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Workplace air — Assessment of dermal exposure —

Part 1: Framework for dermal exposure assessment

Air des lieux de travail — Évaluation de l'exposition cutanée —

Partie 1: Cadre pour l'évaluation de l'exposition cutanée

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 146, *Air quality*, Subcommittee SC 2, *Workplace atmospheres*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 137, *Assessment of workplace exposure to chemical and biological agents*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 13977 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

Dermal exposure assessment explores the dynamic interaction between environmental contaminants and the skin. For thousands of chemicals in the workplace, the contribution of the dermal route to total-body exposure has yet to be determined. Historically, the assessment of occupational exposure has focused on inhalation of chemical agents. However, evidence from studies investigating the exposure pattern for different occupational conditions indicates that dermal contact can serve as the primary route of exposure for many chemical substances.

The penetration and permeation of substances through the skin can cause local and systemic effects, respectively. Substances in contact with the skin can penetrate the stratum corneum to cause local effects (irritation, corrosion or sensitization). Substances can also permeate through the skin reaching systemic circulation leading to systemic effects, using different exposure pathways, namely:

— through sweat glands and hair follicles,

— the intercellular route (around the cells), or

— the intracellular pathway (through the cells).

Observational studies show that the most highly exposed body parts are the hands. However, deposition of airborne aerosols or direct contact with substances can also contaminate other body parts (e.g. forearms, chest and forehead). Location of the exposure is of particular interest, since both the thickness of the stratum corneum and the density of the hair follicles vary substantially between body locations. These are important parameters with regard to potential penetration and local effects through the skin but also for potential permeation and systemic effects. In addition to skin physiology, skin conditions and duration of contact, the actual contact site can also be relevant for potential inadvertent oral exposure due to hand-to-mouth contact[1].

The development of a conceptual model was a major milestone in assessing dermal exposure[2]. The multicompartment model systematically specifies the transport of contaminant mass from the source of exposure to the surface of the skin. The model consists of six compartments, eight mass transport processes and two barriers, and provides a structure for both qualitatively and quantitatively evaluating dermal exposure. Many control banding tools, dermal exposure modelling tools and measurement methodologies are specified in scientific and grey literature using this basic concept.

No legally binding dermal limit values (DLVs) for dermal exposure are established at the time of the publication of this document. However, derived no effect levels (DNELs)[3] for the dermal route of exposure, threshold limit value–surface limits (TLV–SLs)[4] and skin notations exist for many substances and should be considered in the risk assessment as prescribed in national regulations. For the assessment of, for example, biocides and plant protection products, (internal) reference values are determined. These values, namely the medium and long-term acceptable exposure level (AEL) derived for biocides and the acceptable operator exposure level (AOEL) derived for plant protection products, indicate the maximum acceptable level of a substance in the body, independent of the pathways that lead to the exposure[5]. As a common practice, the whole-body exposure via all relevant routes is assessed, but for many substances and exposure situations, one pathway (dermal, inhalation or ingestion) is typically dominant.

Dermal exposure assessments can be used for various purposes, such as:

— for the evaluation of exposure processes and pathways, in view of the human interface with workplace processes;

— for the evaluation of control measures or interventions for effectiveness of exposure reduction;

— for risk assessment, identifying hazardous agents that exhibit either local effects or systemic health effects;

— for compliance purposes, where results are compared with DLVs, e.g. DNELs, recommendations from scientific committees, TLV-SLs, action levels and in-house limit values;

— for epidemiological studies, requiring estimates of relevant exposure parameters.

This document is aimed at industrial and occupational hygienists, human exposure scientists, researchers and health and safety professionals to assist recognition, evaluation and control of dermal exposure and its potential consequences.

This document is the basis for future parts of the ISO 13977 series that will elaborate in more detail on the methodologies and approaches that can be applied.

Workplace air — Assessment of dermal exposure —

Part 1:
Framework for dermal exposure assessment

1 Scope

This document specifies a framework introducing the approaches that can be applied to assess the risks linked to dermal exposure to chemical substances in the workplace. This document provides guidance on the different steps to be taken when performing qualitative and quantitative dermal exposure assessments.

This document is not applicable to inhalation, oral, ocular and mucous membranes exposure, biological agents, wet work and mechanical stressors.

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 18158, *Workplace air — Terminology*

EN 1540, *Workplace exposure — Terminology*

ISO/IEC GUIDE 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995) — Supplement 1: Propagation of distributions using a Monte Carlo method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18158, EN 1540 and the following apply.

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/

3.1
contaminant layer
compartments that contain a contaminant or chemical agent

Note 1 to entry: The contaminant layer compartment is characterized by a volume of unknown depth.

Note 2 to entry: Compartments include source, air, surface, skin, inner and outer clothing contaminant layers (see Annex A).

3.2
dermal contact volume
volume containing the mass of the chemical agent present on the *dermal exposure surface area* (3.6)

Note 1 to entry: This theoretical term is equivalent to the volume of the *skin contaminant layer (SCL)* (3.14); however, for practical reasons, it is defined by the mass (in g) of all substances present on the SCL.

3.3
dermal exposure assessment
estimation (qualitative or quantitative) of the magnitude, frequency, duration and extent of exposure to a chemical agent via the dermal route

3.4
dermal exposure loading
dermal exposure mass (3.5) divided by the *dermal exposure surface area* (3.6)

Note 1 to entry: For practical reasons, dermal exposure loading can be expressed as mass of the chemical agent in an exposed part of the *skin contaminant layer (SCL)* (3.14) divided by the surface area of that part, expressed, for example, in milligrams per centimetre squared.

3.5
dermal exposure mass
mass of chemical agent present in the *dermal contact volume* (3.2)

Note 1 to entry: For practical reasons, dermal exposure mass is defined by the amount of the chemical agent present in the *skin contaminant layer (SCL)* (3.14).

3.6
dermal exposure surface area
skin surface area where a chemical agent is present

Note 1 to entry: For practical reasons, the dermal exposure surface is represented by a two-dimensional representation of the *skin contaminant layer (SCL)* (3.14), expressed in centimetres squared.

3.7
dermal hazard assessment
process to identify and characterize the adverse effects of a chemical agent, via the dermal route, based on substance properties that are reflected in hazard statements (H-statements) and similar information

Note 1 to entry: Effects should be considered adverse only if they affect the viability and normal function of the organism under test.

3.8
dermal limit value
DLV
level of exposure to the skin that is not expected to result in adverse biological effects

3.9
dermal risk assessment
overall process to identify potential risks based on a *dermal hazard assessment* (3.7) and a *dermal exposure assessment* (3.3)

Note 1 to entry: A risk assessment usually includes risk mitigation, but this is outside the scope of this document.

3.10
local effect
adverse health effect that occurs at the site of contact with a substance

3.11
penetration
process that occurs when a substance enters the skin

3.12
permeation
process that occurs when a substance passes through the skin

3.13
potential dermal exposure
dermal exposure that can occur on the unprotected skin or clothes

Note 1 to entry: All substance mass that can reach the body without applying any risk management measures (RMMs).

3.14
skin contaminant layer
SCL
compartment on top of the stratum corneum of the human skin formed by sebum lipids, sweat and additional water from transepidermal water loss, also including products from cornification and unshed corneocytes

Note 1 to entry: More information can be found in Annex A.

Note 2 to entry: The SCL compartment is characterized by a volume of unknown depth.

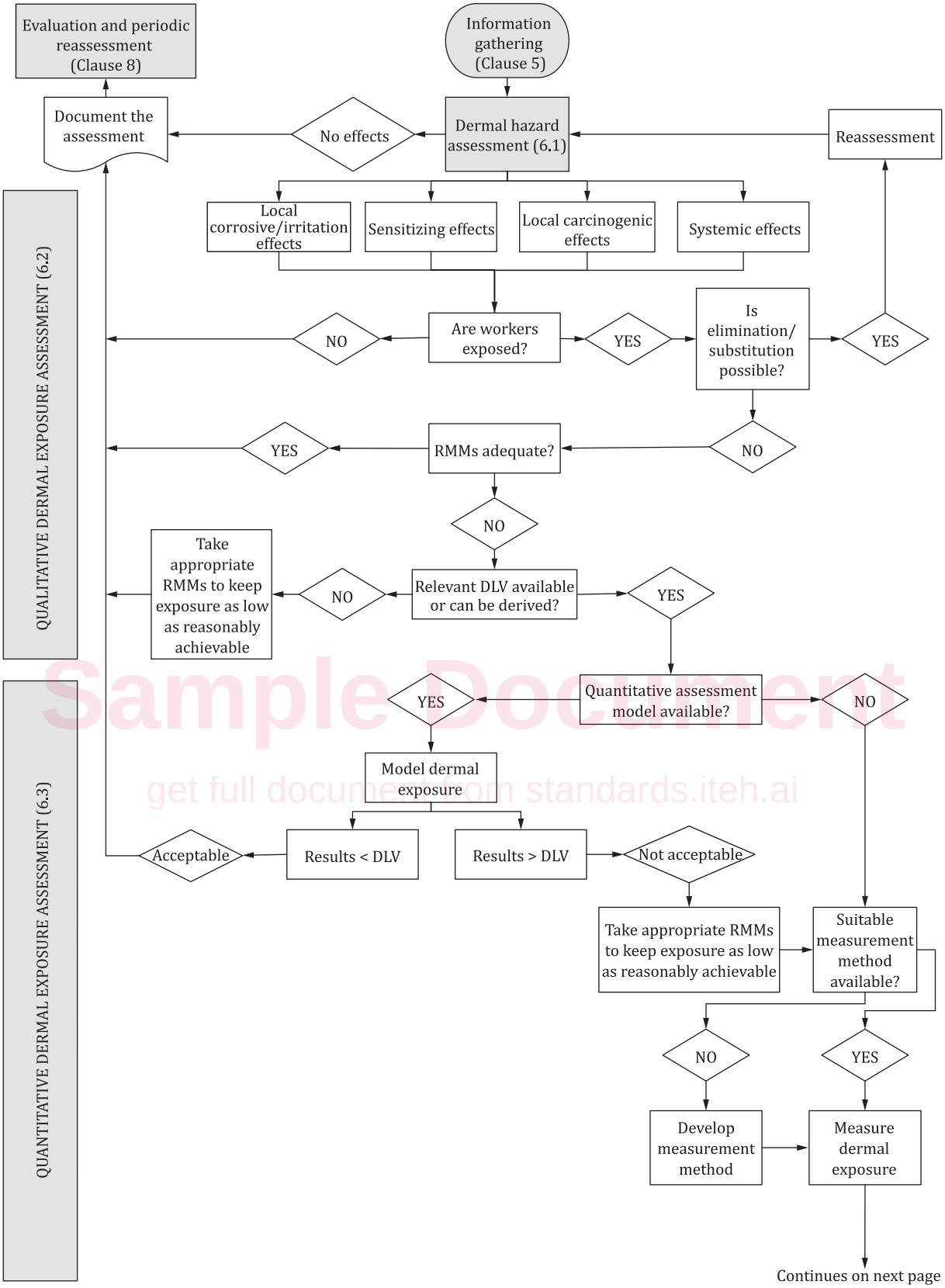
3.15
systemic effect
adverse health effect that occurs in a part of the body distant from the initial point of contact with a substance

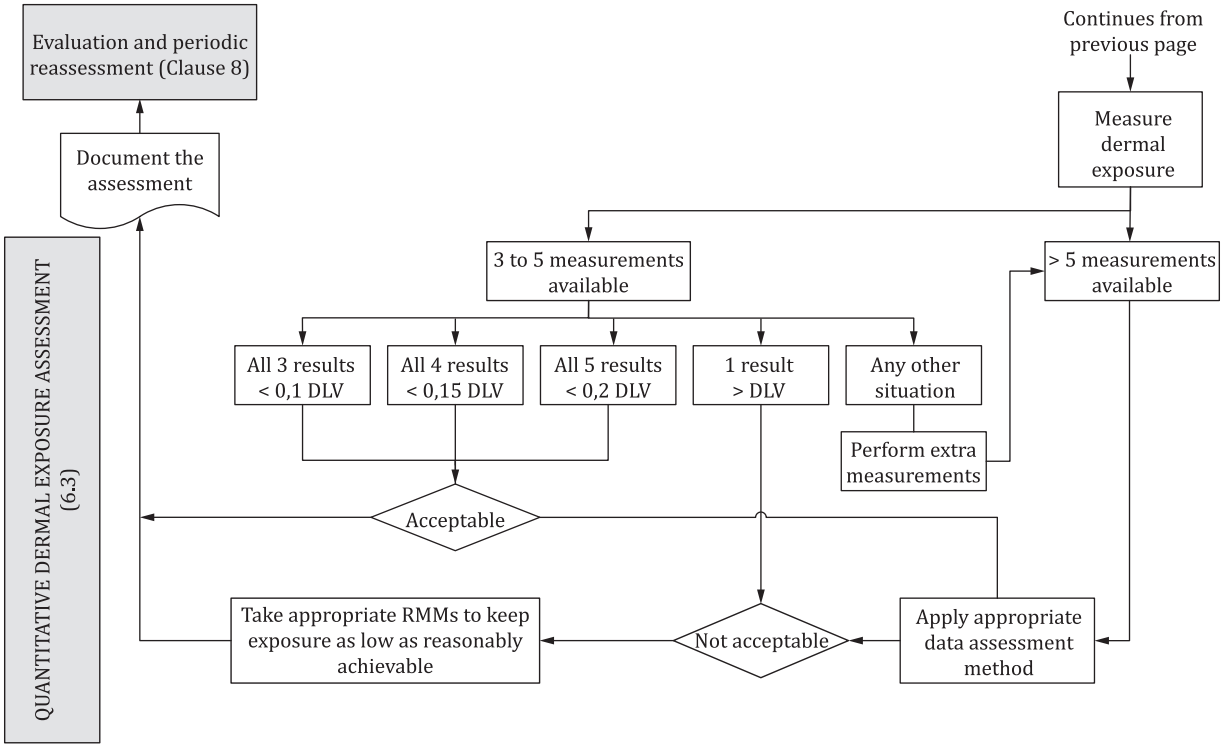
3.16
uptake
concentration-driven transport of a chemical agent from the *skin contaminant layer (SCL)* (3.14) into the skin, i.e. crossing the interface between the skin contaminant layer (exposure surface) and the stratum corneum (absorption barrier)

Note 1 to entry: The time-exposure concentration profile for an identified area of the skin contaminant layer over a defined period of time is relevant for uptake.

4 Schematic overview of the framework for dermal exposure assessment

The assessment of dermal occupational exposure to chemical agents starts with general substance information gathering, identification of the population at risk, description of the workplace [e.g. use of RMMs] and the identification of similar exposure groups (SEGs) described in Clause 5. This is followed by a qualitative dermal exposure risk assessment based on the classification of the product, substance or agent, as defined in 6.2, and when required by a quantitative assessment when a method and DLV is available as per 6.3. The dermal exposure assessments shall be documented, and periodic reassessments shall be conducted when significant changes occur at the workplace that can affect the dermal exposure and for evaluations where no safe situation can be obtained. An annual interval for reassessment is recommended, whatever the outcome, as defined in Clause 7. Figure 1 provides a schematic overview of the framework for dermal exposure assessment.





NOTE DLV can be an OELV, DNEL, TLV, etc. and is used for evaluating the results.

Figure 1 — Schematic overview of the framework for dermal exposure assessment

5 Information gathering

5.1 General

Information shall be obtained to:

— List all products and their constituents used in the activities and process generated substances potentially released during the activities so that toxicological endpoints for effect related to dermal exposure, skin notations or DLVs can be identified.

— Determine the population at risk.

— Identify the workplaces, activities and/or processes and the RMMs currently in place where workers can be at risk.

— Identify SEGs.

5.2 Substance-related information

The preparation of a list of all substances in the workplace is an essential step to the identification of the potential for exposure. The products' safety data sheets (SDSs) and other available data are useful to establish the list, which shall include the following information, if relevant:

— Raw materials, primary products, impurities, intermediates, final products, reaction and process products and by-products, etc.

— The individual substances, identified with chemical registration numbers (e.g. chemical abstracts service number, European Commission number), including process generated emissions.

— Classification and labelling, e.g. the health hazard (H) statements shall be evaluated to identify those which can be relevant to the dermal route (see Table 1, Table 2 and Table 3). Due to local restrictions, other statements can also be relevant, for instance EUH statements [these being additional labelling information used in the European Union (EU)] related to skin or allergic effects[6].

— Substance properties that affect dermal absorption and toxicokinetics, e.g. octanol/water partition coefficient (log P_{ow}), molecular size, ionization and particle size/dustiness,[7] as well as product characteristics, e.g. vehicle used, dilution rate and partitioning between vehicle and stratum corneum.

— Appropriate limit values and additional notations [e.g. 'skin', 'D'(dermal), 'C' (carcinogen), 'M' (mutagen), 'Sk' (skin), 'DSEN' (dermal sensitization notation)] and additional relevant toxicological endpoints for effect.

— Additional information such as vapour pressure, temperature, saturation and concentration.

Table 1 — List of hazard statements relevant to dermal exposure – local corrosive/irritation effects

Code	Hazard statement
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation

Table 2 — List of hazard statements relevant to dermal exposure – sensitizing effects

Code	Hazard statement
H317	Can cause an allergic skin reaction

Table 3 — List of hazard statements relevant to dermal exposure – systemic effects

Code	Hazard statement
H310	Fatal in contact with skin
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H313	Can be harmful in contact with skin
H340	Can cause genetic defects
H341	Suspected of causing genetic defects
H350	Can cause cancer
H351	Suspected of causing cancer
H360	Can damage fertility or the unborn child
H360D	Can damage the unborn child
H360Df	Can damage the unborn child. Suspected of damaging fertility
H360F	Can damage fertility
H360FD	Can damage fertility. Can damage the unborn child
H360Fd	Can damage fertility. Suspected of damaging the unborn child
H361	Suspected of damaging fertility or the unborn child
H361d	Suspected of damaging the unborn child
H361f	Suspected of damaging fertility
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child
H362	Can cause harm to breast-fed children
H370	Causes damage to organs
H371	Can cause damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H373	Can cause damage to organs through prolonged or repeated exposure