RISKOFDERM: Risk Assessment of Occupational Dermal Exposure to Chemicals

The Development of a Toolkit for Risk assessment and Risk Management

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Samenvatting

Huidblootstelling aan chemische stoffen tijdens het werk is van grote betekenis voor de risicobeoordeling. De thans toegepaste werkwijzen bij de beoordeling van huidblootstelling in de Europese regelgeving is niet gebaseerd op feitelijke meetgegevens, eenvoudig omdat die ons in veel gevallen ontbreken. Een groot Europees project (QLK4-CT-1999-01107) met vier onderling verbonden werk pakketten werd door de Europese Commissie (DG Wetenschap) gefinancierd om het genoemde probleem te ondervangen. Het vierjarige project is inmiddels afgerond met een eindrapport. In het onderhavige artikel wordt een overzicht gegeven van een belangrijk onderdeel van het project: de ontwikkeling van een zogenaamde Toolkit for risicobeoordeling en –beheersing van huidblootstelling. De Toolkit schat de potentiële risico's van huidblootstelling, speciaal voor het Midden- en KleinBedrijf. De Toolkit is beschikbaar op het net en is beschikbaar op een CD-rom. De Toolkit bevat een aanzienlijke hoeveelheid tekstuele informatie over de huid en de (risico's van) huidblootstelling. De details van een en ander zijn beschikbaar in de Deliverables van het RISKOFDERM project, die via de auteur kunnen worden verkregen.

Summary

Dermal exposure to industrial chemicals during work is of major concern in the risk assessment of chemicals. Current approaches in procedures for European legislation are not based on experimental data of dermal exposures in workplaces because these are lacking. A large project (QLK4-CT-1999-01107), with four interrelated work parts, was funded by the European Commission (DG Research) in order to overcome large parts of this problem. The 4 year project has been concluded with a final report. In the present paper an overview is given of an important part of the project: the development of a risk assessment and risk management Toolkit for dermal exposure. The Toolkit assesses potential risk of dermal exposure for workplaces, especially in small and medium enterprises (SMEs). The Toolkit is available from the net and is available on CD-rom. The Toolkit contains a lot of textual information on the skin and on (risks of) skin exposure. All details are available in the Deliverables of the RISKOFDERM project, and can be obtained through the author.

Introduction

In a project funded by the European Commission, scientists from 15 Institutes in 10 European countries have been working together with the following major aims:

- to develop a validated/benchmarked predictive model for estimating dermal exposure for use in generic risk assessment for single chemicals;
- to develop a practical dermal exposure risk assessment and management Toolkit for use by small and medium-sized enterprises (SMEs) and others, in actual workplace situations.

Research goals

To achieve the above-mentioned aims, a research programme comprising four interrelated work parts was formulated.

- Qualitative survey in European workplaces to obtain an overview of tasks, processes and determinants relevant for dermal exposure (work part 1).
- Quantitative survey to obtain detailed data on dermal exposure and determinants in the most relevant tasks and processes (work part 2).
- Development of a predictive dermal exposure model (set) using all relevant variables (work part 3).
- Development of a risk assessment and management Toolkit from data on hazard, dermal absorption, dermal exposure and effectiveness of control measures for use in workplaces (work part 4).

The present paper focusses on the development of the Toolkit. The development of the Toolkit is more fully described in other papers [Van Hemmen *et al.*, 2003; Goede *et al.*, 2003; Marquart *et al.*, 2003; Oppl *et al.*, 2003; Schuhmacher-Wolz *et al.*, 2003; Warren *et al.*, 2003].

Results

On the basis of the available evidence it is assumed that dermal exposure, in the right format dimensions, can be extrapolated from one compound to another when it is task based. This may not hold for every task, so expert knowledge is required to check the assumption for the task under consideration. To obtain these 'tasks', Dermal Exposure Operation (DEO) units were defined, with various scenarios for each DEO unit.

The scenarios that have to be defined should, under practical conditions and in real work situations, be: (i) measurable with respect to dermal exposure; (ii) have an observable

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Table 1. DEO units (numbered) and some of the possible scenarios

1 Handling of objects
Filling
Collecting
Maintenance and servicing
Loading
Mixing/diluting
2 Manual dispersion of substance
Wiping
3 Dispersion of substance with hand-held tool
Pouring
Spreading with comb
Rolling
Brushing
4 Spray dispersion of substance
Spraying
5 Immersion
Immersing of objects (electroplating)
6 Mechanical treatment (of solid objects)
Machining
Grinding
Sawing

beginning and end; (iii) relevant for exposure modelling; (iv) be universal: they have to occur in various branches and industries. These DEO units (Table 1) have been defined on the basis of similar routes of exposure and form the basis of the Toolkit. The main purpose of the DEO units is to cluster dermal exposure situations with similar (expected) relations between exposure determinants and exposure levels.

Dermal exposure is considered to occur through three different routes: direct contact, transfer from contaminated surfaces, and deposition and impaction of aerosols [Schneider *et al.*, 1999]. On the basis of a thorough evaluation of the literature on dermal exposure (assessment), some dermal exposure levels were obtained, as well as determinants of exposure and available approaches for modelling. Based on this, a framework of theoretical approaches was developed, including: (1) processes and tasks; (2) substance and product characteristics; (3) situations and conditions. This information (a list of possibly relevant variables) was essential for the experimental work to be done as it was a major input to the measurement strategies and the relevant determinants. In Table 2, the major variables are indicated. The development of this overview is presented elsewhere [Marquart *et al.*, 2003].

For the Toolkit development, the available literature has been analysed for approaches to risk assessment that could be of use for the Toolkit development. For this Toolkit approaches are developed for hazard, exposure and risk assessment of dermal exposure based on label information and MSDSs for the hazard assessment [Schuhmacher-Wolz *et al.*, 2003] and based on the approach taken for exposure assessment [Goede *et al.*, 2003]. The risk assessment is carried out for systemically and locally acting chemicals. The risk management (control) section is based on literature information [Oppl *et al.*, 2003]. For the exposure assessment method an approach is taken that uses all available published dermal exposure studies [Warren *et al.*, 2003]. It is to be noted that the published data were updated on the basis of all RISKOFDERM results in the final report (and Deliverables). From this infor-

Table 2. Major variables relevant for dermal exposure modelling

Direct contact	Surface contact	Deposition and impaction
Physical state (liquid, solid)	Amount on surface	Source terms (concentration in air; energy term;
Viscosity (stickiness) (liquid)	- Intentional application:	evaporation and condensation: temperature
Particle size (solid)	amount applied	spraying and backbouncing: spray pressure
Moistness (solid)	transfer efficiency	resuspension: wind speed
Area of skin immersed	time after application	transport/movement of substance: height
Number of events	- Accidental contamination:	mechanical processes: contact pressure or electrical
power	air concentration	Air to skin
Chances of spillage	chance of spillage	velocity of aerosol
Position of worker relative to source	cleaning (efficiency, etc.)	particle size (dustiness)
Amount on surface	Process, task, situation	concentration
Skin coverage	contact area	skin area exposed
	contact likelihood/frequency	duration
	contact duration	wind speed; turbulence
	pressure during contact	position of worker
	skin moistness	skin coverage
	Substance/product	distance to source
	physical state	
	viscosity (liquid; adherence)	
	particle size and moistness (solid)	
	Skin coverage	

mation typical default values for defined scenarios are derived that can be used to assess dermal exposures, which are then corrected using a graded system for the effect of most of the variables indicated in Table 2.

The draft Toolkit (essentials in Table 3) was considered by an international selection of occupational hygienists and adapted on the basis of the results obtained from an evaluation in practice using the observations and data from the large amount of field work done for the RISKOFDERM project (details are presented in the special issue of The Annals of Occupational Hygiene 2004 (vol. 48/3).

Table 3. Essentials of the Toolkit concept

The Toolkit is transparent and easy-to-handle and should be able to:
Raise awareness
Estimate exposure
Identify control actions
Recognise damaging and/or penetrating potential
Evaluate risks
Use the STOP[a] principle

[a]STOP in hierarchical order: substitution; technical measures; organisational measures; personal protective measures.

The final outcome is a Toolkit on paper as described elsewhere [Oppl *et al.*, 2003], and updated in a RISKOFDERM Deliverable, but is also available in an electronic format that can be distributed on, for example, a CD-ROM or via a website (www.eurofins.com/research_occ_hygiene). The user, who is supposed to be an educated non-expert, must answer relatively simple questions and will be guided by that to obtain qualitative scales for dermal exposure, the resulting risk and suggestions for possible control measures to deal with the risk. There are many text blocks with relevant information on the various issues related to dermal exposure, dermal penetration and risk of locally acting and systemically acting compounds.

Some Toolkit details

The Toolkit estimates exposure, largely based on the quantitative results obtained in the RISKOFDERM project. The hazard assessment is done for locally and systemically acting compounds separately, based on the information in materials safety data sheets (MSDSs). Both exposure and hazard are rated in categories (bands). The risk assessment is then done by comparing exposure and hazard, again by rating in categories. For each risk category a control advice is presented for reducing the exposure to the extent required. Naturally, the assessment is aimed to be conservative, to largely prevent false negative results. In case of doubt or for difficult substances and/or situations the user is referred to ask for expert opinion.

Exposure assessment

Several investigators define exposure differently, and a common nomenclature for the basic mechanisms of dermal exposure had to be agreed[1]. Within this project, exposure is defined as a *mass* (in mg) and consists of the exposure *rate* (in mg/cm^2/h), the *exposed body area* (in cm^2), and the *time* (in h). The exposure *dose* is the combination of rate and time and has units of mg/cm^2. Exposure, then, is the combination of dose and area. These combinations may be done by multiplication, but these values do not always show a linear correlation with health effects. This is why exposure is determined after translating the physical data into a weighted unit, a score. This weighting has to be done differently for chemicals with local or with systemic effects.

Dermal exposure needs to be assessed in three steps, where only two of these are relevant for chemicals with local health effects. A chemical reaching the outer envelope of the body leads to a *potential exposure*. Potential dermal exposure may occur via three different routes of exposure: direct contact with the chemical, contact with contaminated surfaces (e.g. tools, tables, walls), and contact with an aerosol after deposition onto the body. If the exposed part of the body is not covered, then this potential exposure equals the *actual exposure* because all of the substance approaching the outer envelope of the body will reach the skin. Clothing or protective equipment (*e.g.* gloves, aprons, helmets) may retain a significant portion of that amount, depending on the percentage of coverage, the thickness of the clothing and the physical state of the challenge chemical (dust or liquid).

Internal exposure describes the amount that is estimated to be taken up through the skin. The rate of uptake is not known in many cases. Where it is known, the percutaneous uptake rate is found to be highly variable, depending on the specific exposure conditions, carrier effects and individual skin properties. Because of this, in many cases a 'reasonable worst case' assumption of complete percutaneous absorption, had to be used within this Toolkit, and the internal exposure then equals the actual exposure or is of the same order of magnitude. Except for a limited number of chemicals with low skin penetration, the Toolkit considers internal exposure to be less than actual exposure.

The above-mentioned basic procedures are handled differently for substances that exhibit mainly local health effects, or systemic effects after percutaneous uptake, respectively.

In the field, the user of the Toolkit will not have access to all the information necessary to carry out a detailed risk assessment. Another, simpler approach was therefore considered

[1] *Recently, the International Society of Exposure Analysis (ISEA) has adopted a glossary on nomenclature (Zarterian et al., Adoption of an official ISEA glossary, JEAEE 2005; 15:1-5). This glossary is based on a proposal made by the WHO International Programme on Chemical Safety (1999). This terminology has also been adopted by CEN TC 137 WG 6 (Dermal exposure) and published in prCEN/TR 137027 (2005). According to this terminology the present parameter exposure rate would be similar to immission, exposure would be similar to exposure mass and exposure dose would be similar to dermal exposure loading*

necessary. This required some assumptions that are described below. It follows from these assumptions that the exposure assessment is only a rough estimate and not a precise procedure. The results need to be handled with care.
The exposure situations existing in the field were grouped into the six generic categories (DEO) units, and each of those was subdivided into handling a liquid or a solid chemical.
The available quantitative data were analysed for typical potential exposure rates for the whole body and for the hand, and for the corresponding conditions of exposure. Default potential exposure rates were then assigned to the DEO units from an analysis of these data.
These default values do not apply to all real situations because the specific exposure conditions may deviate from those conditions that are correlated with the default exposure values. Goede *et al.* [2003] described the magnitude of the effect that these determinants have on exposure. They delivered a list of modifying factors (e.g. handling large amounts or small amounts of a chemical) for multiplication of the default exposure. They also showed that the impact of these modifiers on exposure varies according to the route of exposure (direct contact, surface contact or exposure by deposition).
Some determinants that are expected to have a certain influence on the magnitude of exposure are not on that list of modifiers for practical reasons. It was judged impossible to integrate these factors without measurement or other actions that most users of the Toolkit will not be able to do. This increases the imprecision of the approach. Nevertheless, the total of the remaining variables will allow a rough estimate of exposure.
Application of these modifiers to the default values will increase or decrease the magnitude of exposure for the situation under investigation. Sometimes these modifiers may impact the same mechanism - e.g. simultaneous application of two complementary controls that each reduces the exposure will not necessarily have double the protective effect. This is taken into account by setting upper limits for the overall modification factor within three groups of similar modifiers (concerning the substance, the workplace or the controls). If the user of the Toolkit is not able to decide which of the modifiers will apply, then the default value without modification will apply (modifying factor = 1).
The Toolkit then takes the default potential exposure rate for the chosen standard situation (DEO unit), corrects it by multiplication with the modifiers, and delivers a potential exposure rate that is specific to the situation under investigation.
Adequate training on how to handle protective clothing is lacking in many work places. Therefore, it is not safe to trust in the proper use of this 'end of the line' protection technique [Garrod *et al.*, 2001].

Local effects, such as burning or itching, will take place after a sufficient dose of the hazardous chemical
has reached the skin. The same holds for skin allergy after initial sensitisation has occurred. The basic elements of actual dermal exposure (exposure rate, time and exposed body area) do not show a linear impact on local health effects. Therefore the Toolkit does not work with physical data but with weighted scores. The occurrence of local health effects is assumed to depend mainly on the *peak values of actual exposure dose,* even if these last only a short time.
The determination of these peak values proved to be difficult when exposure varies over time (which is the normal case). A surrogate was therefore needed for estimating actual exposure peak doses. As hands are usually closest to the source of contamination and thus show the highest exposure in most processes, *hand exposure dose* was chosen as a pragmatic indicator for the peak values of actual exposure dose and was therefore selected as the critical figure for exposure as regards local effects on the skin.

A number of chemicals impair human health by exhibiting *systemic health effects after percutaneous uptake.* The critical figure here is how much of the chemical penetrates the skin barrier and is then available for transport to the target organs that are vulnerable to the hazardous effects. This is described by the internal exposure. The internal exposure score is calculated from potential and actual exposure, time and exposed area.

Hazard assessment

The hazard assessment for the Toolkit is based on information that should be available to SMEs through MSDSs. It differentiates between local and systemic effects as indicated above. R-phrases form the core for the assessment of the hazard in bands (categories). This is substantiated in detail by Schumacher-Wolz et al. [2003].

Risk assessment

The exposure level determines whether a given hazard leads to a significant health risk. Therefore, exposure needs to be estimated and then combined with the hazard to estimate the resulting risk.
Hazard and exposure are independent of each other, and a high hazard chemical at low exposure and a low hazard chemical at high exposure may result in comparable risk levels. If one considers substituting a hazardous chemical with another of lower toxicity, then it is essential to take into account whether the use pattern of the new substance would result in higher exposures, which would more than
offset the benefit of lower toxicity, giving a higher overall risk.
Low exposure to very hazardous chemicals might still pose a problem, whereas some exposure to low hazard chemicals might be acceptable in other cases. When considering substitution of a hazardous chemical with another one of lower toxicity, it is essential to investigate whether the use patterns of the new substance would result in higher exposures, and thus more than offset the effect of the lower toxicity and give a higher overall risk.
The Toolkit delivers two results: one health risk that refers to local health effects, and another health risk that refers to systemic effects after percutaneous uptake. Both risks need to

be handled separately because the health effect of concern, and the impact of exposure on the resulting risk, both differ basically from each other for these two hazard mechanisms. The Toolkit does not integrate different exposure pathways, such as skin exposure, inhalation exposure and ingestion exposure. This integration is important but requires skills that could not be integrated into the simple-to-use Toolkit. If the risk assessment indicated an elevated risk, then the next step is to take control actions to reduce the hazard (by substitution) or the exposure (by technical, organisational or personal protection). If these actions are effective, a new and lower risk will be the result of the new hazard and exposure assessment.

Risk management

If the assessed hazard, exposure or risk is shown to be unacceptable, then, in a next step, control actions are suggested for reducing the hazard (by substitution) or the exposure (by technical, organisational or personal protection). If these actions are effective, a new and lower risk will be the result of a new hazard and exposure assessment.
If the resulting risk is sufficiently low, then the risk assessment will not lead to further requirements. If this does not hold, then an application of further control actions might reduce the risk to an acceptable level. The project group collected possible control actions that are relevant to dermal exposure. Efficiency classes were assigned to these controls as shown in Oppl *et al.* [2003].

In accordance with European law (Chemical Agents at Work Directive 98/24/EEC), the user is encouraged to investigate possible control actions following the STOP hierarchy:
1. Substitution
2. Technical protection
3. Organisational protection
4. Personal protection

If new or additional controls are applied, the Toolkit will recommend that the user carries out a new risk assessment. If the control action is shown to be effective, a lower risk should result. This interactive procedure is intended to manage and reduce health risks from occupational dermal exposure.

Evaluating workshop

Two one day workshops were devoted to each the RISKOFDERM dermal models and the Toolkit . The invited delegates had as background: competent authorities from Member States, representatives of European Directorate Generals, Labour Inspectorates, Industry (mainly representing CEFIC sectors), Trade Unions, and Occupational Health and Safety Services. The workshops were held in January 2004 in Brussels with each 45 participants.

The overall conclusion of workshops was that the RISKOFDERM project has produced a tremendous amount of good, important and useful data and approaches, and has taken dermal exposure assessment a more than significant step forward. This progress will be of great help to regulatory processes, but that the main products are in their current state (at that time) not yet implementable. The main recommendation of the workshop was to combine efforts (expertise and budget) in order to improve and adapt the work done in a relatively short timeframe, since dermal exposure assessment is currently assessed in a way that needs this improvement. The tools should be discussed in detail by the relevant stakeholders, before actual implementation should take place. At that level the user-friendliness will have to be considered.
It was realised by the participants that the development of inhalation exposure assessment and its modelling had a history of many decades, whereas for dermal exposure of general chemicals, this only just started.
The following general conclusions were drawn on the Toolkit in its form at that workshop.

- The general approach/structure for the Toolkit (the hazard banding, exposure banding leading to risk bands, and coupled with control bands) was approved by the audience, although questions were raised about the use of the DEO units, which might have created bias.
- The hazard approach in the Toolkit is largely based on R-phrases, since they should be available in the workplace. Comments were that more attention should have been given to R-phrases of preparations. Furthermore, material safety data sheets (MSDS) may not always be correct for the R-phrases, and for several substances they may not be available at all. What should be the appropriate default to choose for that sort of cases?
- The present list of "excluded chemicals" should be justified and modified with respect to actual concentrations in the product handled.
- The differentiation between local and systemic effects for the hazard and exposure assessment is worthwhile, but appears not of direct relevance for the user of the Toolkit, so this could be handled in the 'background' of the Toolkit.
- For some substances with extreme hazards, preparations and mixtures are not treated optimally (examples: silica in bricks; benzene in gasoline). This results in overly conservative control recommendations.
- Special alerts should be given for specific activities, such as wet work, hot work, high temperature of the chemical/product, abrasions, skin diseases, etc.
- Questions were raised about possible improvements in the area of dermal absorption by using other algorithms. Consideration should be given to skin absorption of vapours.
- The exposure approach is based on the experimental results in the project and some additionally available evidence, modifying effects of exposure determinants, and expert judgement were data were not available. Comments here were mainly directed to the underlying database which was not yet available to the participants, but will be in the near future. The use of expert judgement is always critical and thus criticised.
- The patterns of use (days per year, and within-shift fre-

quency) are not apparent for their use in the Toolkit, but are very relevant for the risk assessment.
- The control bands were considered to be too generic for appropriate use and require revision. It was recommended to further develop this for a more sector-specific approach. The recent developments of the dermal exposure section of COSHH Essentials may be of some help here. On the basis of some trials by participants, it was concluded that the control section appears too conservative, specifically for "high" and "extreme" hazards, and must still contain programming bugs, which should be taken out.
- The control part of the Toolkit should stimulate improvements, and for that matter reflect current occupational hygiene practice.
- The Toolkit should have a more detailed print out summary report, containing a reminder of all data entered to generate the output. Where relevant reference to expert advice should be made.
- In the practice of daily work concomitant inhalation and dermal exposure should be considered. For the longer term these two exposure routes may perhaps be combined in a Toolkit.
- An improved Toolkit should undergo thorough testing/piloting at SME level to determine possible boundaries in its use and interpretation.
- It was considered essential by the participants that the Toolkit should be improved and kept fully alive after the ending of the RISKOFDERM project. Translated versions would be very helpful for improvement of accessibility, but there is a trade-off with improvement of content.

Work in progress

After the workshop the Toolkit was adapted to allow for some criticisms and to delete certain errors in the programming. The current version of the Toolkit can be downloaded (www.eurofins.com/research_occ_hygiene). It will be translated in several languages and be improved when further money becomes available.

In the Netherlands, TNO has considered, stimulated by the Ministry of Social Affairs and Employment to try and integrate the Stoffenmanager (www.stoffenmanager.nl), which deals with inhalation exposure and the RISKOFDERM Toolkit, which deals with dermal exposure. In 2004, an evaluation has been made of the (dis)similarities between the two approaches, and it was considered useful and possible to integrate the two approaches. In 2005 an integrated functional design will be developed in order to allow software programming.

Discussion

The disadvantage of the risk assessment and management tool as presented here is the same as for most simple tools: high uncertainty of the input data and of the algorithms within the Toolkit.
The input data are not very precise and reliable. The legal labelling and the risk phrases are only very rough indications of the possible hazard of a chemical substance or preparation, and several investigators have found that the quality of the assignment of these labels, and of supplementary information in Safety Data Sheets, is not satisfactory in many cases.
If the user supplies the Toolkit with very rough and imprecise information, then the Toolkit will encourage the user to obtain more information, such as a (hopefully high quality) Safety Data Sheet. But even updated and carefully prepared Safety Data Sheets may fail to provide all necessary information on the chemical product. In these cases, the Toolkit will encourage and help the user to obtain more information. This can be done, for example, if the user:
- requests the supplier of the chemical product to deliver specific information on hazardous properties;
- consults any lists of physico-chemical properties of chemicals;
- consults any lists of irritating or sensitising properties of chemicals;
- requests the respective suppliers for the effectiveness of personal protection devices in specific circumstances;
- carries out quantitative exposure monitoring.

The same limited precision applies to the quality of the exposure data that depends on the observation skills of the assessor. Many users of the Toolkit will not have specific knowledge or be familiar with methods of exposure and risk assessment. Therefore the Toolkit is designed to give a rough estimate of dermal risk in very broad categories. In case of doubt, and for scientific purposes, a more detailed investigation of the respective working situation is preferred. It should be noted that the Toolkit is designed for application to liquids and solids only, not to gases and vapours.
In case of mixing or dilution, the Toolkit cannot be used in a reliable manner if the hazard information of the new formulation (e.g. the new solution) is not given by the supplier and cannot be calculated by the user. As hazard information can only be determined for the products in use, risks from exposure to new substances generated by the process cannot be assessed in most cases.

Given the limitations of the Toolkit, it is not recommended that it be used for chemicals that constitute the severest health hazards. The possibility of failing in the risk assessment with the low quality input data would have very serious, and possibly fatal, consequences for the persons concerned. The Toolkit contains a list of chemicals for which the Toolkit is rated as not suitable.

In conclusion it can be stated that, despite of all limitations, the Toolkit allows a risk estimate for situations in which occupational dermal exposure occurs. It helps the user to assess the order of magnitude of hazard and exposure. The Toolkit is a decision logic that gives a rough estimate of the health risk, described in broad categories and leading to advice for better protection.

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Partners in the RISKOFDERM project
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