent to the volume of the skin contaminant layer, and for practical reasons it is defined by the mass in kilograms (kg) of all substances contained in this compartment.

2.4
dermal exposure
process of contact between an agent and human skin at an exposure surface over an exposure period

2.5
dermal exposure concentration
exposure mass divided by the dermal contact volume or the exposure mass divided by the mass contained in the skin contaminant layer

NOTE The dermal exposure concentration is expressed in grams per litre (g/l) or grams per kilogram (g/kg) respectively.

2.6
dermal exposure loading
exposure mass divided by the exposure surface

NOTE For practical reasons it can be expressed as the time-averaged mass divided by area-averaged skin contaminant layer surface area in grams per square centimetre (g/cm^2).

2.7
dermal exposure mass
mass of agent present in the dermal contact volume

NOTE 1 For practical reasons it is defined by the amount of agent in grams (g) present in the skin contaminant layer.

NOTE 2 The outcome of the process of dermal exposure, i.e. the contact, can be expressed by different parameters of exposure.

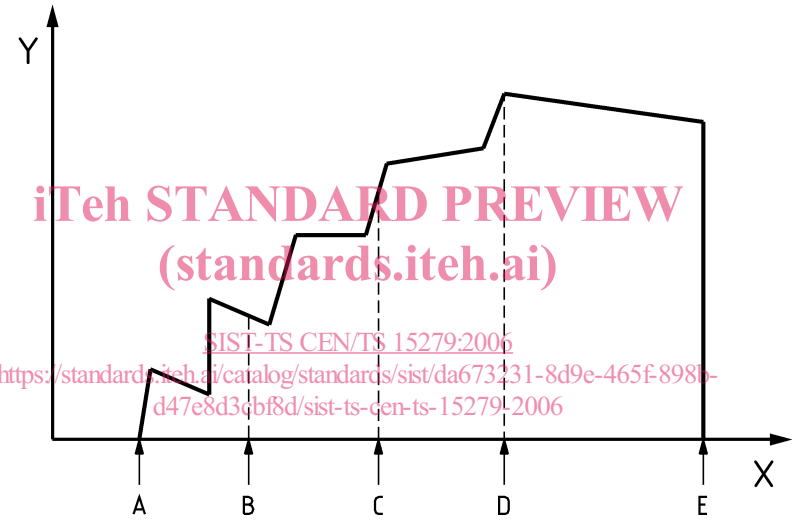
2.8
dermal exposure surface
skin surface area where an agent is present

NOTE For practical reasons this is represented by a two dimensional representation of the skin contaminant layer in square centimetres (cm^2).

2.9
exposure period
time the agent is present in the skin contaminant layer, i.e. contact time

NOTE 1 The process by which an agent crosses an outer exposure surface of a target is called intake. In case of the concentration driven transport from the skin contaminant layer into the skin, i.e. crossing the (exposure surface) interface between SCL and the stratum corneum as an absorption barrier, the process is called uptake. Therefore, relevant for uptake would be the time- exposure concentration profile for an identified area of the skin contaminant layer over a defined period of time.

NOTE 2 Other relevant types of time intervals, e.g. sampling time (B-C), immission or loading time (A-D), and post emission time (D-E), are illustrated in Figure 1.



Key
X time
Y exposure loading
A-E exposure/contact time
A-D immission/loading time
D-E post immission time
B-C sampling time

Figure 1 — Different types of time intervals relevant in view of dermal exposure

2.10
immission
transport of an agent from a defined source to the skin or outer clothing contaminant layer compartment

2.11
limit of detection
LOD
background level plus three times estimated standard deviation of measured blank substrate mass

NOTE Adapted from ISO 15767.

2.12
limit of quantitation
LOQ
background level plus ten times estimated standard deviation of measured blank substrate mass

NOTE Adapted from ISO 15767.

2.13 overall method efficiency

2.13.1
overall method efficiency
<for interception and removal methods> sampling efficiency multiplied by recovery efficiency

2.13.2
overall method efficiency
<for in situ methods> mass of agent detected divided by mass of agent in analysed contact volume

NOTE Mass of agent detected either directly or indirectly by use of a tracer.

2.14
overall uncertainty
<of a measuring procedure or of an instrument> quantity used to characterise as a whole the uncertainty of the result given by an apparatus or measuring procedure

NOTE It is expressed, as a percentage, by a combination of bias and precision usually according to the formula:

$$\frac{\left|\bar{x} - x_{\text{ref}}\right| + 2s}{x_{\text{ref}}}$$

where

$\bar{x}$ is the mean value of results of a number (n) of repeated measurements;

x_{ref} is the true or accepted reference value of concentration;

s is the standard deviation of the measurements.

[EN 1540:1998, 3.17]

2.15
potential dermal exposure mass
mass retrieved from (outer and inner clothing contaminant layer and exposure mass, i.e. mass retrieved from the covered and uncovered by clothing) parts of the skin contaminant layer compartment

NOTE For practical reasons related to sampling methodology and strategy the term potential exposure mass has been introduced. It refers to the agent mass that has the *potential* the reach the skin (contaminant layer) since it has landed on the clothing and the agent mass that has actually reached the skin. The conceptual model distinguishes between outer and inner clothing contaminant layer compartment, respectively, and characterises the clothing itself as a buffer layer.

2.16
precision
the closeness of agreement between independent test results obtained under stipulated conditions

[ISO 6879:1995, 5.2.16]

2.17
quality control sample
blank substrate that undergoes the same handling as the sampling substrate and can either be fortified with the agent or not

2.18
recovery efficiency
<for interception and removal methods> mass of agent recovered from collection substrate divided by mass of agent present on the substrate immediately after collection

NOTE For in situ methods recovery efficiency is not applicable.

2.19sampling efficiency

NOTE For in situ methods sampling efficiency is not applicable.

2.19.1
sampling efficiency
<for interception methods> mass of agent on collection substrate at end of sampling divided by immission of agent to sampled area integrated over sampling time

2.19.2
sampling efficiency
<for removal methods> mass of agent on collection substrate divided by dermal exposure loading by agent times sampled area

2.20
skin contaminant layer compartment
compartment on top of the stratum corneum of the human skin

NOTE The skin contaminant layer compartment is formed by sebum lipids, sweat and additional water from transepidermal water loss, rest products from cornification and unshed corneocytes, and is given by its three dimensional volume.

2.21
workplace
the defined area or areas in which the work activities are carried out

[EN 1540:1998, 3.36]

3 Principles and methods

3.1 Measurement principles

Table 1 gives the three major measurement principles for dermal exposure assessment and an overview of the more frequently used sampling methods. Agents collected by interception techniques can be detected by e.g. chemical analysis of extracts from the removal matrix such as wash liquid, wipe fabrics. Agents collected by removal techniques can be detected by e.g. chemical analysis of extracts from the collection matrix.

The measurement methods do not attempt to quantify the role of dermal uptake. Choice of measurement methods in cases where dermal uptake is an issue described in CEN/TR 15278.

Table 1 — Measurement methods for dermal exposure assessment

Measurement principle / sampling technique	Sampling method
interception techniques, i.e. interception of agent mass transport by the use of collection media placed at the skin surface or replacing work clothing during the sampling time	patch
	whole body
removal techniques, i.e. removal of the agent mass from the skin surface (i.e. the skin contaminant layer) at any given time	manual wipe
	tape-stripping
	hand wash hand rinse
direct assessment, i.e. In situ detection of the agent or a tracer at the skin surface, e.g. by image acquisition and processing systems, at a given time	detection of UV fluorescence of agent or added tracer as a surrogate for the agent by video imaging, Attenuated Total Reflection FTIR, or using a light probe

The measurement results should be interpreted in relation to the measurement strategy as described in CEN/TR 15278.

Since the results obtained by different sampling principles are influenced by a range of mass transport processes (see Table 1), and may have to be extrapolated beyond the sampled contact volume, all sampling methods are faced with fundamental problems, such as:

— interception and retention characteristics of interception techniques differ from real skin or clothing;

— removal methods, e.g. tape stripping, solvent washing, and use of surfactants, can influence the characteristics of the skin. They can also be of limited use for repeated sampling;

— removal techniques, e.g. skin washing, are not appropriate for all body parts;

— extrapolation from small areas sampled, e.g. patches or skin strips, to the whole exposed area can introduce substantial errors;

— the behaviour of a (fluorescent) tracer introduced in the mass transport when using in situ-techniques can differ from the behaviour of the substances of interest.

3.2 Selection of sampling methods

Selection of the appropriate sampling method will depend on a range of factors. These include the sampling objectives, the compartment or transport process of interest, and the nature of the agent and the analytical methods to be used. Selection of sampling methods should be part of a coherent and documented sampling strategy. More information about sampling strategies can be found in CEN/TR 15278.

Details of the various test methods are provided in Annexes A to E. In these annexes the principles behind each of the approaches, the test methods themselves, the materials that have been used and how the procedures are carried out are described. Applications and limitations of each of these test methods are also described.

4 Quality issues

4.1 General

Various quality issues that are important to some or all of the methods are described in a generic sense in 4.2 to 4.7.

4.2 Sampling efficiency

In practice, sampling efficiency can only be determined approximately due to methodological limitations. Methods for determining sampling efficiencies are given in Annexes A to E.

4.3 Recovery efficiency

Fortified quality control samples (generated by dispersing a known and relevant quantity of the agent under investigation onto sampling the sampling substrate) may be used to quantify the recovery efficiency. Fortified quality control samples should be collected, handled, transported and stored in conjunction with the experimental samples. Ideally a separate set of quality control samples should be included at each site on each day of monitoring for each relevant dosimeter. The same approach may be used in laboratory experiments to determine recovery efficiency.

4.4 Background and contamination

Blank quality control samples should be used to determine the upper limit of the agent in question present in the sampling substrate dosimeters or skin not arising from direct sampling but due to background contamination and/or contamination due to sample handling, transport and storage. The blank quality control samples should be handled, transported and stored in conjunction with the experimental samples. Ideally a separate set of quality control samples should be included at each site on each day of monitoring for each relevant sampling substrate.

4.5 Maximum capacity

The maximum capacity of the dosimeter against the test agent should be assessed. If it is considered that this may be exceeded in the experimental study, the maximum capacity should be quantified experimentally.

4.6 Sample stability

The sample stability will vary by storage and transport method and by agent and should be assessed as part of the field recovery investigation.

4.7 Analytical method

The analytical method used, should be validated according to standard laboratory analysis quality control protocols. Details, specific for the various sampling methods are given in Annexes A to E.

5 Report

The report should contain all necessary information (core information) to carry out the measurements:

a) purpose of the assessment;

b) sampling strategy used;

c) sampling method;

- description of each procedure. The description should contain all necessary information to carry out the sampling procedure, information about the attainable overall uncertainty, specified measuring range, averaging time, interferences and information on environmental or any other conditions, which can influence the performance of the procedure. It should include, where appropriate for the specific sampling method:

  - sampling medium;