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Workplace atmospheres - Assessment of dermal exposure - Part 1: Framework for Dermal exposure assessment (ISO/DIS 13977-1:2025)

Arbeitsplatzatmosphäre - Beurteilung der Hautbelastung - Teil 1: Rahmen zur Beurteilung der Hautbelastung (ISO/DIS 13977-1:2025)

Atmosphères des lieux de travail - Évaluation de l'exposition cutanée - Partie 1: Cadre pour l'évaluation de l'exposition cutanée (ISO/DIS 13977-1:2025)

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Workplace atmospheres — Assessment of dermal exposure —

Part 1: Framework for Dermal exposure assessment

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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 documents 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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 146, 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 may penetrate the stratum corneum to cause local effects (irritation, corrosion or sensitization). Substances may also permeate through the skin reaching systemic circulation leading to systemic effects, using different exposure pathways, namely 1) through sweat glands and hair follicles, 2) the intercellular route (around the cells), or 3) 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 may 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 describes 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 described 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.

This document is aimed at industrial/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 part of the document provides the framework introducing the approaches that can be applied to assess the risks linked to dermal exposure in the workplace. In addition, it is the basis for future parts of this document that will elaborate in more detail the methodologies and approaches that can be applied.

Workplace atmospheres — Assessment of dermal exposure —

Part 1: Framework for Dermal exposure assessment

1 Scope

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

These 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 local effects and/or systemic health effects;

— For compliance purposes, where results are compared with existing or new established dermal OELVs;

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

NOTE *Ocular and mucous membranes exposure, biological agents, wet work and mechanical stressors are outside the scope of this document.*

It is acknowledged that in practice, other pathways like inhalation or ingestion are considered as well.

There is a relationship between skin contamination and inadvertent ingestion.

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 78-2, *Chemistry — Layouts for standards — Part 2: Methods of chemical analysis*

ISO 18158, *Workplace air — Terminology*

ISO 20581, *Workplace air — General requirements for the performance of procedures for the measurement of chemical agents*

EN 689, *Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values*

EN 1540, *Workplace exposure - Terminology*

3 Terms and definitions

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

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

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

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

3.1
contaminant layer compartment
layers 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**

Note 1 to entry: This theoretical term is equivalent to the volume of the *skin contaminant layer (SCL) compartment*; 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 concentration
concentration of the chemical agent contained within the *skin contaminant layer (SCL) compartment*

Note 1 to entry: The dermal exposure concentration (in g/kg) is the *dermal exposure mass* divided by the *dermal contact volume* or the *dermal exposure mass* divided by the mass contained in the *skin contaminant layer (SCL) compartment*.

3.5
dermal exposure loading
dermal exposure mass divided by the *dermal exposure surface area*

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) compartment* divided by the surface area of that part, expressed for example in milligrams per centimetre squared.

3.6
dermal exposure mass
mass of chemical agent present in the *dermal contact volume*

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) compartment*

3.7
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) compartment*, expressed in centimetres squared

3.8
dermal hazard assessment
process to identify and characterize the adverse effects of a chemical agent to which individuals could be exposed via the dermal route

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

3.9
dermal limit value (DLV)
level of exposure to the skin that is not expected to result in adverse biological effects

Note 1 to entry:

3.10
dermal risk assessment
overall process to identify potential risks based on a dermal hazard assessment and a dermal exposure assessment

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

3.11
local dermal effect
effect that involves the skin (stratum corneum, epidermis and derma). It can be after acute or chronic exposure

3.12
penetration
occurs when a substance enters into the skin

3.13
permeation
occurs when a substance pass through the skin

3.14
potential dermal exposure
dermal exposure expected to occur on the unprotected skin or clothes

Note 1 to entry: all substance mass that could reach the body without any exposure reducing methods being applied

3.15
skin contaminant layer (SCL) compartment
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.

3.16
systemic dermal effect
systemic toxicity occurs when skin exposure contributes to the overall body burden, resulting in other organ toxicities

[SOURCE: Andersen & Meade (2014)[6]]

3.17
uptake
concentration-driven transport of a chemical agent from the *skin contaminant layer (SCL) compartment*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 risk management measures (RMMs)) and the identification of similar exposure groups (SEGs) Clause 5. This

is followed by a dermal exposure risk assessment based on the classification of the product, substance or agent Clause 6 and when required by a quantitative assessment when a method and DLV is available 6.3. The dermal exposure assessments shall be documented and periodic reassessments shall be conducted when significant changes occur at the workplace that may affect the dermal exposure and for evaluations where no safe situation can be obtained. An annual interval for reassessment is recommended, whatever the outcome is Clause 7. Figure 1 provides a schematic overview of the framework for dermal exposure assessment.