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A Toolkit for Dermal Risk Assessment and Management: An Overview

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The European Research project RISKOFDERM (QLK4-CT-1999-01107) has two major goals. One is the development of a conceptual model for dermal risk assessment for regulatory purposes, such as the registration of new chemicals. The other goal is to develop a simple-to-use toolkit for assessment and management of health risks from occupational dermal exposure. This toolkit was constructed by analysing the major determinants of dermal hazard and dermal exposure. The results were combined in the form of a decision-tree that leads the user of the toolkit through a number of questions on the hazardous properties of the chemical in use, and on the exposure situation. The toolkit translates the information given by the user into broad data categories of hazard and exposure that lead to a rough estimate of health risk from dermal exposure. This is done separately for local skin effects and skin allergy on the one hand, and systemic effects after skin penetration on the other hand. After going through the decision-tree, the user is advised to act to control the risk, and to read general information on dermal exposure and a statement describing the uncertainty of the risk estimate produced by the toolkit. The final version of the toolkit will be available for use on portable or stationary computers and runs the decision algorithms in the background so that the non-expert user only will see the judgements, the recommendations and the general information. The toolkit will be evaluated before release by experts on the various elements included in the toolkit and by field experts in its practical use. The toolkit is an attempt to adapt elements of exact science to a situation where the necessary input data are of limited quality and are only estimates. The toolkit does not claim to give precise answers based on imprecise information. The purpose is to enable the user to estimate the order of magnitude of hazard, exposure and risk, and to encourage the user to deal with the issues of dermal hazard, exposure and control.

Keywords: dermal exposure; exposure assessment; risk assessment; risk management; skin exposure

INTRODUCTION

Occupational skin disease is one of the major remaining health risks at work. Several sets of national statistics of occupational diseases estimate that 20–30 % of all registered cases are skin related, being caused by local skin or allergenic hazards from chemicals (e.g. HSE, 2001). Additionally, systemic health effects after dermal exposure and skin penetration offer a considerable risk for a number of chemicals.

The European Research project RISKOFDERM (funded partially by the European Commission, project QLK4-CT-1999-01107) has two major goals. One is the development of a conceptual model for dermal risk assessment for regulatory purposes, such as the registration of new chemicals. The other goal is to develop a simple-to-use toolkit for assessment and management in the field of health risks from occupational dermal exposure.

The toolkit for dermal exposure risk assessment and management is a decision logic that helps to improve dermal risk management by users of

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hazardous chemicals. It is available on paper in the form of a decision tree where the user is asked to enter information, and to read the respective ranking given by the toolkit. The existing version will undergo evaluation by experts and be improved according to their comments. The final version is planned to be available on a CD-ROM or for download from the Internet. The user will then collect the necessary information on hazard and exposure, and enter it into a portable or stationary computer.

The toolkit applies to health risks from occupational dermal exposure to both single substances and mixtures (products, preparations) and can be used for a number of purposes:

1. Comparison of the skin-related hazardous properties of chemical products: assessment and comparison of the skin-damaging or skin-penetrating potency of chemical substances or preparations. This is done typically at a company when planning a new product.
2. General recommendations for risk control either for a specific chemical product with many different applications, or for a whole trade (e.g. hairdressers, or wall painting with solvent-free paints) with many different work places. This is done typically at a company that issues Safety Data Sheets according to directive 91/155/EU, or at occupational health and safety services.
3. Assessment of health risk from skin exposure for a specific working task in the field, e.g. cleaning of motors at an individual car repair shop. This is done typically by occupational and health services of companies, or of work inspection authorities.

The toolkit is targeted at employers, safety officers, technical staff and consultants in companies of any size, but particularly small and medium sized enterprises, that should have access to

- hazard labels on the packages (according to the European Dangerous Substances Directive 67/548/EEC);
- risk phrases on the packages (according to directive 67/548/EEC), describing relevant hazards, e.g. R38 = Irritating to skin—see Table 1;
- Safety Data Sheets (according to directive 91/155/EEC);
- supplementary basic information usually available upon request from the supplier of the chemicals in question;
- supplementary basic information usually available in easily accessible media, e.g. in handbooks;
- supplementary basic information contained in the final version of the toolkit itself;
- information on the specific exposure at the workplaces (obtained from inspections of workplaces, from work simulation experiments, or from a literature survey).

Table 1. Risk phrases from the European Dangerous Substances Directive used within the toolkit for dermal exposure and risk assessment

	No.	Description
R	20	Harmful by inhalation
R	21	Harmful in contact with skin
R	22	Harmful if swallowed
R	23	Toxic by inhalation
R	24	Toxic in contact with skin
R	25	Toxic if swallowed
R	26	Very toxic by inhalation
R	27	Very toxic in contact with skin
R	28	Very toxic if swallowed
R	29	Contact with water liberates toxic gas
R	31	Contact with acids liberates toxic gas
R	32	Contact with acids liberates very toxic gas
R	33	Danger of cumulative effects
R	34	Causes burns
R	35	Causes severe burns
R	38	Irritating to skin
R	39	Danger of very serious irreversible effects
R	40	Possible risk of irreversible effects
R	43	May cause sensitization by skin contact
R	45	May cause cancer
R	48	Danger of serious damage to health by prolonged exposure
R	60	May impair fertility
R	61	May cause harm to the unborn child
R	62	Possible risk of impaired fertility
R	63	Possible risk of harm to the unborn child
R	64	May cause harm to breastfed babies
R	66	Repeated exposure may cause skin dryness or cracking
R	67	Vapours may cause drowsiness and dizziness

The toolkit is not targeted at experts in occupational hygiene, physicians, toxicologists or enterprises with the capability to carry out more detailed dermal risk assessments. However, these experts may find the toolkit useful as an initial rough estimate of dermal hazard, dermal exposure and dermal health risk before starting in-depth investigations.

The assumptions within the toolkit have been elaborated elsewhere (RISKOFDERM, 2001, 2002, 2003). This publication intends to give an overview of the structure and the basic assumptions of the toolkit. The details of the toolkit are under evaluation. This publication describes the current state of affairs (March 2002) and how the toolkit makes use of the exposure approach that is described in the consecutive series of papers on the exposure assessment (Goede *et al.*, 2003; Marquart *et al.*, 2003; Warren *et al.*, 2003).

The toolkit is an attempt to adapt elements of exact science to a situation where the necessary input data are of poor quality and precision. The toolkit does not claim to give precise answers based on imprecise information. The purpose is to enable the user to estimate the order of magnitude of hazard, exposure and risk, and to encourage the user to deal with the issues of dermal hazard, exposure and control.

METHODS AND APPROACHES

Eleven existing approaches for estimation of risk from occupational exposure, mostly to airborne chemical hazards, were analysed—including COSHH Essentials (United Kingdom), AUVA work place assessment scheme (Austria), GISCODE and TRGS 440 (Germany), and MAL code (Denmark). These approaches rank the hazard, or the exposure, or both, into broad categories. Then they combine this information into an estimate of the severity of hazard, or of exposure, or of risk. Some of the approaches result in recommendations for appropriate control actions. The analyses of these approaches were summarized as one of the project deliverables (RISKOFDERM, 2001, 2002).

Taking into account the methodology of these approaches for risks from airborne exposure, it was decided to develop a similar scheme for dermal exposure in a number of steps. The toolkit would be built by fitting relevant information into broad categories (scores). After combining these data, the results would also be given in broad bands. It was decided to assess hazard and exposure separately and then combine them to assess the health risk. The toolkit would then advise control actions to the user, with an indication of the remedial efficiency.

Basic structure of dermal risk management in the toolkit

Hazard. The possible harm to human health in cases of significant exposure is an intrinsic property of a chemical substance or preparation and needs to be assessed in a first step. If two chemicals with very different hazards can be used for a specific working procedure, then the hazard assessment alone can already lead to a recommendation of substitution without any exposure assessment, assuming all other relevant variables to be the same. And when specific exposure conditions are unknown, or when exposure conditions vary greatly, the selection of alternative products may be based on hazard considerations alone.

Exposure and risk. 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.

Control. 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, organizational or personal protection). If these actions are effective, a new and lower risk will be the result of a new hazard and exposure assessment.

The structure of dermal risk assessment and management is shown in Fig. 1.

Skin relevant hazard

The skin relevant hazard of a product needs to be assessed separately for local effects on the one hand, and for systemic effects after uptake through the skin on the other hand. In both cases, the respective intrinsic toxicity is read from toxicological data, such as lethal doses, allergenic potency, skin irritation strength and threshold, and similar data. As this information is not available in the field, the legal labelling and the risk phrases, as required by the European Dangerous Substances Directive 67/548/EEC, are used as surrogates, possibly complemented by data on acidity and on solubility in skin fat ($P_{o/w}$) if these can be read from a Safety Data Sheet. The skin relevant risk phrases are given in Table 1.

Hazardous chemicals that show local health effects

Risk phrases that indicate different levels of local health damage are ranked according to an Intrinsic Toxicity score, IT, given in Table 2. If several risk phrases or combinations of risk phrases apply, then

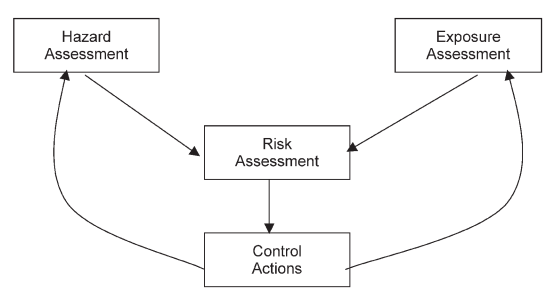

Fig. 1. Basic steps of dermal risk assessment and management in the toolkit.

Table 2. Scores for intrinsic toxicity (for substances with local health effects: skin damaging, carcinogenic or sensitizing properties)

Reading	Intrinsic toxicity (IT) score
None of those below	Low
R 66	Moderate
R 38	
R 34	High
pH < 2 or pH ≥ 11.5[a]	
R 35	Very high
R 43	
R 45	Extreme

[a]Applicable only to aqueous dilutions or mixtures.

Table 3. Scores for intrinsic toxicity (for substances with systemic health effects after percutaneous uptake)

Reading	Intrinsic toxicity (IT) score
No R phrases at all	No IT
None of those below	Low
R67	
R20, R21, R22	Moderate
R40 with 20,21 or 22	
R48 with 20, 21 or 22	
R62, R63	
R23, R24, R25, R29	High
R31, R33, R40, R41, R64	
R39 with 23, 24 or 25	
R48 with 23, 24 or 25	
R26, R27, R28, R32	Very high
R39 with 26, 27 or 28	
R60, R61	
R45, R46	Extreme

the highest IT factor is used. Also, very low and very high pH values are integrated into this scheme. Risk phrases and the pH value are only default estimates of potential local action: in cases where the user has better information because there are substance-specific data, these should be considered and experts may use these for a more accurate ranking of the intrinsic toxicity, by applying the principles as laid down in the European directive 67/548/EEC.

The toolkit contains tables for applying the IT ranking to dilutions with water. Some hints are given for checking the validity of the given information with simple measures, and for adapting the IT scores if additional research for information indicates this to be necessary, e.g. in the presence of organic peroxides.

The checked and adapted IT score then equals the *Hazard Score* (local).

Hazardous chemicals that show systemic health effects after uptake

Risk phrases that indicate different levels of systemic health damage are ranked into an IT score as given in Table 3. If several R phrases or combinations of R phrases apply, then the highest IT score is used.

The toolkit contains tables for applying the IT ranking to dilutions with water. Some suggestions are given for checking the validity of the given information with simple measures, and for adapting the IT scores if additional research for information indicates this to be necessary, e.g. in the case of low permeation through skin coefficient.

The checked and adapted IT score then equals the *Hazard Score* (systemic).

The basic approach towards dermal exposure

Several investigators define exposure differently, and a common nomenclature for the basic mechanisms of dermal exposure had to be agreed. 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, EBA* (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 ‘reasonably

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.

Internal exposure, then, is related to standard body weight by dividing the internal exposure by the standard weight of an adult person (70 kg)—the unit, thus, is mg/kg.

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

A pragmatic approach towards dermal exposure

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 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 six generic categories called Dermal Exposure Operational (DEO) units (RISKOFDERM, 2001), and each of those was subdivided into handling a liquid or a solid chemical, see Table 4 (Warren *et al.*, 2003). Literature was surveyed for each of these situations. The published data were analysed for typical potential exposure rates for the whole body and for the hand, and for the corresponding conditions of exposure. Warren *et al.* (2003) assigned default potential exposure rates 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. Marquart *et al.* (2003) analysed how exposure is modified by different exposure conditions, called determinants of exposure. 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.

Table 4. Dermal Exposure Operational (DEO) units

Task group
Handling contaminated objects
Manual dispersion
Hand tool dispersion
Spray dispersion
Immersion
Mechanical treatment

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.

$$\mathrm{PER_{BODY}} = \text{default potential exposure rate (body)} \times \text{overall modifiers} \quad (1a)$$

$$\mathrm{PER_{HANDS}} = \text{default potential exposure rate (hands)} \times \text{overall modifiers} \quad (1b)$$

where PER is the potential exposure rate (in $mg/cm^2/h$).

Depending on the clothing that covers the exposed body areas, the potential exposure rate is transformed into the actual exposure rate by applying a modifying factor of 0.5 (light clothing) or 0.1 (thick clothing).

$$\mathrm{AER_{BODY}} = \text{potential exposure rate (body)} \times \text{clothing reduction factor} \quad (2a)$$

$$\mathrm{AER_{HANDS}} = \text{potential exposure rate (hands)} \times \text{clothing reduction factor} \quad (2b)$$

where AER is the actual exposure rate (in $mg/cm^2\,h$).

Protective clothing is not considered within the exposure assessment because unexpected contamination may occur for two reasons. In many cases the protective clothing or gloves in use do not provide a sufficient barrier towards the chemical challenge in

spite of expectations, leading to high dermal exposure (Oppl, 2002). Also, bad handling leads to contamination inside the equipment when putting it on or taking it off. 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).

Exposure to chemicals that show local health effects

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 sensitization 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.

Marquart *et al.* (2003) and Warren *et al.* (2003) substantiated this assumption with a survey of literature on dermal exposure studies. The qualitative study of dermal exposure that was done by another working group within the RISKOFDERM project (RISKOFDERM, 2003) supported that assumption—with the exception of spraying where many body parts were found to be exposed to similar amounts. With these assumptions in mind, the following procedure for exposure estimation was established.

Within the toolkit, the potential exposure rate, PER, and the actual exposure rate, AER, of the situation under investigation are determined as described above, by selecting a default that is then multiplied by modifying factors. The exposure rate for the hands was selected as a best estimate of the peak exposure rate AER_{PEAK} and is assigned to the peak actual exposure rate score (AER_{PEAK} score):

$$AER_{PEAK}\ \text{score} = \text{value of actual exposure rate of the hands (see eq. 2b)} \quad (3)$$

where AER_{PEAK} score is the peak actual exposure rate score.

The activity time, AT, is handled in a non-linear manner to reflect both the thresholds before any effect takes place and the fact that above a certain duration of skin impairment the effect will no longer increase linearly with the amount of chemical that is depositing onto the skin. A higher score is assigned to corrosive substances because of their massive impairment of the skin, even after a short time. Time is ranked as given in Table 5 and then multiplied by the AER_{PEAK} score, giving the peak actual exposure dose score (AED_{PEAK} score):

$$AED_{PEAK}\ \text{score} = AER_{PEAK}\ \text{score} \times \text{AT score} \quad (4)$$

where AED_{PEAK} is the actual exposure dose, AER_{PEAK} is the actual exposure rate and AT is the activity time.

The AED_{PEAK} score is then ranked as given in Table 6. This ranking reflects the fact that there is no linear increase of effect with dose after the damage started to take place. The size of the exposed body area, EBA, is not handled linearly either. Although it is worse to have damaged larger areas of the skin, damage to smaller areas is a severe impairment of human health that needs to be avoided. For this reason, the toolkit weights the exposed body area EBA as scores, as given in Table 7.

The peak actual exposure (AE_{PEAK} score) is then estimated from area and peak dose by multiplication

Table 5. Scores for activity time, AT (for substances with local health effects)

Time (h/day)	R34, R35, pH (indicators of corrosive properties)	Other risk phrases from Table 1
<0.1	1	0.1
0.1–<0.5	3	0.1
0.5–<1	3	0.3
1–4	3	1
>4	3	3

Table 6. Scores for peak actual exposure dose, AED (for substances with local health effects)

AER_{PEAK} score × AT score	AED_{PEAK} score
<0.01	0.1
0.01–<0.1	0.3
0.1–3	1
>3	3

Table 7. Scores for exposed body area, EBA (for substances with local health effects)

EBA (cm^2)	EBA score
<10 (size of a large coin; small splashes)	0.1
10–500 (one hand or less)	0.3
501–2000 (hands and lower arms, or hands and head)	1
>2001 (more than hands and head)	3

of the EBA score and the AED_{PEAK} scores. The quantitative result is transformed into a banding scheme that indicates the significance of actual exposure. Those bands are called the AE score. Depending on the results, the toolkit makes a choice from six AE scores, as given in Table 8.

$$AE_{PEAK}\ \text{score} = AED_{PEAK}\ \text{score} \times \text{EBA score} \quad (5)$$

where AE_{PEAK} is the peak actual exposure, AED_{PEAK} is the peak actual exposure dose and EBA is the exposed body area.

The toolkit combines the hazard score and the exposure score into a health risk score as given in Table 9. This is not the result of pure science but rather a matter of ethical and political decisions as to whether a certain risk is acceptable or not. The table was set up by agreement between the participants in the process (for a list of the participants, see the Acknowledgements).

Exposure to chemicals that show systemic health effects after uptake

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.

Within the toolkit, the potential exposure rate, PER, and the actual exposure rate, AER, of the situation under investigation are determined as described above, by selecting a default that is then multiplied by modifying factors. The actual exposure rate was selected as a best estimate of the exposure rate and is assigned to the exposure rate (ER) score:

$$\text{ER score} = \text{value of the actual exposure rate (see eq. 2a)} \quad (6)$$

where AER is the actual exposure rate. This value is modified for chemicals that show low skin penetration. The toolkit will assign low skin penetration if the chemical is among these categories:

- solids, dusts
- gases
- substances that show a low solubility in outer skin (as indicated by a molecular weight > 500, or octanol–water coefficient $P_{O/W}$ <–1 or >5, or permeability $K_P < 0.0010$).

For such substances the exposure rate score will be:

$$\text{ER score} = 0.1 \times \text{value of actual exposure rate} \quad (7)$$

The activity time, AT, is handled in a non-linear manner to reflect the fact that there is a certain threshold before a substance passes through intact skin. On the other hand, that skin becomes damaged and thus more permeable in many cases when uptake occurs over a longer time (hours). Time is ranked as given in Table 10, and multiplied by the exposure rate, ER, score, giving the exposure dose (ED) score.

$$\text{ED score} = \text{ER score} \times \text{AT score} \quad (8)$$

where the ED score is the exposure dose score, the ER score is the exposure rate score and the AT score is the activity time score.

Table 8. Peak actual exposure (AE) scores (for substances with local health effects)

AED_{PEAK} score × EBA score	Actual exposure AE_{PEAK} scores
0.002 or less	Negligible
>0.002–0.02	Low
>0.02–0.2	Moderate
>0.2–2	High
>2–20	Very high
>20	Extreme

Table 9. Health risk score—for substances with local health effects

Actual exposure score (local)	Hazard score (local)				
	Low (no risk)	Moderate	High	Very high	Extreme
Negligible	1	1	2	5	8
Low	1	2	5	5	10
Moderate	2	3	6	6	10
High	2	4	6	8	10
Very high	3	7	7	9	10
Extreme	7	9	9	9	10

Meaning of the risk scores: 1, no action; 2, no special measures to be taken, basic skin care; 3, exposure reduction, if easily accomplished; 4, action necessary: primarily exposure reduction to be considered; 5, hazard reduction desirable; 6, action necessary: mixture of measures, priority for detailed analyses; 7, exposure reduction urgent; 8, only exceptionally tolerable, substitute, if any possible; 8, reduce exposure drastically in any case, stop working; 9, substitute in any case, stop working.

Table 10. Scores for activity time, AT (for substances with systemic health effects after percutaneous uptake)

Time, h/day	AT score
<0.5	0.1
0.5–<4	0.3
>4	1
Frequent immersion	3

Table 11. Scores for exposure dose, ED (for substances with systemic health effects after percutaneous uptake)

ER score × AT score	ED score
<0.01	0.01
0.01< (ER score × AT score) < 6	= value of (ER score × AT score)
>6 mg/cm^2	6

Table 12. Scores for exposed body area, EBA (for substances with systemic health effects after percutaneous uptake)

EBA (cm^2)	EBA score
Any area	= value of EBA

Table 13. Internal exposure (IE) scores (for substances with systemic health effects after uptake)

ED score × EBA score	Relative IE score	IE score
0.5 or less	0.007 or less	Negligible
>0.5–5	>0.007–0.07	Low
>5–50	>0.07–0.7	Moderate
>50–500	>0.7–7	High
>500–5000	>7–70	Very high
>5000	>70	Extreme

The ED score is ranked as given in Table 11. Dose is calculated linearly here, as the effect shows a dose–response relationship in most cases. A lower and an upper limit were set. The lower limit corresponds to a level were no health effect should be expected. The upper limit is from the maximum amount of a chemical that can be absorbed in the outer layer of the skin.

The exposed body area, EBA, is handled linearly because the exposed area influences the absorbed dose directly, see Table 12. The internal exposure (IE) score is then estimated from area and dose by multiplying the EBA and ED scores. The quantitative result is transformed into a banding scheme that indicates the significance of internal exposure. Those bands of internal exposure are called the IE scores. Depending on the results, the toolkit makes a choice from six IE scores, as given in Table 13.

$$\text{IE score} = \text{ED score} \times \text{EBA score} \qquad (9)$$

For a toxicological interpretation, the IE score is related to the standard body weight of 70 kg. In this form the relative IE score is assumed to be of the same order of magnitude as the real internal exposure value expressed in mg/kg. This assumption is based on the fact that the scores do not differ much from the absolute values of the underlying parameters—the exposed body area, EBA (cm^2), the exposure dose, ED (mg/cm^2), and the activity time, AT.

$$\text{IE}_{\text{REL}}\ \text{score} = \text{IE score}/70 \qquad (10)$$

The toolkit combines the hazard score and the exposure score into a health risk score as given in Table 14. This is not the result of pure science but rather a matter of ethical and political decisions whether a certain risk is acceptable or not. The table was set up by agreement between the participants in the process (for a list of the participants, see the Acknowledgements).

Considerations of 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 (see Table 9), and another health risk that refers to systemic effects after percutaneous uptake (see Table 14). 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, organizational or personal protection). If these actions are effective, a new and lower risk will be the result of the new hazard and exposure assessment.

Control

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 Table 15. The assignment was based on the

Table 14. Health risk score—for substances with systemic health effects after uptake

Internal exposure score (systemic)	Hazard score (systemic)				
	Low (no risk)	Moderate	High	Very high	Extreme
Negligible	1	1	2	5	8
Low	1	2	5	8	10
Moderate	2	3	6	8	10
High	2	4	6	8	10
Very high	3	7	7	9	10
Extreme	7	9	9	9	10

Meaning of the risk scores: 1, no action; 2, no special measures to be taken, basic skin care; 3, exposure reduction, if easily accomplished; 4, action necessary: primarily exposure reduction to be considered; 5, hazard reduction desirable; 6, action necessary: mixture of measures, priority for detailed analyses; 7, exposure reduction urgent; 8, only exceptionally tolerable, substitute, if any possible; 9, reduce exposure drastically in any case, stop working; 10, substitute in any case, stop working.

Table 15. Efficiency classes of control actions

Control efficiency class	Exposure multiplied by factor	Description	Examples
4	0	No remaining exposure/risk	Complete elimination of exposure to hazardous chemicals, either by substitution or by containment
3	0.01	Almost complete control of exposure/risk	Complete containment of the hazardous chemicals but short-term exposure when, for example, taking samples or connecting pipes
2	0.1	Considerable effect	Complete separation of the hazardous chemical from the workers but contaminated objects (e.g. degreased parts) are handled outside the contained area
1	0.3	Slight effect	More frequent washing/cleaning of skin, e.g. 4 times a day, reduces source strength of chemicals on the skin but does not prevent harmful effects from the beginning of exposure until the contaminant is removed by washing/cleaning
0	1	No effect	Use of barrier cream as protection against skin penetrating chemicals
–1	3–10	Unintended higher overall risk after implementation of an improper measure	Use of unsuitable gloves gives higher exposure by increasing contact time, *plus* risks from sensitizing components of the glove itself

empirical knowledge of the participants in the project group (for a list of the participants, see the Acknowledgements).

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. Organizational 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.

DISCUSSION

The toolkit allows a risk estimate for situations in which occupational dermal exposure occurs. It helps the user to assess the qualitative character and 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.

Limitations of the approach

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 (Kolp *et al.*, 1995; Kaup and Pohl, 1999; Rühl and Hamm, 2001).

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 sensitizing 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.

Exclusion of very severe hazards from the application of the toolkit

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.

CONCLUSION

The toolkit is an attempt to allow a risk estimate for situations in which occupational dermal exposure occurs. It allows the user to assess the qualitative character and the order of magnitude of hazard and exposure. The toolkit is a decision logic that combines these to estimate the risk, described in broad categories, and leads to advice for better protection. The toolkit deals with both local health effects and systemic health effects after uptake through the skin. When applying the toolkit, it should be borne in mind that the input data are not very precise, as they have to be available in the field without any exposure measurement or toxicological assessment. The toolkit is open to further refinement after evaluation in field situations.

A detailed assessment of the exposure variables is presented elsewhere in this issue (Goede *et al.*, 2003; Marquart *et al.*, 2003; Warren *et al.*, 2003). The hazard characterization as used for the toolkit is further described in this issue (Schuhmacher-Wolz *et al.*, 2003).

APPENDIX

Use of the toolkit

The toolkit will not show all the detailed considerations to the normal user. Rather, the user will be asked some questions that will be translated by the system into hazard, exposure and risk categories. As the toolkit is still under evaluation, the final version may contain questions other than those described below. In the following, some examples will be given to illustrate how the user will see the toolkit.

Intro

The user reads that this toolkit will help to estimate health risks that may arise from skin contamination by chemical products at work.

The user is then recommended to read some general information on skin, dermal disease, uptake and general precautions for prevention of any unacceptable risk. Advanced users may skip this step.

The user is also asked to check from the label on the container and from the Safety Data Sheet whether any ingredient is on a list of especially dangerous substances (supplied with the toolkit)—in that case, he is requested not to use the toolkit but to obtain the advice of a qualified expert.

The user is then told that a risk assessment with the toolkit is possible only for each chemical product and each exposure separately. If several exposure scenarios occur, then the combination of the individual exposure needs additional expertise.

Hazard

The user is asked to enter the following information:

- The identification of the chemical used
- The risk phrases
  —a disclaimer will warn the user that insufficient labelling may occur, and that in such cases the result of the assessment will fail;

—the user is asked to request the supplier to confirm the accuracy of the labelling. Without that confirmation given, or equivalent knowledge, the hazard is rated as high because of the uncertainty.
- Any additional information if available, such as pH and the physical state of the chemical

Advanced users are asked to compare the list of ingredients with databases containing information on irritating and burning chemicals, to look for organic peroxides, and to look for octanol/water partition coefficients, etc.

That information is translated into two hazard categories, one for hazards concerning local effects on skin, and one category concerning systemic effects after uptake through the skin. The user will receive information on both risks. These are described as:

- Negligible
- Low
- Moderate
- High
- Very high
- Extreme

If the user wants to compare the hazard of two chemicals, then he is requested to go through that procedure once more for the second chemical. In that case the system compares the resulting hazards and delivers a rating of how urgent a substitution of one chemical by the other one is. This urgency can be

- Low
- Moderate
- High

If the user is assessing only one chemical, he/she then proceeds to the exposure assessment.

Exposure

The user is asked to enter the following information:

- The identification of the workplace or process that is assessed.
- Which one out of a list of standard situations will fit best:
  —Handling contaminated objects (solid)
  —Handling contaminated objects (liquid)
  —Manual dispersion of solids
  —Manual dispersion of liquids
  —Hand tool dispersion of solids
  —Hand tool dispersion of liquids
  —Spray dispersion of solids
  —Spray dispersion of liquids
  —Immersion (solids)
  —Immersion (liquids)
  —Mechanical treatment (exposure to solid)
  —Mechanical treatment (exposure to liquid)

From that information the toolkit will apply a default exposure rate to that specific situation but without showing that procedure to the user. Next, the user will be asked a number of questions on the specific situation under investigation. The answer is given from a multiple-choice list. For example, there may be the question: 'How can the product best be described?' For a liquid, the answers can be 'like a solvent', 'like water' or 'like oil or grease'. For a solid the answers can be 'like dry coarse sand', 'like dry flour' or 'like dry granules or pellets'.

The user is then asked to give the exposure time per day (described as the duration of the activities that lead to dermal exposure) in these categories: 'less than 0.1 h (6 min)', 'between 0.1 and ½ an hour', 'between ½ and 1 hour', 'between 1 and 4 h', 'more than 4 h', 'repeated full immersion of the exposed body parts'.

Finally, the user is asked for the exposed body area, with a list of body parts to which the toolkit assigns area values. For chemicals exhibiting mainly local skin challenges, the possible answers are: 'less than a coin, small splashes', 'one hand or less', 'hands and lower arms, or hands and head' or 'more area than the other descriptions'.

The actual exposure score and the internal exposure score are then calculated in the background and used in the next step.

Risk

The toolkit combines the hazard score and the exposure score with the estimated health risk score from dermal exposure. The algorithm is not shown to the user; only the results are given. These show up separately for local skin challenges and skin uptake/systemic effect challenges. Both the magnitude of the risk and a basic comment on control actions are given. A disclaimer repeats information on the limitations of this approach.

Control

Along with showing the resulting dermal risk, the user is asked to go through the control section of the toolkit. This is a list of control actions, presented in the order of substitution → technical control → organizational control → personal protection. Any item has a control efficiency class. In the computerized version of the toolkit, only those controls that are not already in use are shown. The user is asked whether one or some of these actions can be applied to reduce the hazard and/or the exposure. The system recommends reapplying the toolkit to the new situation after control actions have been taken.

The computerized version of the toolkit will allow printing and storing of the risk assessment files. This

might include the intermediate assignment of values to the different parameters if expressly requested by an advanced user.

Evaluation

The current version of the toolkit is still under evaluation. Predictions of exposure by the toolkit will be compared with results of actual measurements that have been done within the RISKOFDERM project. The toolkit will be tried out in practice and revised if it has shortcomings that can be improved.

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